TRADITIONAL MEDICINE. THE CASE FOR ITS INCLUSION IN SUSTAINABLE DEVELOPMENT. NO ONE SHOULD BE LEFT BEHIND.

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Abstract

This research takes an interdisciplinary approach to examine how developing and least-developed countries can advance considerably towards achieving the United Nations 2030 Agenda for Sustainable Development. Successful collective action for achieving this Agenda is dependent on the realisation of Goal 3, which aims to ensure healthy lives and promote well-being for all at all ages (without leaving anyone behind) by eradicating the epidemics of malaria, tuberculosis, HIV/AIDS and other chronic communicable and noncommunicable diseases by 2030.

The Agenda aims to achieve this by promoting universal health coverage and access to affordable essential medicines for these diseases that predominantly impact developing and least-developed countries through (a) the negotiation of a binding convention on drug research and development (R&D) that prioritises the needs of developing and least-developed countries, and delinks the cost of R&D from the end prices of medicines; and (b) the reinforcement of the full use by developing and least-developed countries of the flexibilities contained in the Agreement on the Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS flexibilities).

To achieve the primary objective of progress towards sustainable development by 2030 in developing and least-developed countries, this research has four ancillary objectives. First, it critically assesses the effectiveness of the strategy of utilising TRIPS flexibilities and negotiating a convention on drug R&D in promoting universal health coverage and delivering timely access to medicines in developing and least-developed countries by 2030. Secondly, it examines whether traditional medicine can contribute to achieving sustainable development by promoting universal health coverage and providing treatments for malaria, tuberculosis and HIV/AIDS. Thirdly, it determines whether there are challenges to using traditional medicine for health care and if so, proffers solutions. Fourthly and intimately connected with the latter, it considers how traditional medicine can be appropriately integrated into the health systems of developing and least-developed countries.

Essentially, this research argues that relying on the use of TRIPS flexibilities by developing and least-developed countries to promote access to medicines is problematic and that there are great complexity and uncertainty surrounding the conclusion of a binding convention on drug R&D in time for meeting the 2030 date for global progress towards sustainable development. The research finds that traditional medicine has immense potential to contribute towards attaining sustainable development by promoting universal health coverage and access to affordable medicines, and on this note, proposes its integration into the national healthcare systems of developing and least-developed countries as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D. It concludes that there is need for developing and least-developed countries to formulate national policies on traditional medicine; regulate traditional medicine practices and therapies; educate and licence traditional medicine practitioners; and enact domestic legislation for the conservation of biological diversity and sustainable use of its components, as well as for the protection of traditional medical knowledge and the fair and equitable sharing of benefits arising from its utilisation with indigenous and local communities in order to appropriately exploit traditional medicine's potential for sustainable development.

Abbreviations

ABS	Access and Benefit-Sharing
AIDS	Acquired Immunodeficiency Syndrome
ANVISA	National Sanitary Surveillance Agency
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
BPH	Benign Prostate Hyperplasia
CAM	Complementary and Alternative Medicine
CESCR	Committee on Economic, Social and Cultural Rights
COP	Conference of Parties
CPM	Chinese Proprietary Medicines
CSIR	Council of Scientific and Industrial Research
CTCMPD	China Traditional Chinese Medicine Patent Database
DEA	Department of Environmental Affairs
DNP+	Delhi Network of Positive People
EBM	Evidence-based Medicine
ECOWAS	Economic Community of West African States
EML	Essential Medicines List
EPO	European Patent Office
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GAP	Good Agricultural Practice
GATT	General Agreement on Tariffs and Trade
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSP	Good Supplying Practice
GSPOA	Global Strategy and Plan of Action on Public

	Health, Innovation and Intellectual Property
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immunodeficiency Virus
HSA	Health Science Authority
ICESCR	International Covenant on Economic, Social and Cultural Rights
IDA	International Dispensary Association
IFC	International Finance Corporation
ILO	International Labour Organization
I-MAK	Initiative for Medicines, Access and Knowledge
IPC	International Patent Classification
JCRC	Joint Clinical Research Centre
MATs	Mutually Agreed Terms
MDGs	Millennium Development Goals
MFN	Most Favoured Nation
MPP	Medicines Patent Pool
MRC	Medical Research Committee
MSF	Médecins Sans Frontières
NAFDAC	Nigerian National Agency for Food and Drug Administration and Control
NBA	National Biodiversity Authority
NBSAP	National Biodiversity Strategies and Action Plans
NCI	National Cancer Institute
NGOs	Non-governmental Organisations
NSAIDS	Nonsteroidal Anti-inflammatory Drugs
PBRs	Plant Breeders' Rights
RCT	Randomised Controlled Trial
R&D	Research and Development
RITAM	Research Initiative on Traditional Antimalarial Methods
RSBY	Rashtra Swastya Bima Yojana
SAHSMI	South African Herbal Science and Medicine Institute

SANBI	South African National Biodiversity Institute
SDGs	Sustainable Development Goals
SMEs	Small and Medium-Sized Enterprises
STDs	Sexually Transmitted Diseases
TBGRI	Tropical Botanic Garden and Research Institute
TCEs	Traditional Cultural Expressions
TCM	Traditional Chinese Medicine
TGA	Therapeutic Goods Act
TGAC	Therapeutic Goods Advertising Code
THETA	Traditional and Modern Health Practitioners Together Against AIDS
TKDL	Traditional Knowledge Digital Library
TPP	The Trans-Pacific Partnership Agreement
TRIPS	Agreement on the Trade-Related Aspects of Intellectual Property Rights
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children's Fund
UN	United Nations
UPOV	International Union for the Protection of New Varieties of Plants
USPTO	United States Patent and Trademark Office
USTR	Office of the United States' Trade Representative
WAHO	West African Health Organization
WG-ABS	Ad Hoc Open-ended Working Group on Access and Benefit-sharing
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WIPO-IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional

	Knowledge and Folklore
WTO	World Trade Organization

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Declaration of Originality

I hereby declare that my thesis entitled ***Traditional Medicine. The Case for its Inclusion in Sustainable Development. No One Should be Left Behind.*** is the result of my own work and includes nothing which is the outcome of work done in collaboration except as declared in the Introduction and specified in the text, and is not substantially the same as any that I submitted, or, is currently submitted for a degree or diploma or other qualification at the University of Buckingham or any other University or similar institution except as declared in the Introduction and specified in the text. I further state that no substantial part of the thesis has already been submitted for any such degree, diploma, or other qualifications at the University of Buckingham or any other University or similar institution except as declared in the Introduction and specified in the text.

Signature: **Date:**

INTRODUCTION

The overarching objective of this research is to examine how developing and least-developed countries can advance considerably towards achieving the United Nations (UN) 2030 Agenda for Sustainable Development. Impetus was derived from an appeal to the Human Rights Council by Michael Kirby, former Justice of the High Court of Australia and a member of the UN High-Level Panel on Innovation and Access to Health Technologies – a panel convened by the UN's Secretary-General in 2015 which had the terms of reference to propose solutions for 'remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies'[1] – who said:

> We should never forget the voices of those who are left behind, many of them women or girls, families forced to beg for charity for patented medicines… Unless the world and the UN, and this Council act now, there is no way that Goal 3 (on the right to health) of the UN 2030 Sustainable Development Goals will be reached… Millions will be left behind, and millions will die…[2]

Goal 3 of the UN 2030 Agenda for Sustainable Development aims to ensure healthy lives and promote well-being for everyone (without leaving anyone behind) by aspiring to eradicate the epidemics of malaria, tuberculosis, HIV/AIDS and other chronic communicable and noncommunicable diseases by 2030, through achieving universal health coverage and promoting access to affordable essential medicines for these diseases predominantly affecting developing and least-developed countries.[3] Over and above the appeal by Michael Kirby, this research recognises this goal as pivotal for the successful collective action to realise *all* other developmental goals (social, economic and environmental). The reason is that the health both of individuals and population plays an

[1] United Nations, 'Secretary-General Appoints Two Former Presidents, 14 Others as Members of High-Level Panel on Access to Medicines' (2015) <https://www.un.org/press/en/2015/sga1608.doc.htm> accessed 1 December 2015.
[2] Catherine Saez, 'UN High-Level Panel on Access to Medicines Takes Next Step at Human Rights Council' <https://www.ip-watch.org/2017/03/09/un-high-level-panel-access-medicines-takes-next-step-human-rights-council> accessed 13 July 2017.
[3] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (United Nations 2015) Goal 3.

essential role in realising sustainable development; whereas good health is a consequence and precursor of sustainable developmental patterns,[4] individuals and populations need some degree of health and well-being to participate in, contribute to and enjoy the fruits of sustainable development. However, the global reality is the prevalence of malaria, tuberculosis, HIV/AIDS, and other chronic communicable and noncommunicable diseases in developing and least-developed countries, and the lack of access to essential medicines for millions of people resident in these countries to treat diseases and alleviate suffering.[5] This problem of access to essential medicines is partly attributed to the interference of the patent regime globalised by the Agreement on the Trade-Related Aspects of Intellectual Property Rights 1994 (the TRIPS Agreement), the most comprehensive international regime that provides for minimum standards of intellectual property protection,[6] which creates an incentive system that fosters the pricing of medicines well beyond the means of patients who need them.[7]

To rectify this apparent conflict between public health and the rights of inventors in order to pave way for sustainable development by 2030, both the Agenda and the UN High-Level Panel put forward as solutions (a) the reinforcement by governments of developing and least-developed countries of the use of the flexibilities contained in the TRIPS Agreement to promote access to affordable essential medicines and; (b) the negotiation of a binding convention on drug research and development (R&D) of medicines for diseases that mainly afflict developing and least-developed countries, and that delinks the cost of research and development from the end prices of medicines.[8] In proffering these solutions, neither the 2030 Agenda nor the UN High-Level Panel considered whether or not traditional medicine had the potential to contribute to progress towards Goal 3 by 2030. While Goal 15 of the Agenda for Sustainable Development acknowledged that as much as 80 per cent of people living in rural areas of developing and least-developed

[4] World Health Organization, 'World Health Statistics: Monitoring Health for The SDGs, Sustainable Development Goals' (World Health Organization 2017).
[5] Ellen F M 't Hoen, *Private Patents and Public Health* (Diemen: AMB 2016).
[6] Susy Frankel and Daniel Gervais, *Advanced Introduction to International Intellectual Property* (Edward Elgar Publishing Limited 2016) 28-29.
[7] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies' (Geneva: UNHLP, September 2016).
[8] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 3; see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).

countries rely on 'traditional plant-based medicines' for basic health care, it only noted this point – among other things – to emphasise the urgent need for conservation and sustainable use of biological diversity.[9] Notwithstanding, this suggests albeit tacitly that traditional medicine could play a vital role in realising sustainable development.

Traditional medicine embodies practices that have strong historical and cultural roots[10] and involves the use of plants, animals and mineral-based medicines, spiritual therapies and manual techniques for diagnosing, preventing and treating physical, mental and spiritual illnesses.[11] It has been utilised in many indigenous and local communities for centuries to improve health, maintain well-being and relieve suffering.[12] The broader perspective (in this thesis) is that if it is substantiated that traditional medicine consists of curative and palliative remedies for malaria, tuberculosis and HIV/AIDS, then developing and least-developed countries should *appropriately* integrate traditional medicine into their health systems as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D with the aim of making significant progress towards sustainable development by 2030.

Hypothesis

It is speculated that the strategy of utilising the TRIPS flexibilities and negotiating a convention on drug R&D may not promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030. It is further theorised that if traditional medicine can provide treatments for malaria, tuberculosis and HIV/AIDS, then it may contribute to achieving the 2030 Agenda for Sustainable Development if appropriately integrated into the national health systems of developing and least-developed countries.

[9] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 15.
[10] Margaret Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (World Health Organization 2015).
[11] World Health Organization, 'WHO Traditional Medicine Strategy 2014-2023' (World Health Organization 2013); issues touching on uncompensated exploitation of traditional knowledge, as well as access and benefit-sharing arising from the utilisation of traditional knowledge and the legal protection of rights over traditional medical knowledge need to be addressed and are covered extensively in Chapter six.
[12] World Health Organization, 'WHO Traditional Medicine Strategy 2002-2005' (World Health Organization 2002).

Research objectives

As already noted, the overall objective of this research is to consider how developing, and least-developed countries can make progress towards achieving the UN 2030 Agenda for Sustainable Development. Nonetheless, there are four ancillary objectives to achieve the main aim: first, this research will critically examine the effectiveness of the strategy of utilising the TRIPS flexibilities and negotiating a binding convention on drug R&D for promoting universal health coverage and timely access to affordable medicines in developing and least-developed countries for realising Goal 3 of the UN 2030 Agenda for Sustainable Development. Secondly, it probes into the traditional medicine system to determine whether it can contribute to realising the 2030 Agenda through providing medicines for treating malaria, tuberculosis and HIV/AIDS. Thirdly, it investigates whether there are challenges to the proper use of traditional medicine for health care and if so, proffers solutions. Fourthly, the research assesses how traditional medicine can be appropriately integrated into the national health systems of developing and least-developed countries.

Research questions

(a) Can the strategy of utilising the TRIPS flexibilities and the negotiation of a convention on drug R&D promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030?

(b) Can traditional medicine contribute to achieving sustainable development by 2030 through providing treatment for malaria, tuberculosis and HIV/AIDS?

(c) Are there challenges confronting the use of traditional medicine for health care?

(d) How can traditional medicine be integrated into the national health systems of developing and least-developed countries?

Research methodology

While maintaining the doctrinal core of legal scholarship, this research adopts an interdisciplinary approach. Most (if not all) legal research projects begin with the doctrinal method as it 'provides a systematic exposition of the rules governing a particular legal category, analyses the relationship between [the] rules, explains areas of difficulty and, perhaps, predicts future developments'.[13] It also enables a critical examination of various sources of law from which relevant elements may be synthesised to 'establish an arguably correct and complete statement of the law' and make recommendations regarding any matter at issue.[14] In this connection, using the doctrinal method this research reviews primary sources together with secondary literature to critically discuss and analyse relevant concepts and critical issues such as the TRIPS Agreement and its impact on access to medicines, sustainable development, the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and related matters.

Also, the research cuts across or takes place between four disciplines or branches of learning, namely: ethnopharmacology, health policy, law and medical anthropology. Ethnopharmacology and medical anthropology concern the study of traditional medicine, biocultural adaptation and healthcare systems and practices of various indigenous and local communities concerning human health and diseases.[15] Whereas, health policy refers to 'decisions, plans, and actions that are undertaken to achieve specific healthcare goals within a society'.[16] Drawing knowledge from these disciplines, this research proposes how developing and least-developed countries can considerably advance towards achieving the UN 2030 Agenda for Sustainable Development by attaining Goal 3. In this

[13] Terry Hutchinson, 'Doctrinal Research: Researching the Jury' in Dawn Watkins and Mandy Burton (eds), *Research Methods in Law* (2nd edn, Routledge 2018) 15.
[14] ibid 10-11.
[15] Nina L Etkin, 'Ethnopharmacology: The Conjunction of Medical Ethnography and the Biology of Therapeutic Action' in Carolyn F Sargent and Thomas M Johnson (eds), *Medical Anthropology Contemporary Theory and Method* (Westport, Connecticut: Praeger Publishers 1996); see also Ann McElroy and Patricia K Townsend, *Medical Anthropology in Ecological Perspective* (3rd edn, Boulder, Colorado: Westview Press 1996) and Ann McElroy, 'Medical Anthropology' in David Levinson and Melvin Ember (eds), *Encyclopaedia of Cultural Anthropology* (New York: Henry Holt and Co. 1996).
[16] 'WHO | Health Policy' (*Who.int*, 2018) <http://www.who.int/topics/health_policy/en/> accessed 18 April 2018; see also Karin Olson, Richard A Young and Izabela Z Schultz, *Handbook of Qualitative Health Research for Evidence-Based Practice* (Springer 2015) 530.

regard, this research can be described as interdisciplinary, which refers to research in law 'of or pertaining to two or more disciplines or branches of learning; contributing to or benefiting from two or more disciplines'. [17]

The advantages of this methodology are that it enables the synthesis of ideas and characteristics and allows the researcher to leverage knowledge and insights from four disciplines to answer the research questions and proffer solutions. It also permits the incorporation of existing empirical evidence to establish, in the case of this research, the merit and potential of traditional medicine for sustainable development and thus, is practical because it saves time and resources. However, the shortcoming of the methodology is that this research suffers from the same limitations as such empirical evidence that it incorporates – for instance, the poor research methodologies adopted in some of the clinical studies discussed in Chapter three conducted to validate the safety and efficacy of traditional medicine. In this connection, this research acknowledges in Chapters four and five the need for more rigorous clinical trials to expand the evidence-base regarding the safety and efficacy of traditional medicine.

Even though this research cites case studies from various jurisdictions (mostly developing and least-developed countries), particularly in Chapter five, it is not a comparative work. Locating evidence on traditional medicine is challenging. This can be attributed to China and India being the only countries that have *fully* integrated traditional medicine into their national health systems. Notwithstanding the existence of substantial literature on these jurisdictions, the limitation is that they do not cover all the issues that this research discusses such as certain aspects of the rational use, quality, safety and efficacy of traditional medicine. Moreover, the majority of the evidence on the use of traditional medicine is not documented in the English language. Mindful that some jurisdictions other than China and India have partially integrated or merely tolerated traditional medicine in their health systems, this research collects evidence of best practices of traditional medicine from various jurisdictions, with the intention of determining how traditional medicine can be appropriately utilised to provide affordable care in the

[17] Paul Roberts, 'Interdisciplinarity in Legal Research' in Mike McConville and Wing Hong Chui (eds), *Research Methods for Law* (2nd edn, Edinburgh University Press 2017) 90.

national health systems of developing and least-developed countries for sustainable development.

Also helpful in this enquiry is the fact that the World Health Organization (WHO) has developed a number of technical guidelines to assist its member states in developing national regulations to ensure the proper use of traditional medicine, notably: Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine 2004; Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004; Guidelines on the Assessment of Herbal Medicines 1991; and Traditional Medicine Strategy 2014-2023, as well as the works of and insights from Dr Tara Kelly, who has conducted extensive research on traditional medicine, ethnobotany, female infertility, children's ailments (particularly malaria) and chronic illnesses, especially in Oku, Cameroon since 1999. Again, the fact that many examples are collected from China and India does not suggest that other developing and least-developed countries should model their regulations or policies on traditional medicine after those of these jurisdictions. Since realities differ from country to country, examples of how China and India have integrated traditional medicine into their health systems should essentially serve as lessons from which other developing and least-developed countries can formulate policies, regulations or practices on traditional medicine that best cater to their circumstances.

Chapter outline

This research is structured in six chapters excluding the introductory and concluding chapters:

Chapter one examines the relationship between health and sustainable development and explains why the enjoyment of the right to health and the right to share in the benefits of scientific advancements are important to the realisation of any sustainable development agenda. It establishes, from exploring existing literature, that multiple factors derogate these rights, the most complex of which is the incoherence between the justifiable rights of inventors, trade rules, international human rights and public health.

Chapter two considers this incoherence between the justifiable rights of inventors, trade rules, international human rights and public health. Particularly, it assesses the impact of the patent protection required by the World Trade Organization's trade agreement (TRIPS) on access to medicines in developing and least-developed countries. Further, Chapter two enquires into whether the strategy of utilising the flexibilities contained in TRIPS and the negotiation of a convention on drug R&D can promote universal health coverage and deliver timely access to medicines for sustainable development.

Chapter three attempts to enable a comprehensive understanding of the traditional medicine system in operation. This is aimed at ascertaining whether the traditional system of medicine can further the sustainable development goal of eradicating malaria, tuberculosis and HIV/AIDS by 2030 through the provision of curative, as well as palliative medicines for these diseases.

Chapter four determines whether there are challenges confronting the use of traditional medicine in providing health care. In this regard, it assesses the challenges of lack of adequate national policies and regulatory frameworks, and issues of rational use, access, quality, safety and efficacy of traditional medicine.

Following this, *Chapter five* considers strategic actions for addressing these challenges and explores ways through which traditional medicine can be appropriately integrated into the national healthcare systems of developing and least-developed countries.

Finally, *Chapter six* focuses on the potential for unsustainable use of biological diversity and uncompensated exploitation of traditional medical knowledge to undermine access to quality, safe and effective traditional medicine, and the need for developing and least-developed countries to adopt legislative, administrative or policy measures for the conservation of biological diversity and the sustainable use of its components, the fair and equitable sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge, and the legal protection of traditional medical knowledge, including how these can be implemented in practice.

Materials

This research uses primary and secondary legal and non-legal sources. The primary sources include legislation and case law, some of which are found in scholarly legal databases such as Westlaw, LexisNexis, and HeinOnline. While the secondary sources include: journal articles; non-legal databases; relevant textbooks and handbooks; academic blogs and other online websites; and official reports, policies and consultation documents of relevant national, regional and international bodies and institutions, including non-governmental organisations available online. The primary and secondary sources will also be obtained through library visits and inter-library loans.

Research proposals

Due to the problems associated with using the TRIPS flexibilities, and the complexity and uncertainty surrounding the timely completion of a binding convention on drug R&D for promoting universal health coverage and access to affordable medicines in developing and least-developed countries, this research will propose the integration of traditional medicine into the national health systems of developing and least-developed countries as a complementary measure to the use of TRIPS flexibilities and (probably) a convention on drug R&D if it is determined that it can provide treatment for malaria, tuberculosis and HIV/AIDS. In relation to this, the research will further propose strategic actions for developing and least-developed countries to address the challenges of using traditional medicine and for appropriately integrating it into their health systems through the formulation of national policies on traditional medicine; the regulation of traditional medicine practices and therapies; the training and licencing of traditional medicine practitioners; and the implementation of legislative, administrative or policy measures for the conservation of biological diversity and the sustainable use of its components, the fair and equitable sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge, and the legal protection of traditional medical knowledge, including how these can be implemented in practice.

Contribution and significance of research

This research takes an interdisciplinary approach to examine how developing and least-developed countries can considerably progress towards achieving the UN 2030 Agenda for Sustainable Development. It makes an original contribution to knowledge by investigating the potential for traditional medicine to serve as a complementary measure to the use of TRIPS flexibilities and (probably) a convention on drug R&D to further the objectives of the 2030 Agenda for Sustainable Development in developing and least-developed countries. The research also makes a novel contribution by evaluating the functionality of the strategy of the Agenda for Sustainable Development for promoting universal health coverage and access to affordable medicines in developing and least-developed countries to realise Goal 3 by 2030.

The findings of this research will be significantly useful for governments of developing and least-developed countries in establishing national frameworks for operationalising the sustainable development goals, particularly Goal 3. As previously noted, and will also be seen in Chapter one, this research recognises Goal 3 as central to the realisation of all other development goals, besides the fact that it is essential to attaining the internationally recognised right to health and the right to share in the benefits of scientific advancements in developing and least-developed countries. This research will further serve as a veritable guide to developing and least-developed countries for harnessing the potential of traditional medicine through appropriate integration into their national healthcare systems. In addition to contributing to the body of existing knowledge and serving as a valuable basis for further research, the hope is that this research will assist developing and least-developed countries in improving the situations of millions who lack access to essential and affordable health care.

Limitations of the research

Whereas this research notes that there are multiple barriers to access to medicines in developing and least-developed countries such as under-resourced health systems, lack of qualified and skilled healthcare workers, lack of good governance, poor physical

infrastructure and distribution systems, corruption, taxes and tariffs on medicines,[18] it nonetheless only covers the incoherence between the justifiable rights of inventors (patents), trade rules, international human rights and public health. More than any other barrier to access to medicines, this interaction between patents, trade rules, international human rights and public health presents a more complex issue as will be seen in Chapter two and has received increased attention from the international community – more recently within the UN and the High-Level Panel on Innovation and Access to Health Technologies.[19]

Furthermore, although Goal 3 of the 2030 Agenda for Sustainable Development also aims to reduce global maternal mortality, end preventable deaths of newborns and children under five years, eradicate neglected tropical diseases and combat hepatitis, waterborne diseases and other communicable and noncommunicable diseases by 2030, [20] this research, for clarity of purpose and analysis, is limited to the potential of traditional medicine to provide treatments for malaria, tuberculosis and HIV/AIDS – which are among the leading 10 causes of death in developing and least-developed countries according to WHO in 2017.[21] Nevertheless, traditional remedies for other diseases are mentioned while analysing other matters pertaining to traditional medicine.

As already noted, the majority of evidence on the use of traditional medicine, especially regarding its safety and efficacy (as will be seen in Chapter five) is not documented in the English language. Thus, this research collects evidence of best practices of traditional medicine from various jurisdictions, particularly China and India, to determine how traditional medicine can be appropriately utilised to promote universal health coverage and access to medicines in the national health systems of developing and least-developed countries for sustainable development.

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[18] Carol Adelman and Jeremiah Norris, *The Patent Truth About Health, Innovation and Access* (Hudson Institute 2016) 18.
[19] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) Executive Summary.
[20] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 3.
[21] 'WHO Updates Fact Sheet on Top 10 Causes of Death (27 January 2017)' (*communitymedicine4asses*, 2017) <https://communitymedicine4asses.wordpress.com/2017/02/01/who-updates-fact-sheet-on-top-10-causes-of-death-27-january-2017/> accessed 1 February 2017.

Lastly, as previously mentioned in respect of the methodology, this research embodies the limitations of some of the clinical studies it uses to establish the potential of traditional medicine to contribute to sustainable development. Accordingly, it recognises the need for more clinical trials to validate the safety and efficacy of traditional medicine for providing health care.

CHAPTER ONE

REALISING THE UNITED NATIONS 2030 AGENDA FOR SUSTAINABLE DEVELOPMENT: DOES TRADITIONAL MEDICINE HAVE ANY ROLE?

The world's most comprehensive blueprint for sustainable development, the United Nations (UN) 2030 Agenda, Goal 3, seeks to ensure healthy lives and well-being for all at all ages by targeting the eradication of malaria, tuberculosis, HIV/AIDS and other chronic communicable and noncommunicable diseases by 2030 through achieving universal health coverage, and promoting access to affordable essential medicines for these diseases in developing and least-developed countries. The presupposition is that achieving universal health coverage and access to affordable essential medicines for treating these pandemics would result in healthy lives and well-being for all people. In other words, access to essential medicines and affordable preventive, promotive and rehabilitative care will be vital for realising this sustainable development goal. The health-related sustainable development goal is regarded as central to achieving other sustainable development goals (social, economic and environmental).[22] As will be seen further on, this is because, as much as health is an outcome and indicator of sustainable development, individuals and populations need some degree of health and well-being to participate in, contribute to and enjoy the fruits of sustainable development. Thus, if it is established that traditional medicine can provide curative and palliative remedies for malaria, tuberculosis and HIV/AIDS, then it has the potential to contribute to realising sustainable development by 2030.

Following from these points, this chapter examines the relationship between sustainable development and health and explains why the enjoyment of the right to health and the right to share in the benefits of scientific advancements are important to the realisation of any sustainable development agenda. It further notes the problem of access to medicines in developing and least-developed countries and shows that this represents an obstacle to the realisation of the 2030 Agenda for Sustainable Development, besides the fact that the strategy to remedy lack of access proposed by the Agenda and the UN High-Level Panel on Access to Health Technologies cannot deliver on the promise of timely access to

[22] World Health Organization, 'Progress in the Implementation of the 2030 Agenda for Sustainable Development: Report of the Secretariat' (WHO 2016).

medicines. It is in this light that this chapter gives an insight into the relevance of traditional medicine for achieving sustainable development by 2030, thereby setting the tone for discussion in the chapters that follow.

1.1. 'Sustainable Development' and 'Health': Any Connection?

The concept of sustainable development centres on ensuring that the dividends of development are not only enjoyed by the present but also future generations[23] and arose out of the need to exploit natural resources in a manner that did not imperil ecological systems and the environment. There was a realisation that developmental activities perpetrated by humans, when projected into the future, could potentially result in biophysical impossibilities.[24] During the advent of the environmental movement, especially at the United Nations Conference on the Human Environment held in Stockholm, Sweden in 1972, many countries believed that economic development and environmental protection were mutually exclusive and incompatible – a view which remains among some countries today.[25] Thus, the main strengths of the concept of sustainable development are that it proposes that economic development and environmental protection are 'mutually reinforcing' and consequently seeks to provide practical solutions to the 'traditional conflict' between the two.[26]

While the exact meaning of sustainable development remains unclear, the definition popularised by the World Commission on Environment and Development (otherwise 'the Brundtland Commission') – an independent organisation created by the UN General Assembly in 1983 to tackle environmental and developmental problems and propose solutions[27] – is that it connotes 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs'.[28] This definition

[23] Gro Harlem Brundtland, *Our Common Future* (Oxford University Press 1991).
[24] Robert Goodland, 'The Concept of Environmental Sustainability' (1995) 26 *Annual Review of Ecology and Systematics* 26.
[25] Sumudu Atapattu, 'Sustainable Development, Myth or Reality? A Survey of Sustainable Development Under International Law and Sri Lankan Law' (2001) *Georgetown International Environmental Law Review*.
[26] ibid.
[27] Brundtland (n 23).
[28] ibid.

has been criticised by many commentators for being 'vague' and 'imprecise'.[29] However, it is noteworthy that irrespective of the vague and imprecise character of the definition, it takes cognisance of different and conflicting interests, and this accounts for the popularity and resilience of the concept.[30] Thus, sustainable development scholars have often disagreed on the question of the legal and normative status of the concept, with some insisting that it lacks a norm-creating character as it has been mostly developed through soft-law instruments, and there has been no instance of the application of the concept to reach a determination binding upon states.[31] On the other hand, others propound that sustainable development has acquired a place in international law because of reference to it in treaties, thereby transforming its status from a legal principle into a more binding customary law.[32]

Suffice it to say that sustainable development is not simply a principle of international law but has attained a normative force by being essential to the process of adjudication.[33] In this sense, Lowe has argued that:

> Norms may function primarily as rules for decision, of concern to judicial tribunals, rather than as rules of conduct. … It is in the area of these norms that I believe the search for the normative force of the concept of sustainable development should be sought. Sustainable development can properly claim a normative status as an element of the process of judicial reasoning. It is a meta-principle, acting upon other legal rules and principles--a legal concept exercising

[29] Andrea Ross, 'Modern Interpretation of Sustainable Development' (2009) 36(1) *Journal of Law and Society* 34; see also A B M Marong, 'From Rio to Johannesburg: Reflections on the Role of International Legal Norms in Sustainable Development' (2003) 16(1) *Georgetown International Environmental Law Review* 21-76, 56.
[30] Ross (n 29) 34.
[31] Vaughan Lowe, 'Sustainable Development and Unsustainable Arguments' in Alan Boyle and David Freestone (eds), *International Law and Sustainable Development: Past Achievements and Future Challenges* (Oxford University Press 1999); see also Mirjam van Harmelen, Matthijs S van Leeuwen and Tanja de Vette, 'International Law of Sustainable Development: Legal Aspects of Environmental Security on the Indonesian Island of Kalimantan' (2005) Institute for Environmental Security.
[32] Philippe Sands, 'International Law in the Field of Sustainable Development: Emerging Legal Principles' in Winfried Wang (ed), *Sustainable Development and International Law* (London; Boston: Graham & Trotman/M Nijhoff 1995) 56; see also Philippe Sands and Jacqueline Peel, *Principles of International Environmental Law* (Cambridge University Press 2018) 254-255.
[33] Lowe, 'Sustainable Development and Unsustainable Arguments' (n 31) 21.

> a kind of interstitial normativity, pushing and pulling the boundaries of true primary norms when they threaten to overlap or conflict with each other.[34]

Therefore, sustainable development is a normative concept operating between the interstitial space of primary norms, such as the right to development and the duty to protect the environment, when they overlap or conflict.[35] In other words, sustainable development acts upon principles and rules which originate from both prior and emerging international law in the fields of the environment, economic development and human rights.[36] While previously these fields developed independently, with the emergence of the concept of sustainable development 'they will be increasingly treated in an integrated and interdependent manner'.[37]

There are two key concepts that are derivable from the Brundtland definition of sustainable development: first, is the 'needs' concept, which encapsulates the essential needs of the poor to which the greatest priority should be given; and secondly, the notion of limitations imposed by humankind on the ability of the environment to meet present and future needs.[38] The latter is implied in 'sustainable', which captures environmental protection concerns; whereas 'development' covers issues of economic growth and social equality.[39] Meaning that for developmental projects to be sustainable, they must address *environmental*, *economic* and *social* concerns (also known as 'the sustainable development triad').[40] Put differently, sustainable development must cater for essential human needs such as food, water, sanitation, energy, jobs and healthcare.[41] The report of the Brundtland Commission, which was only advisory, underscored the importance of healthcare as a product of and contributor to sustainable development.[42] According to Dr Gro Harlem Brundtland, Chair of the World Commission on Environment and

[34] ibid 31.
[35] Vaughan Lowe, 'The Politics of Law-Making: Are the Method and Character of Norm Creation Changing?' in Michael Byers (ed), *The Role of Law in International Politics: Essays in International Relations and International Law* (Oxford University Press 2001) 213; see also van Harmelen et al. (n 31).
[36] Sands, 'International Law in the Field of Sustainable Development' (n 32).
[37] ibid.
[38] Brundtland (n 23); see also Sands and Peel, *Principles of International Environmental Law* (n 32) 253.
[39] Yasmin von Schirnding and Catherine Mulholland, 'Health in The Context of Sustainable Development' (World Health Organization 2002).
[40] Brundtland (n 23).
[41] ibid.
[42] ibid.

Development, health should be considered 'both as a precious asset in itself, and as a means of stimulating economic growth and reducing poverty'.[43]

Since the report of the Brundtland Commission, the conceptualisation of sustainable development has broadened to take cognisance of the concept as a new horizon for promoting health, whereas health must be considered a precondition for achieving sustainable development. In 1992, the United Nations Conference on Environment and Development, also known as the 'Earth Summit', was held in Rio de Janeiro.[44] This conference, which is considered to be one of the largest gatherings of many heads of states, diplomats, non-governmental organizations and scientists, was aimed at reconciling the impact of human socio-economic activities on the environment and vice versa.[45] It led to the adoption of the Rio Declaration on Environment and Development, comprised of a set of principles intended to establish international cooperation among states in preserving the global environment and developmental system,[46] and Agenda 21 – a non-binding comprehensive action plan of the UN in response to the Brundtland Commission's call for more concrete global initiatives for sustainable development into the 21st century.[47] Principle 1 of the Rio Declaration recognises that '[h]uman beings are at the centre of concerns for sustainable development' and 'are entitled to a healthy and productive life in harmony with nature'.[48] Further buttressing this point, Chapter six (on Protecting and Promoting Human Health) of Agenda 21 notes that health and sustainable development are intimately interconnected; thus, it was paramount to address the primary health needs of the world's populations, since they are integral to the realisation of sustainable development goals.[49]

[43] World Health Organization, 'World Summit on Sustainable Development' <https://www.who.int/wssd/en/> accessed 12 December 2018.
[44] The United Nations Conference on Environment and Development, The Rio Declaration on Environment and Development 1992 (subsequently 'The Rio Declaration on Environment and Development').
[45] Chief Executives Board Secretariat, 'United Nations Conference on Environment and Development – UNCED (1992)' (*United Nations System*, 23 February 2017) <https://www.unsystem.org/content/united-nations-conference-environment-and-development-unced-1992> accessed 17 December 2018.
[46] The Rio Declaration on Environment and Development 1992.
[47] The United Nations Conference on Environment and Development, *Agenda 21: The United Nations Programme of Action from Rio* (The United Nations Department of Public Information 1994).
[48] The Rio Declaration on Environment and Development 1992, Principle 1.
[49] Agenda 21: The United Nations Programme of Action from Rio (n 47) 42.

Ten years after the 1992 Rio Earth Summit, the World Summit on Sustainable Development (WSSD) was held in Johannesburg, South Africa, 26 August - 4 September 2002 to discuss more effective ways to achieve sustainability.[50] It has been explained that while sustainability is 'an end-state in which the needs of humankind and the needs of nature are both satisfied within some form of dynamic equilibrium', sustainable development is the 'means or process by which sustainability might be achieved'.[51] In essence, rather than an end in itself, sustainable development is a means to an end. Accordingly, a sustainable society is considered to be a society that has achieved sustainability through the process of sustainable development.[52] The WSSD was mainly concerned with the reasons minimal headway was made towards realising the Rio sustainable development goals.[53] A general consensus was that this was not a consequence of the quality of Rio's Agenda 21 – indeed, it was reliable and a document of high-quality.[54] Instead, that it failed to meet what was agreed in 1992 was due to inadequate implementation.[55] At the WSSD, delegates from 191 UN member states and representatives of major stakeholders adopted the Johannesburg Declaration on Sustainable Development,[56] which reaffirmed the world's commitment to sustainable development and included a resolve to build 'a humane, equitable and caring global society, cognizant of the need for human dignity for all'[57]; and the Plan of Implementation of the World Summit on Sustainable Development, to build upon the achievements of the Earth Summit by taking further concrete actions at all levels to enhance international cooperation and promote the integration of the three pillars of

[50] Report of the World Summit on Sustainable Development (New York: United Nations 2002).
[51] Donald Hector, Carleton Christensen and Jim Petrie, 'Sustainability and Sustainable Development: Philosophical Distinctions and Practical Implications' (2014) 23 *Environmental Values* 7-28; see also T Waas, J Hugé, A Verbruggen and T Wright, 'Sustainable Development: A Bird's Eye View' (2012) 3 *Sustainability* 1637-1661.
[52] Mark Diesendorf, 'Sustainability and Sustainable Development' in D Dunphy, J Benveniste, A Griffiths, P Sutton (eds), *Sustainability: The Corporate Challenge of the 21st Century* (Sydney: Allen & Unwin 2000) 19-37.
[53] L Hens and Bhaskar Nath, 'The Johannesburg Conference' in L Hens and Bhaskar Nath (eds), *The World Summit on Sustainable Development: The Johannesburg Conference* (Springer Science and Business Media 2006) 1-33.
[54] ibid.
[55] ibid.
[56] ibid.
[57] *Report of the World Summit on Sustainable Development* (n 50) Annex, Johannesburg Declaration on Sustainable Development 1.

sustainable development – economic development, social development, and environmental protection.[58]

More than the Earth Summit, the WSSD focused on the impact of health on sustainable development in recognition of its centrality to achieving sustainable development.[59] The Johannesburg Declaration noted that worldwide conditions, such as the lack of access to health care and endemic, chronic and communicable diseases such as malaria, tuberculosis and HIV/AIDS posed severe threats to sustainable development. [60] Consequently, it resolved to give priority attention and increase access to health care through decisions on targets, timetables and partnerships.[61] Similarly, Chapter VI (on Health and Sustainable Development) of the Plan of Implementation of the World Summit on Sustainable Development, reiterating that humankind is at the centre of concerns for sustainable development and, therefore, entitled to a healthy and productive life according to the Rio Declaration on Environment and Development, urged the need to address the causes of ill health, including environmental causes, and their impact on sustainable development, paying particular attention to the vulnerable members of society.[62] It also noted the urgent need to strengthen the capacity of healthcare systems to deliver accessible and affordable health services to prevent and treat diseases through research, programmes and initiatives, partnerships, and improved access to safe and essential medicines.[63] Thus, underlying the concept of sustainable development is the increasing realisation that the world's populations can only meet the targets of sustainable development goals in the absence of a high prevalence of debilitating diseases, and that the health of the population is a product and indicator of sustainable development.[64]

'Health' or being 'healthy' is a concept that eludes a comprehensive definition. It is a relative concept in that a person may feel the effects of a particular disease, yet feel

[58] ibid. Annex, Plan of Implementation of the World Summit on Sustainable Development 39.
[59] von Schirnding and Mulholland, 'Health in The Context of Sustainable Development' (n 39).
[60] *Report of the World Summit on Sustainable Development* (n 50) Annex, Johannesburg Declaration on Sustainable Development 3.
[61] *Report of the World Summit on Sustainable Development* (n 50) Annex, Johannesburg Declaration on Sustainable Development 3.
[62] ibid.
[63] ibid.
[64] ibid; see also von Schirnding and Mulholland, 'Health in The Context of Sustainable Development' (n 39).

healthy; whereas another may feel unhealthy as a result of minor pain or discomfort.[65] Thus, health or being healthy is much more than the absence of disease.[66] According to the World Health Organization (WHO), health is a 'state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity'.[67] However, this definition is limited for two reasons: first, it does not contemplate spiritual well-being which, although not important to some people, matters to others.[68] As will be seen from discussions in Chapter three, some patients opt for traditional treatments over conventional medicine because the traditional medicine system not only considers the physical, mental and social causes of sickness when performing healing but also considers the patient's interaction with supernatural forces and attempts to restore a balance where such interaction has been disturbed.[69] Secondly, the definition does not capture the socio-ecological viewpoint which perceives health as a component of not only social dynamics and determined not merely by social systems and individual characteristics and behaviour, but also by the biophysical environment and economic systems.[70] In this perspective lies the connection between sustainable development and health: that the level of health enjoyed by the world's populations is determined by environmental, economic and social patterns of development; whereas health plays a significant role in pursuing any sustainable development agenda because the population requires some degree of health to participate in, contribute to and enjoy the dividends of development.

Unsustainable environmental, economic and social patterns of development have had adverse impacts on global health. The excessive use of fossil fuels and the burning of biomass by power stations to generate electricity are examples of development trends that have been estimated to cause millions of deaths annually due to air pollution, which results in respiratory illnesses such as cases of chronic respiratory infection and

[65] Alex G Stewart, Ewan Wilkinson and C Vyvyan Howard, 'Health: A Necessity for Sustainable Development' in Hens and Nath (eds), *The World Summit on Sustainable Development* (n 53) 152.
[66] ibid.
[67] Constitution of the World Health Organization, as Adopted by the International Health Organization, New York, 19-22 June 1946 (Official Record of the World Health Organization, No 2).
[68] Stewart et al. (n 65) 152.
[69] Chidi Oguamanam, International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine (Toronto Buffalo London: University of Toronto Press 2006).
[70] Ilona Kickbusch, 'The Food System: A Prism of Present and Future Challenges for Health Promotion and Sustainable Development' (Health Promotion Switzerland 2010); see also Bente Kjærgård, Birgit Land and Kirsten Bransholm Pedersen, 'Health and Sustainability' (2013) 29(3) *Health Promotion International* 558-568.

pneumonia.[71] Another incident that instantiates this point is the gas tragedy of 2-3 December 1984 at the Union Carbide India Limited – a pesticide factory – in Bhopal, Madhya Pradesh, India (commonly known as 'the Bhopal gas tragedy'), considered to be the world's worst industrial disaster, which claimed the lives of an estimated 25,000 people, with 500,000 suffering from lingering health problems.[72] Due to the absence of adequate safety procedures, about 40 tons of methyl isocyanate gas and other chemicals spewed from the factory into the air and water causing cancer, tuberculosis, pneumonia, internal haemorrhage, paralysis and death to Bhopal's residents.[73] It is notable that the factory was established to take advantage of India's Green Revolution, which was a commitment to technology by the government, to solve the problem of food shortages that confronted its growing population in the early 1960s.[74] Also, the 26 April 1986 Chernobyl nuclear power plant explosion and 11 March 2011 Fukushima Daiichi Nuclear Disaster are other instances of accidents resulting from industrial activities that increased the risks of cancer for humans.[75] Likewise, the chemical spill from Sandoz, a chemical factory in Switzerland, on 1 November 1986 released toxic agrochemicals into the air and tons of pollutants into the Rhine River, which contaminated drinking water.[76] 60 million people were estimated to have died as a result of polluted drinking water and malnutrition, many of whom were children.[77]

Furthermore, despite the fact that technological advancement has led to many discoveries by medical sciences which have meant better health care services to treat a whole range

[71] Johannesburg Declaration on Health and Sustainable Development (adopted 22 January 2002).
[72] Apoorva Mandavilli, 'The World's Worst Industrial Disaster is Still Unfolding' *The Atlantic* (10 July 2018) <https://www.theatlantic.com/science/archive/2018/07/the-worlds-worst-industrial-disaster-is-still-unfolding/560726/> accessed 19 December 2018.
[73] ibid; see also Prabhash K Dutta, 'Bhopal Gas Tragedy: What Had Happened This Day 33 Years Ago That Killed Thousands? *India Today* (India, 3 December 2017) <https://www.indiatoday.in/india/story/bhopal-gas-tragedy-what-had-happened-this-day-33-years-ago-that-killed-thousands-1099247-2017-12-03> accessed 19 December 2018.
[74] Mandavilli (n 72).
[75] Steve Mulvey, 'Chernobyl's Continuing Hazards' *BBC* (2006) <http://news.bbc.co.uk/1/hi/world/europe/4942828.stm> accessed 1 October 2017; see also Will Ripley, Junko Ogura and James Griffith, 'Fukushima: Five Years After Japan's Worst Nuclear Disaster' *CNN* (11 March 2016) < http://edition.cnn.com/2016/03/08/asia/fukushima-five-year-anniversary/index.html> accessed 4 October 2017.
[76] BBC News, '1986: Chemical Spill Turns Rhine Red' (2005) <http://news.bbc.co.uk/onthisday/hi/dates/stories/november/1/newsid_4679000/4679789.stm> accessed 3 October 2017; see also Brundtland (n 23).
[77] Brundtland (n 23).

of diseases, the corollary has been greater longevity and population growth.[78] In turn, overpopulation has created more wastes that end up in the air through combustion, in water bodies through wastewater treatment, stormwater runoff and industry discharges.[79] More, the increased density of human populations has promoted the increase of infectious diseases such as tuberculosis, HIV, cholera and black death.[80] On the other hand, underdevelopment breeds poverty, which is at the root of the burden of disease worldwide:[81] first, people living in low-income settlements with poor infrastructure are exposed to the health problems of social instability, communicable and noncommunicable diseases, as well as environmental hazards.[82] Secondly, lack of education affects the ability of the poor to identify and take action to improve their health, and secure their basic needs.[83] Thirdly, shortfalls in agricultural production and lack of land reform directly affect food security and lead to malnutrition, which in turn, results in illnesses and susceptibility to infection.[84] Therefore, by addressing concerns connected with the environment, industrial activities, housing, water, sanitation, and urban and rural livelihoods, sustainable development improves the living standards of the population, which results in better health.[85]

As for the importance of health in realising sustainable development, pursuing development requires the participation, effort and contribution of the population as noted in the Declaration on the Right to Development 1986, Article 1.[86] An afflicted person or community would lack the capacity to give time, effort and resources to make the necessary adjustments required for attaining sustainable development.[87] For instance, it has been reported that malaria slows the economic growth in Africa by 1.3 per cent each

[78] 'Overpopulation: Causes, Effects and Solutions - Conserve Energy Future' (*Conserve Energy Future*) <http://www.conserve-energy-future.com/causes-effects-solutions-of-overpopulation.php> accessed 10 May 2016.
[79] May Linda Samuel, 'The Link Between the Human Health and Sustainability' (2008) 2 *Forum on Public Policy* 1.
[80] David Pimentel, Maria Tort, Linda D'Anna, Anne Krawic, Joshua Berger, Jessica Rossman, Fridah Mugo, Nancy Doon, Michael Shriberg, Erica Howard, Susan Lee, Jonathan Talbot, 'Ecology of Increasing Disease: Population Growth and Environmental Degradation' (1998) 48(10) *Bioscience* 1-24; see also Samuel (n 79).
[81] Johannesburg Declaration on Health and Sustainable Development 2002.
[82] von Schirnding and Mulholland, 'Health in The Context of Sustainable Development' (n 39).
[83] von Schirnding and Mulholland, 'Health in The Context of Sustainable Development' (n 39).
[84] ibid.
[85] Johannesburg Declaration on Health and Sustainable Development 2002; see also Stewart et al. (n 65).
[86] Declaration on the Right to Development 1986, art 1.
[87] Stewart et al. (n 65).

year, while HIV/AIDS set back the economy in high prevalence developing and least-developed countries by 2.6 per cent.[88] The high burden of these diseases and lack of access to essential medicines for treatment heavily impact on the workforce, leading to loss of many days of productive work, which translates into the loss of billions of dollars and untold hardship.[89] At the family level, poor health increases poverty, as the existence of diseases without effective public health service or prepayment system leads to debt that impoverishes families, thereby sabotaging their potential to develop.[90] In contrast, enhanced physical ability and increased cognitive ability enable children to acquire education.[91] In like manner, a healthy workforce equals productivity and resilience, as workers would have more energy and better mental health.[92] Also, there is the potential for higher rates of savings and investment, greater enterprise and agrarian productivity, as well as increased foreign direct investment and tourism, where members of a community enjoy good health.[93] Thus, it is usually one of the cardinal objectives of any sustainable development agenda that members of the community possess sufficient levels of health to further development goals. For instance, both the UN's Millennium Development Goals (MDGs) of 2000 and the 2030 Agenda for Sustainable Development (discussed later) emphasise the importance of health in accomplishing a sustainable path to development.[94]

One of the primary means for ensuring sufficient levels of health for sustainable development is promoting access to essential medicines for treatment. In explaining 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' as enshrined in the United Nations International Covenant on Economic, Social and Cultural Rights (ICESCR) (a multilateral treaty which is part of the

[88] Johannesburg Declaration on Health and Sustainable Development 2002.
[89] von Schirnding and Mulholland, 'Health in The Context of Sustainable Development' (n 39); see also Johannesburg Declaration on Health and Sustainable Development 2002.
[90] World Health Organization, 'Health and Sustainable Development: Meetings of Senior Officials and Ministers of Health – Summary Report' (World Health Organization 2002).
[91] Ilona Kickbusch and Callum Brindley, 'Health in the Post-2015 Development Agenda: An Analysis of the UN-Led Thematic Consultations, High-level Panel Report and Sustainable Development Debate in the Context of Health' (World Health Organization 2013) 20.
[92] ibid.
[93] Kickbusch and Brindley, 'Health in the Post-2015 Development Agenda' (n 91) 20.
[94] United Nations, 'The Millennium Development Goals Report 2015' (New York: United Nations 2015); see also United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).

International Bill of Human Rights consisting of 164 state parties),[95] the Committee on Economic, Social and Cultural Rights (CESCR) – a body of independent experts that monitor its implementation[96] – posited that the right to health entailed the right to enjoy a variety of facilities, goods, services and conditions, which included access to essential medicines of suitable quality on a non-discriminatory basis.[97] This means that access to medicines is an indispensable part of the right to attain the highest standard of health.[98] Augmenting this right is the provision of Article 15(1)(b) ICESCR, which affirms the right of everyone to 'enjoy the benefits of scientific progress and its applications' on an equitable and non-discriminatory basis.[99] Here, the benefits of progress in science and its applications encapsulate the end product of research, as well as the processes, methodologies and tools of scientific enquiry.[100] A logical inference from this is that everyone, whether rich or poor, is entitled to access health technologies derived from scientific research, such as medicines.[101]

This emphasis on access to essential medicines connotes the importance of medicines for sustaining health, for, as noted by the UN Special Rapporteur on the Right of Everyone to Enjoy the Highest Attainable Standard of Physical and Mental Health, medicines are indispensable to providing treatment for, and prevention and control of diseases.[102] Medicines have a significant impact on the leading causes of morbidity and mortality

[95] International Covenant on Economic, Social and Cultural Rights 1966, art 12.
[96] 'OHCHR – Introduction' (*Ohchr.org*) <http://www.ohchr.org/EN/HRBodies/CESCR/Pages/CESCRIntro.aspx> accessed accessed 6 October 2017.
[97] Committee on Economic, Social and Cultural Rights, 'General Comment 14: The Right to the Highest Attainable Standard of Health (Article 12)' (2000) Office of the High Commissioner for Human Rights para 9, 12(a), (b), (d).
[98] Paul Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (UN General Assembly, 61st Session Agenda Item 66(b) 2006); see also Philippe Cullet, 'Patents and Health in Developing Countries' in John Hatchard and Amanda Perry-Kessaris (eds), *Law and Development: Facing Complexity in the 21st Century* (Routledge 2012).
[99] International Covenant on Economic, Social and Cultural Rights 1966, art 15(1)(b).
[100] Treatment Action Group (TAG), 'Submission to the Office of the United Nations High Commissioner for Human Rights to Report on Sustainable Development Goal and Health' (*Treatment Action Group*, 16 October 2017) <http://www.treatmentactiongroup.org/content/submission-office-united-nations-high-commissioner-human-rights-report-sustainable> accessed 5 November 2017.
[101] ibid.
[102] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2006) (n 98).

such as malaria, tuberculosis, HIV/AIDS and other chronic diseases.[103] Thus, to ensure the ability of the population to participate in, contribute to, and enjoy sustainable development, it is all-important that there is access to medicines in a timely and affordable fashion to provide medical care in the event of sickness. In recent times, however, the path to sustainable development has been clogged with the prevalence of malaria, tuberculosis, HIV/AIDS and other communicable and noncommunicable diseases, including the lack of access to essential medicines for treating these pandemics, especially in developing and least-developed countries. Since health is a crucial determinant of sustainable development, this situation could potentially thwart global initiatives to achieve sustainable development. The next section elaborates on these obstacles to sustainable development.

1.2. The Breach of the Right to Health and its Potential Impact on Sustainable Development

The enjoyment of the human right to health is far from being a reality in light of the present state of public health. Since the 1980s, more than 35 million people are said to have died from AIDS-related diseases.[104] At the end of 2016, about 36.7 million people were living with HIV, with 25.6 million of them located in the African Region.[105] Tuberculosis is also one of the top 10 causes of death worldwide. In 2015, the disease struck 10.4 million people and claimed 1.8 million lives.[106] It is noteworthy that 95 per cent of the deaths occurred in developing and least-developed countries, notably: China, India, Indonesia, Nigeria, Pakistan, and South Africa.[107] Equally important is the fact that tuberculosis is a leading killer in HIV-positive patients, and a form of the infection is now caused by bacteria which is resistant to treatment (multidrug-resistant tuberculosis) using two of the known most effective anti-tuberculosis medications (isoniazid and rifampin).[108] Malaria, another life-threatening disease, is caused by parasites that are

[103] Management Sciences for Health, *MDGs-3: Managing Access to Medicines and Health Technologies* (Arlington, VA: Management Sciences for Health 2012) 1.3-1.4.
[104] 'HIV/AIDS' (*World Health Organization*, 2017) <http://www.who.int/mediacentre/factsheets/fs360/en/> accessed 8 October 2017.
[105] 'HIV/AIDS' (*World Health Organization*, 2017) (n 104).
[106] 'Fact Sheet About Tuberculosis' (*World Health Organization*, 2017) <http://www.who.int/mediacentre/factsheets/fs104/en/> accessed 8 October 2017.
[107] ibid.
[108] ibid; see also World Health Organization, 'What is Multidrug-Resistant Tuberculosis (MDR-TB) and How Do We Control It?' (*World Health Organization*, 2017) <http://www.who.int/features/qa/79/en/>

transmitted to humans through the bites of infected female Anopheles mosquitoes.[109] There were 212 million of such malaria cases worldwide in 2015 with an estimated 429,000 deaths.[110] About 92 per cent of these deaths occurred mainly in sub-Saharan Africa.[111] While these examples represent only a fraction of the pandemics that currently afflict the human race, one can argue the question of the likelihood of realising sustainable development since good health is necessary for the population to participate in, contribute to, and enjoy sustainability.

Further detracting from the achievability of sustainable development goals, millions of people around the world, mainly in developing and least-developed countries, lack access to essential medicines to treat diseases or reduce suffering.[112] The UN Special Rapporteur on the Right of Everyone to Enjoy the Highest Attainable Standard of Physical and Mental Health in 2006 and the WHO in its World Medicines Situation Report of 2011 pegged the number of people without access at almost 2 billion, mostly in developing and least-developed countries.[113] This deprivation has resulted in untold suffering: ill health, fear, pain, loss of dignity and life, whereas, improved access to essential medicines could save as many as 10 million lives, with the majority of them in Africa and South-East Asia.[114] Indeed, there has been improved access to treatment in the last 10 years. According to a 2014 report by UNAIDS – the Joint United Nations Programme on HIV/AIDS to help prevent new HIV infections, care for people living with HIV and mitigate the impact of the disease[115] – over 13 million people receive antiretroviral treatment for HIV, 87 per cent of whom reside in sub-Saharan Africa.[116]

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accessed 8 October 2017; and Kwonjume J Seung, Salmaan Keshavjee and Michael L Rich, 'Multidrug-Resistant Tuberculosis and Extensively Drug-Resistant Tuberculosis' (2015) 5(9) *Cold Spring Harbor Perspectives in Medicines.*

[109] 'Fact Sheet About Malaria' (*World Health Organization*, 2017) <http://www.who.int/mediacentre/factsheets/fs094/en/> accessed 9 October 2017.

[110] ibid.

[111] ibid.

[112] 't Hoen, *Private Patents and Public Health* (n 5); see also Cullet, 'Patents and Health in Developing Countries' (n 98).

[113] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2006) (n 98); see also Warren Kaplan and Colin Mathers, 'The World Medicines Situation 2011. Global Health Trends: Global Burden of Disease and Pharmaceutical Needs' (World Health Organization 2011).

[114] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2006) (n 98).

[115] 'About' (*UNAIDS*) <http://www.unaids.org/en/aboutunaids> accessed 9 October 2017.

[116] UNAIDS, 'The Gap Report' (Geneva, Switzerland: UNAIDS 2014); see also 't Hoen, *Private Patents and Public Health* (n 5).

Nevertheless, access to medicines is far from being regular; 61-63 per cent of people in need of treatment still do not have access to medicines.[117] Multiple barriers, based on scientific research, have been cited by specialised agencies of the UN, various civil society organisations and other stakeholders, as impediments to access to medicines in developing and least-developed countries.[118] They include under-resourced health systems, lack of qualified and skilled healthcare workers, lack of good governance, poor physical infrastructure and distribution systems, corruption, taxes and tariffs on medicines, exclusion, stigmatisation, and lack of policies that incentivise individuals and businesses to develop new technologies for growth and prosperity.[119]

The other side of the story reveals that granting patent rights to pharmaceutical companies is equally blameworthy for lack of access to medicines. The patent regime enables pharmaceutical companies to price medicines beyond the means of sick people in developing and least-developed countries through the monopoly rights that it vests in these companies.[120] The most comprehensive international agreement on intellectual property rights, the Agreement on the Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') which is within the scope of the World Trade Organization (WTO), entitles an inventor of anything new, involving an inventive step and capable of industrial application, to patent rights which confer on such inventor the right to exclude third party acts, such as using, making, offering for sale, selling or importing the patented invention[121] for a minimum of 20 years from the date of filing the patent application.[122] As will be seen in Chapter two, the logical basis for affording pharmaceutical companies this monopoly is to serve as an incentive to invest in the research and development (R&D)

[117] 't Hoen, Private Patents and Public Health (n 5).
[118] Adelman and Norris (n 18) 18.
[119] ibid; see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7); International Policy Network, 'Civil Society Report on Intellectual Property, Innovation, and Health' (London: International Policy Network, 2006) 59; and Tefo Pheage, 'Dying from Lack of Medicines' *AfricaRenewal* (December 2016 – March 2017) <http://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines> accessed 14 July 2017.
[120] Philippe Cullet, 'Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health' (2003) 79(1) *International Affairs* 139-160.
[121] TRIPS 1994, art 28(1).
[122] ibid. art 33.

of new medicines.[123] R&D of new medicines requires large investments involving about US$2.56 billion to US$2.87 billion per drug.[124] Thus, allowing third parties to exploit the product of this investment at no cost would be commercially unfair to pharmaceutical companies. In light of this, the grant of the patent monopoly allows them to recover the substantial cost invested in R&D of medicines, and to collect profits as well by demanding high prices for their products.[125]

However, this has a negative consequence: offering medicines at very high prices excludes the poor in developing and least-developed countries who cannot afford to pay for accessing life-saving medications. This situation is exacerbated by the fact that healthcare services are rendered based on out-of-pocket payment in some developing and least-developed countries, particularly in the African Region.[126] In those where there is social health protection, for instance, Kenya, Senegal and South Africa, the system caters for formal sector workers and their families alone.[127] This is the reality for an estimated 150 million people who are forced to spend almost half of their income on health care, and who will most likely either be pushed below the poverty line or even deeper into poverty.[128] This set of facts draws attention to the potential of traditional medicine to contribute to sustainable development: as will be seen in Chapter three, it is less expensive when compared to conventional medicine, and it offers flexibility in terms of *how* and *when* fees for treatment are paid, thereby taking cognisance of the economic status of the patient.[129]

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[123] Javier Esparaza, 'Indian Patent Law: Working Within the TRIPS Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health' (2014) 24 *Journal of Transnational Law & Policy* 205.
[124] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 35.
[125] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 29.
[126] Dan Kaseje, 'Health Care in Africa: Challenges, Opportunities and An Emerging Model for Improvement' (Paper Presented at The Woodrow Wilson International Centre for Scholars, 2006) 4; see also 't Hoen, *Private Patents and Public Health* (n 5) 4; and Cullet, 'Patents and Health in Developing Countries' (n 98).
[127] 'Social Health Insurance in Developing Countries: Breaking the Poverty-Health Care Link' (*International Labour Organization*, 13 December 2005).
[128] ibid.
[129] Susanna Hausmann Muela, Adiel K Mushi and Joan Muela Ribera, 'The Paradox of the Cost and Affordability of Traditional and Government Health Services in Tanzania' (2000) 15(3) *Health Policy and Planning* 296-302, 301.

Intellectual property rights advocates do not agree that patent monopolies are partly responsible for the current problems surrounding access to medicines in developing and least-developed countries. On the contrary, they firmly assert that patents have incentivised the pharmaceutical industry to develop revolutionary drugs that have saved millions of lives, including those of the poor in developing and least-developed countries.[130] The development of zidovudine for HIV in 1987 and the Highly Active Anti-Retroviral Therapy (HAART) in 1996 is almost always referred to in support of this assertion.[131] The summation of their argument is that it is beneficial to maintain this system of 'financially' rewarding investments in transformative innovation relating to terminal diseases through the grant of patent rights.[132] However, this model of incentivising the pharmaceutical industry has resulted in the business tactic of prioritising the development of treatments for 'profitable diseases' affecting the affluent in developed countries, while often neglecting the medical needs of the poor and marginalised in the developing world who cannot afford exorbitant prices charged for medicines.[133] Examples of this are the type II diseases that disproportionately, but not exclusively affect developing and least-developed countries, such as malaria, HIV/AIDS, and dengue, which have received some, but not enough R&D; and type III diseases that exclusively affect the developing world – the 'most neglected diseases' – which receive little or no R&D, such as neglected tropical diseases.[134]

Besides, although there has been moderate improvement in global access to medicines, the system of relying on financial reward as the predominant means to incentivise innovation is problematic, as newer medicines remain out of reach of the poor due to excessive pricing.[135] Unarguably, this situation has negative consequences for the realisation of sustainable development because access to essential medicines is needed to

[130] Amanda Glassman and Miriam Temin, *Millions Saved, New Cases of Proven Success in Global Health* (Washington DC: Centre for Global Development 2016); see also Iain M Cockburn, Jean O Lanjouw and Mark Schankerman, 'Patents and the Global Diffusion of New Drugs' (2016) 106(1) *American Economic Review* 136-164; and Cullet, 'Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health' (n 120) 139-160.
[131] Adelman and Norris (n 18) 4, 13-14.
[132] ibid 4.
[133] FXB Centre for Health and Human Rights, 'How is Access to Medicine a Human Rights Issue' in *Health and Human Rights Resource Guide* (FXB Centre for Health and Human Rights and Open Society Foundations 2017).
[134] 't Hoen, Private Patents and Public Health (n 5) 121.
[135] 't Hoen, *Private Patents and Public Health* (n 5) 121; see also Jacqui Wise, 'Access to AIDS Medicines Stumbles on Trade Rules' (2006) 84(5) *Bulletin of the World Health Organization* 337-424.

ensure the maintenance of sufficient levels of health. Thus, if it is agreed that access to essential medicines is an indispensable part of the right to attain the highest standard of health and the right of everyone to enjoy the benefits of scientific advancement and its application, as confirmed by the ICESCR, then it means that patent protection for pharmaceuticals (ostensibly to spur innovation) is in obvious conflict with internationally guaranteed human rights.

The state and the pharmaceutical industry are the main perpetrators of the violation of these international human rights. As will be pointed out in Chapter two, states have the core duty to ensure that existing medicines are available to their populations, and that essential medicines are developed and made accessible within their borders.[136] The implication of this is that developing and least-developed countries neglect their obligation to provide essential medicines when they fail to make use of the flexibilities contained in the TRIPS Agreement, for instance, by not producing low-cost generics using the compulsory licencing system and when they impose tariffs and taxes on drugs.[137] Because access to medicines forms part of the right to health and the right of everyone to share in scientific progress, this act of negligence amounts to a breach of these human rights.

Likewise, the pharmaceutical industry has a duty to take all reasonable measures to make new medicines 'as available as possible' for those who are in need of treatment.[138] As noted by Paul Hunt[139] and Rajat Khosla,[140] pharmaceutical companies have the responsibility to make medicines accessible to those who cannot pay the high cost, using

[136] Paul Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (UN General Assembly, 63rd Session, Agenda Item 67(b) 2008).
[137] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2006) (n 98).
[138] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2008) (n 136); see also Mary Robinson, 'The Business Case for Human Rights' in *Visions of Ethical Business* (Financial Times Management 1998); and S Vieira de Mello, 'Human Rights: What Role for Business?' (2003) 2(1) *New Academy Review* 19.
[139] Former United Nations Special Rapporteur on the Right of Everyone to Enjoy the Highest Attainable Standard of Physical and Mental Health.
[140] A Human Rights Adviser at the World Health Organization.

a 'viable business model'.[141] Based on this, one can infer that when pharmaceutical companies vigorously seek or enforce patent protection; or when they do not develop needed medicines for diseases they consider unprofitable, they breach their responsibilities under the right to health. Therefore, although other barriers to access to medicines are important and worth examining, it is this complex interaction between the justifiable rights of inventors, trade, international human rights and access to medicines, plus the potential for this interaction to stall sustainable development strides, that places it at the centre stage in international discussions regarding access to medicines – more recently under the UN 2030 Agenda for Sustainable Development and the High-Level Panel on Innovation and Access to Health Technologies. (More reflection on the interaction in Chapter two.)

On 25 September 2015 at the United Nations Sustainable Development Summit in New York, US, world leaders belonging to the 193 member states of the UN adopted a development agenda titled: *Transforming Our World: the 2030 Agenda for Sustainable Development*. [142] This Agenda recognises the interdependence of sustainable development and health, as it emphasises that health policies can contribute to sustainable development and poverty reduction if people have access to the information and services needed to protect and promote health.[143] In line with this thinking, one of its goals is to ensure a healthy life and promote well-being for all, primarily through enhancing access to medicines for treatment.[144] This confirms that access to essential medicines is indispensable to the achievement of sustainable development because it advances the enjoyment of good health. Mindful of this, one of the objectives of this research is to investigate whether traditional medicine could contribute to sustainable development by providing treatments for malaria, tuberculosis and HIV/AIDS if integrated into the national health systems of developing and least-developed countries, as will be seen in Chapter three. The next section assesses the 2030 Agenda for Sustainable Development

[141] Paul Hunt and Rajat Khosla, 'Are Drug Companies Living up to their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)' (2010) 7(9) *PLoS Medicine*.
[142] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).
[143] World Health Organization, 'Health in 2015 from MDGs to SDGs' (World Health Organization 2015).
[144] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 3.

and its action plan for remedying the access to medicines problem in developing and least-developed countries with the aim of realising sustainable development.

1.3. The 2030 Agenda: Remedying Lack of Access to Essential Medicines

The 2030 Agenda for Sustainable Development is the most comprehensive blueprint for catering to the needs of the present without mortgaging the needs of future generations, which is founded on social inclusion, poverty reduction and environmental stewardship.[145] It is comprised of a set of 17 goals and 169 targets which took effect from 1 January 2016.[146] These goals are integrated, indivisible, and universally applicable.[147] They recognise and respect the differences in realities, levels of development, capacity, and priorities of the different UN member states.[148] Because the targets of the Agenda are global and aspirational, member states are permitted to set their national targets guided by the global level of ambition but taking into account national circumstances.[149] This means that the 2030 sustainable development goals are not legally binding;[150] they are merely global developmental aspirations aimed at guiding policy formulation and decision-making with the aim of achieving sustainable development by 2030.[151] Based on this understanding, governments are expected to take ownership and establish national frameworks for the achievement of the 17 goals.[152] In this light, one of the implications of this research could be the inclusion by governments of developing and least-developed countries of traditional medicine as a complementary tool to the use of TRIPS flexibilities and a convention on drug R&D in their national frameworks on sustainable development in order to provide the much needed health care. More, governments have the primary responsibility to account to their citizens by conducting 'a follow-up and review at the

[145] 'World Health Statistics: Monitoring Health for the SDGs, Sustainable Development Goals' (n 4).
[146] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).
[147] ibid.
[148] ibid.
[149] ibid.
[150] 'United Nations Sustainable Development Agenda' (*United Nations Sustainable Development*) <http://www.un.org/sustainabledevelopment/development-agenda/ > accessed 6 November 2017; see also Joachim Monkelbaan, *Governance for the Sustainable Development Goals: Exploring an Integrative Framework of Theories, Tools, and Competencies* (Springer 2018) 4.
[151] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).
[152] 'United Nations Sustainable Development Agenda' (*United Nations Sustainable Development*) (n 150).

national, regional and global levels' to ascertain the progress made in implementing the goals and targets over the 15-year target period for global progress.[153]

The 2030 Agenda for Sustainable Development reaffirmed commitment to the outcomes of major United Nations' conferences and summits which have laid the foundation for sustainable development, including the Rio Declaration on Environment and Development and the World Summit on Sustainable Development.[154] The Agenda also seeks to build on and redress the failings of the MDGs.[155] The MDGs, adopted in 2000, aimed at reducing poverty, hunger, diseases and gender inequality, and improving access to water and sanitation.[156] However, its achievements were uneven, especially in developing and least-developed countries. Operational deficiency (that implicates stakeholders in both developed and developing countries) was one of the reasons for this unequal progress.[157] Developed countries also reneged on their promises to provide assistance to developing and least-developed countries.[158] Recognising this, member states committed through the sustainable development goals to provide a focused and scaled-up assistance to developing and least-developed countries in special situations.[159] The sustainable development goals will redress the shortcomings of the MDGs by reaching out to the most vulnerable.

Described as 'more bold and ambitious than anything that has come before them',[160] the sustainable development goals cover a broader scope than the MDGs, as they propose a wide range of economic, social and environmental objectives while maintaining development priorities, such as education, poverty eradication, food security, nutrition and health.[161] In health terms, the Agenda frames health and well-being as *outcomes* and

[153] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).
[154] ibid.
[155] ibid preamble.
[156] ibid.
[157] Jeffery D Sachs, 'From Millennium Development Goals to Sustainable Development Goals' (2012) 379 *The Lancet* 2206.
[158] ibid.
[159] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3).
[160] Stéphanie Thomson, 'What are the Sustainable Development Goals?' (*World Economic Forum*, 15 September 2015) <https://www.weforum.org/agenda/2015/09/what-are-the-sustainable-development-goals/> accessed 31 January 2016.
[161] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3); see also Monkelbaan (n 150) 4; and Raj Kumar, 'Critics of the Sustainable Development Goals were wrong. Here's why' (*World Economic Forum*, 30 January 2017)

foundations of social inclusion, poverty reduction and environmental protection.[162] In other words, from a health perspective, development qualifies as 'sustainable' when resources – natural and manufactured – are managed in ways which support the health and well-being of both present and future generations;[163] whereas, good health is a precondition for and contributes to progress towards other social, economic and environmental goals (sustainable development triad).[164] This explains the reason the Agenda links promoting health and well-being to all 17 sustainable development goals, as mentioned in the introductory chapter.[165] Nonetheless, critical analyses point out the inconsistency in the sustainable development goals, especially between socio-economic development and environmental protection goals.[166] Such analyses reveal that the sustainable development goals are more focused on 'economic growth and consumption as a means of development' than environmental protection.[167] Questions are also raised about the difficulty in quantification, implementation, monitoring and funding of the broadly framed sustainable development goals.[168] Moreover, being a voluntary rather than a binding agreement, there is a likelihood that states may default on their commitments.[169] However, this also presents an opportunity, in that states may be willing to adopt a more ambitious agenda in the absence of legally binding obligations.[170]

These sustainable development goals are guided by the objectives and principles of the Charter of the United Nations, grounded in the Universal Declaration on Human Rights and other international human rights treaties, and informed by other instruments such as

<https://www.weforum.org/agenda/2017/01/turns-out-sdg-critics-were-wrong/> accessed 22 December 2018.

[162] 'World Health Statistics: Monitoring Health for the SDGs, Sustainable Development Goals' (n 4).

[163] ibid.

[164] World Health Organization, 'Progress in the Implementation of the 2030 Agenda for Sustainable Development' (n 22).

[165] ibid.

[166] Ranjula Bali Swain, 'A Critical Analysis of the Sustainable Development Goals' in Walter Leal Filho (ed), *Handbook of Sustainability Science and Research* (World Sustainability Series, Springer 2018) 341-355.

[167] Viktoria Spaiser, Shyam Ranganathan, Ranjula Bali Swain and David J T Sumpter, 'The Sustainable Development Oxymoron: Quantifying and Modelling the Incompatibility of Sustainable Development Goals' (2016) *The International Journal of Sustainable Development & World Ecology*; see also Swain, 'A Critical Analysis of the Sustainable Development Goals' (n 166).

[168] Swain, 'A Critical Analysis of the Sustainable Development Goals' (n 166); see also Rotimi Jaiyesimi, 'The Challenges of Implementing the Sustainable Development Goals in Africa: The Way Forward' (2016) 20(3) *African Journal of Reproductive Health* (Special Edition on SDGs) 14.

[169] Thomas Pogge and Mitu Sengupta, 'Assessing the Sustainable Development Goals from a Human Rights Perspective' (2016) 32(2) *Journal of International and Comparative Social Policy* 83-97.

[170] ibid.

the Declaration on the right to Development.[171] In particular, the nucleus for realising the right to health and the right to share in the benefits of scientific progress is Goal 3 of the Agenda: 'Ensure healthy lives and promote well-being for all at all ages,' *leaving no one behind*, especially the populations of developing and least-developed countries.[172] One of the aspirations embodied in this goal is to eradicate the epidemics of malaria, tuberculosis, HIV/AIDS and other communicable and noncommunicable diseases that predominantly afflict the developing world by 2030.[173] Underscoring the importance of access to medicines to the enjoyment of health and scientific progress, the 2030 Agenda aims to end these diseases through R&D of vaccines and medicines, promoting universal health coverage, and enhancing access to affordable essential medicines by encouraging developing and least-developed countries to utilise the policy spaces contained in the TRIPS Agreement.[174] These policy spaces are referred to as 'TRIPS flexibilities'.

The rationale behind this strategy is the recognition that millions of people, particularly in developing and least-developed countries, do not have access to essential medicines to treat these diseases and alleviate suffering. What is more, by encouraging developing and least-developed countries to utilise TRIPS flexibilities, the 2030 Agenda recognised the impact of patent protection on international human rights and public health in the context of access to medicines. It was in view of this complex relationship that the former Secretary-General of the UN, Ban Ki-moon, convened a High-Level Panel on Innovation and Access to Health Technologies soon after the adoption of the 2030 Agenda on Sustainable Development in 2015, to propose 'solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies'.[175]

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[171] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 3.
[172] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 3.
[173] ibid.
[174] ibid.
[175] 'Secretary-General's message on the Report of the High-Level Panel on Access to Medicines, "Promoting Innovation and Access to Health Technologies"' (*United Nations Secretary-General*, 22 November 2016) <https://www.un.org/sg/en/content/sg/statement/2016-11-22/secretary-generals-message-report-high-level-panel-access-medicines-> accessed 13 July 2017.

The High-Level Panel's terms of reference reiterated the fact that millions of people, especially in developing and least-developed countries, lack access to essential drugs to treat diseases such as malaria, tuberculosis, HIV, hepatitis and noncommunicable diseases, as a result of high cost of medicines owing to patent protection.[176] The resulting report of the High-Level Panel, which is but advisory, opined that market-based models, which ostensibly incentivise innovation, often culminated in inadequate investment in R&D for diseases that predominantly affect the poor, and the high prices charged by rightsholders place severe burdens on health systems and individual patients in developing and least-developed countries.[177] Consequently, the Panel suggested, among other things, that countries reinforce the use of TRIPS flexibilities as a fundamental part of the TRIPS Agreement – not as an exception. It also encouraged the engagement in transparent priority setting and coordination to prevent infectious diseases, as well as negotiating a binding R&D convention that delinks the costs of R&D from end prices of health technologies.[178] As explained in Chapter two, the idea behind this concept of delinkage is that the incentives and reward for pharmaceutical companies for investing in the costs and risks associated with R&D of medicines should be by means other than the price of the product.[179]

This thinking emanates from the fact that allowing innovators to recoup investments and generate profits by charging exorbitant prices that are more than the cost of production, constitutes a critical barrier to access to medicines in developing and least-developed countries where sick people pay out-of-pocket and thus, cannot afford expensive medicines. [180] Regarding the TRIPS flexibilities, the recommendation for their reinforcement means that governments of developing and least-developed countries should enact these flexibilities in national legislation and apply them to access affordable essential medicines, thereby ameliorating the adverse impact of patents on the right to

[176] 'United Nations Secretary- General's High-Level Panel on Access to Medicines: The Process' (*United Nations Secretary-General's High-Level Panel on Access to Medicines*, May 25, 2016) <http://www.unsgaccessmeds.org/the-process/> accessed 26 July 2017.
[177] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[178] FXB Centre for Health and Human Rights (n 133).
[179] World Health Organization, World Intellectual Property Organization and World Trade Organization, *Promoting Access to Medical Technologies and Innovations: Intersections between Public Health, Intellectual Property and Trade* (Geneva: WHO, WIPO and WTO 2012).
[180] ibid.

health. These flexibilities are notably: the right of member states to determine patentability criteria (which can exclude the patenting of trivial developments);[181] the right of states to issue compulsory licences to permit the state or a third party to manufacture a generic version of a patented drug;[182] parallel importation of patented drugs sold in another state at a lower price without the consent of the patent holder;[183] and protecting test data against unfair commercial use (and not granting it a period of exclusivity).[184] These are further discussed in Chapter two.

This research questions whether the strategy of utilising the TRIPS flexibilities and negotiating a convention on drug R&D can promote timely access to medicines in developing and least-developed countries to realise sustainable development by 2030. This appears to be highly improbable, for while it is a fact that few developing and least-developed countries have successfully employed TRIPS flexibilities to promote access to medicines within their territories – for instance, India rejected the patentability of a new form of an existing anticancer drug in *Novartis v Union of India*[185] because the modification failed to make the existing product more efficacious,[186] and Thailand issued compulsory licences in 2007 for the production of low-cost antiretroviral drugs for HIV patients[187] – free trade agreements (FTAs) constitute a major impediment to reinforcing the use of TRIPS flexibilities to enhance access to affordable medicines.

More often than not, developing and least-developed countries perceive trade liberalisation as an avenue for capital flows, jobs and generation of wealth, whereas public health objectives, such as access to medicines and universal health care involve

[181] Carlos Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (2011) Research paper No 41 South Centre.
[182] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) *Journal of International Economic Law* 73, 2.
[183] R D Smith, C Correa and C Oh, 'Trade, TRIPS and Pharmaceuticals' (2009) 373 *The Lancet* 684.
[184] Carlos Correa and Duncan Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to health' (2011) United Nations Development Programme 10.
[185] (2013) 6 SCC 1 96.
[186] The Patents (Amendment) Act 2005, s 3(d).
[187] ITPC, 'The Campaign for Use of Compulsory Licensing in Thailand' (*Make Medicines Affordable*, 18 February 2015) <http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/> accessed 12 September 2016.

large expenditures.[188] To gain access to foreign markets, therefore, developing and least-developed countries negotiate FTAs with their developed counterparts, who usually demand very stringent intellectual property protection in exchange for trade favours.[189] This demand is enshrined in these trade agreements, through its provisions known as 'TRIPS-plus provisions', because they require higher intellectual property protections than the TRIPS Agreement.[190] The consequence of acceding to higher protections for developing and least-developed countries is that any attempt to exploit the policy spaces in the TRIPS Agreement with the aim of circumventing patent protection is considered by developed countries as a breach of the provisions of the trade agreement, and met with threats of political or trade retaliation.[191] Thus, it is difficult to see how this practice would not undermine the use of TRIPS flexibilities to achieve health and well-being by 2030 without leaving the poor in developing and least-developed countries behind.

The same goes for the idea of negotiating a binding convention on R&D; besides the complex and bureaucratic nature of treaty negotiations, the presence of multiple actors with varying interests to safeguard and the existence of contentious issues that must be agreed upon in order for the convention to be workable, have the potential to result in a protracted process, and possibly an impasse. First and foremost, developed countries and the pharmaceutical industry, who would no doubt be prominent actors, would have the aligned objective of procuring a convention on R&D which would not interfere with their economic interests. On the other side of the divide would be the developing and least-developed countries together with non-governmental organisations (NGOs), whose motivation would be to secure a convention which would promote the R&D of medicines for diseases that predominantly plague their populations, as well as ensures access to the end products at affordable prices.

[188] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[189] Smith et al. (n 183) 684.
[190] Sean Baird, 'Magic and Hope: Relaxing TRIPS-Plus Provisions to Promote Access to Affordable Pharmaceuticals' (2013) 33 *Boston College Journal of Law & Social Justice* 107,111.
[191] Christopher Arup, 'TRIPS: Across the Global Field of Intellectual Property' (2004) *European Intellectual Property Review* 9; see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).

Further aggravating this clash of interests, parties would need to determine whether pharmaceutical companies and other research institutions would be allowed under the convention to acquire patent rights over the end product of research. This is acutely fundamental as that allowance is most likely to defeat the purpose of the convention, given the fact that the system of incentivising innovation engendered by the patent regime led to the public health problems of high prices of medicines and deficit in R&D for diseases affecting the developing world in the first place. Therefore, it is on the basis of these improbabilities surrounding the use of TRIPS flexibilities and the negotiation of a convention on drug R&D to promote universal health coverage and access to medicines in developing and least-developed countries, that this research investigates the potential for traditional medicine to contribute to sustainable development.

1.4. A Brief Insight into Traditional Medicine and Why it may be Useful for Achieving Sustainable Development

In a world where: the poor lack access to treatment due to rising cost of health care; essential medicines are unavailable owing to deficient policies and substandard infrastructure; there has been a massive reduction in the development of new molecular entities in spite of ever increasing investment;[192] patients 'want more control over what is done to their bodies' as opposed to being treated as 'a collection of specialised body-parts on an assembly line';[193] some patients are distrustful that chemical drugs may have side effects that have either not been discovered or have been withheld by pharmaceutical companies,[194] this research reasons that the traditional system of medicine may represent a viable tool for complementing the use of TRIPS flexibilities and (probably) a convention on drug R&D, for providing more robust health care in developing and least-developed countries. This system of medicine consists of age-long practices within various indigenous societies, which precede the emergence of conventional medicine, and involve the use of plants, animals and mineral-based medicines, spiritual therapies and

[192] Graham Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-based Biopiracy' (2011) 33(4) *European Intellectual Property Review* 237, 238; see also Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (n 10).
[193] Margaret Chan, 'The Contribution of Traditional Chinese Medicine to Sustainable Development: Keynote Address at the International Conference on the Modernization of Traditional Chinese Medicine' (World Health Organization 2016).
[194] ibid.

manual techniques designed to treat illnesses and maintain well-being.[195] The logic behind this research's reasoning is that if traditional medicine can provide treatments for illnesses, especially malaria, tuberculosis and HIV/AIDS, and maintain well-being, then it will be useful in realising Goal 3 thereby enabling the populations of developing and least-developed countries to participate in, contribute to and enjoy sustainable development. In this way, it can be instrumental to realising the 2030 Agenda for Sustainable Development.

As will be seen from discussions in Chapter three, the fact that traditional medicine has much to offer in terms of providing primary health care and universal coverage, especially having regard to the rapid growth of chronic communicable and noncommunicable diseases, has been validated by notable international organisations. In particular, the WHO, whose opinion is very important in the context of health, being the relevant international body entrusted with global public health policy and governance,[196] has noted that for the millions who inhabit the rural areas of developing and least-developed countries, traditional treatments, such as herbal medicines, are the primary, and in some cases, the only source of health care.[197] This is because, in comparison to conventional medicine, they are forms of care that are close to homes, accessible and affordable.[198] Those who administer traditional treatments usually consist of prominent members of the community whose abilities and remedies are supported by public confidence.[199] Traditional medicine has been used to soothe, treat various common diseases, reduce suffering and alleviate pain. The traditional knowledge and practices used to effectuate healing have been generated over centuries, and are deeply rooted in the community's culture and belief system; for example, the traditional Chinese medicine and the Ayurveda system historically rooted in India.[200] This point is one of the reasons some patients favour traditional over conventional medicine, as it does not only lend itself to the physical, mental and social understanding of the causes of sickness but equally, the cultural and spiritual aspects, as will be assessed in Chapter three.

[195] Ryan Abbott, 'Documenting Traditional Medical Knowledge' (2014) World Intellectual Property Organization (WIPO), 3.
[196] Constitution of the World Health Organization 1946.
[197] Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (n 10).
[198] ibid.
[199] ibid.
[200] ibid.

Also, whereas the 2030 Agenda does not consider traditional medicine as a means for achieving Goal 3, it acknowledges the potential for 'traditional plant-based medicines' to contribute to sustainable development under Goal 15. Goal 15 seeks to 'sustainably manage forests, combat desertification, halt and reverse land degradation, and halt biodiversity loss'.[201] It aims to achieve this through *inter alia*, the conservation of biodiversity in order to enhance its capacity to provide benefits that are essential for sustainable development, to promote the fair and equitable sharing of benefits arising from the utilisation of genetic resources, and promote appropriate access to such resources, as internationally agreed.[202] According to Goal 15, one of such benefits is that 80 per cent of people living in rural areas of developing and least-developed countries rely on 'traditional plant-based medicines' for primary health care and only less than 1 per cent of over 80,000 tree species have been studied for potential use.[203] Thus, it recognises the need for the conservation and sustainable use of biodiversity in order to ensure sustained access to traditional medicine based on the realisation that it contributes to sustainable development by promoting universal health coverage and access to medicines for those in developing and least-developed countries.

However, the traditional system of medicine is not without flaws. Chapter four notes that there has been trepidation regarding the lack of sufficient evidence of its safety and efficacy. Also, there are concerns that the manufacturing processes of herbal medicines do not comply with quality assurance standards demanded by Good Manufacturing Practices (GMPs).[204] These have obvious implications for the health and safety of patients. Further intensifying these misgivings have been reports of practices of charlatans who claim to have special knowledge of and the ability to use the healing properties of plants, prescribing fake remedies that have resulted in either grievous bodily

[201] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 15.
[202] ibid.
[203] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 15.
[204] Anthony Lin Zhang, Charlie Changli Xue and Harry H.S. Fong, 'Integration of Herbal Medicine into Evidence-based Clinical Practice: Current Status and Issues' in IFF Benzie and S. Wachtel-Galor (eds), *Herbal Medicines: Biomolecular and Clinical Aspects* (2nd edn, Boca Raton (FL): CRC Press/Taylor & Francis 2011).

harm or death to many people seeking treatment.[205] This set of circumstances is indicative of poor policy and regulatory measures for traditional medicine practices, products and practitioners, which has consequently adversely affected its safety, efficacy and quality.

It must be emphasised that this shortcoming in its institutional framework cannot lead to the conclusion that traditional medicine has nothing to offer in terms of enhancing access to medicines and universal health coverage. As already pointed out, the conventional medicine system also has some weaknesses regarding how expensive some of its treatments are, its approach to treatment, and its safety, efficacy and quality.[206] Yet, millions of people around the world depend on some of its highly effective and emergency measures that make a difference in life-and-death situations.[207] And even if it is established that traditional medicine can provide some of the much needed treatments to achieve sustainable development, the objective of this research is not for traditional medicine to be a substitute for (i.e. completely replace) conventional medicine, as it cannot always do so.[208] Rather, if it can provide treatments for malaria, tuberculosis and HIV/AIDS, this research reasons that governments of developing and least-developed countries should properly integrate traditional medicine into their national health systems as a complementary measure to the use of TRIPS flexibilities and (probably) a convention on drug R&D to promote access to affordable medicines and universal health coverage. As will be seen in Chapters five and six, this can be achieved through addressing these challenges confronting the proper use of traditional medicine for health care. Addressing these challenges would require the formulation of not only adequate national policies and regulatory frameworks for traditional medicine, but also adequate measures for the training and licencing of traditional practitioners, and measures to ensure the safety, efficacy and quality of traditional medicine practices and therapies.

[205] IRIN 'Authorities Urge Caution on Popular "Cure-All" Herb' (Dar Es Salam: 4 April 2011) <http://www.irinnews.org/report/92360/tanzania-authorities-urge-caution-popular-cure-all-herb> accessed 4 May 2017.
[206] Margaret Chan, 'The Contribution of Traditional Chinese Medicine to Sustainable Development' (n 193).
[207] Margaret Chan, 'Address at the WHO Congress on Traditional Medicine' (World Health Organization 2008).
[208] Chan, 'Address at the WHO Congress on Traditional Medicine' (n 207).

In conclusion, the connection between health and sustainable development that makes access to medicines indispensable is that both concepts are mutually dependent. While health is determined by social, economic and environmental dynamics (the sustainable development triad), and therefore, a product and indicator of sustainable development, health is pivotal to the realisation of all sustainable development goals (social, economic and environmental) because individuals and populations require some level of good health in order to participate in, contribute to and enjoy sustainable development. Thus, to maintain a reasonable measure of health and well-being to achieve sustainable development, access to essential medicines is fundamental for preventing and treating diseases. So, if it is found that traditional medicine has the potential to provide curative and palliative remedies for malaria, tuberculosis and HIV/AIDS, then there is a good case for it to be exploited through appropriate integration into the national health systems of developing and least-developed countries. The aim is to realise sustainable development by 2030 without leaving those in the developing world behind as envisaged by the UN Agenda.

Next, Chapter two evaluates in depth the interference of the patent regime with access to medicines and makes a case for why the strategy of utilising TRIPS flexibilities and negotiating a binding convention on drug R&D may not deliver on the Agenda's aspiration of eradicating malaria, tuberculosis, HIV/AIDS and other communicable and noncommunicable diseases by 2030 through promoting timely access to medicines and universal health coverage.

CHAPTER TWO

THE SKIRMISH BETWEEN TRADE AGREEMENTS AND PUBLIC HEALTH IN THE CONTEXT OF ACCESS TO ESSENTIAL MEDICINES

Chapter one established that sustainable development and health are mutually dependent in that while environmental, economic and social dynamics (sustainable development triad) determine the levels of health enjoyed by individuals and populations, health is fundamental to the realisation of all sustainable development goals as individuals and populations require some level of good health in order to participate in, contribute to and enjoy sustainable development. In this connection, Goal 3 of the United Nations (UN) 2030 Agenda for Sustainable Development recognises the potential for malaria, tuberculosis, HIV/AIDS and other chronic communicable and noncommunicable diseases prevalent in developing and least-developed countries, as well as the lack of access to essential medicines for treatment partly created by the policy incoherence between patent rights of inventors, international human rights and public health in the context of health technologies to hinder progress towards sustainable development.

Thus, Goal 3 aims to eradicate these diseases by 2030 through promoting universal health coverage and access to essential medicines for these diseases in developing and least-developed countries. According to the Agenda and the UN High-Level Panel on Innovation and Access to Health Technologies, this is to be achieved through the reinforcement by developing and least-developed countries of the use of TRIPS flexibilities as a fundamental part of the Agreement on the Trade-Related Aspects of Intellectual Property Rights 1994, and the negotiation of a binding convention on drug research and development (R&D) that delinks the costs of drug R&D from end product prices and redirects R&D to pressing public health needs.

Against this backdrop, this chapter assesses whether the strategy of utilising the TRIPS flexibilities and the negotiation of a convention on drug R&D can promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030. First, it considers the incoherence between the justifiable rights of inventors, trade rules, international human rights and public health, and assesses the role of patent protection in the lack of access to medicines in developing and least-developed

countries. This chapter also discusses the Doha Declaration on the TRIPS Agreement and Public Health which first confirmed the right of WHO member states to use TRIPS flexibilities to further public health objectives. In this regard, it evaluates the flexibilities and demonstrates how they can be used to protect public health and enhance access to medicines in developing and least-developed countries. It further considers the higher intellectual property standards implemented by developing and least-developed countries sometimes as a result of TRIPS-plus obligations of free trade agreements (FTAs) with developed countries or due to political pressures and threats of trade retaliation from governments of developed countries; other times, voluntarily to gain economic and political advantages.

This chapter notes that these higher standards prevent developing and least-developed countries from using TRIPS flexibilities to address public health problems and reflects on how this would unquestionably obstruct the use of these flexibilities to promote universal health coverage and access to medicines to attain Goal 3. Extrapolating from the history of the negotiation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity 2010, and the ongoing process within the World Intellectual Property Organization's Intergovernmental Committee (WIPO-IGC) relating to the intellectual property protection of genetic resources, traditional knowledge and traditional cultural expressions/folklore, this chapter also suggests that the negotiation of a binding convention on drug R&D would involve an arduous and complicated process due to the presence of multiple stakeholders with competing interests, as well as certain controversial issues which would need to be agreed upon. Consequently, it proposes the integration of traditional medicine into the national health systems of developing and least-developed countries to complement the use of TRIPS flexibilities and (probably) a convention on R&D, if Chapter three establishes that traditional medicine can contribute to sustainable development.

2.1. Why Patent Rights Play a Major Role in the Access to Medicines Conundrum

> [Will this] have a [significant] effect on our business model? No, because we did not develop this product for the Indian market, let's be honest. We developed this

> product for Western patients who can afford this product, quite honestly. It is an expensive product, being an oncology product.[209]

This was according to Marijn Dekkers, former chief executive officer of Bayer AG – a German multinational chemical, pharmaceutical and life sciences company – in response to India's issuance of a compulsory licence to produce Bayer's cancer drug sorafenib (also called Nexavar) in 2013.[210] A compulsory licence enables the state or a third party (acting on its behalf) to manufacture a generic version (an equivalent) of a patented drug.[211] Reacting to messages such as this which unequivocally assert that the health needs of populations of developing and least-developed countries are not contemplated in the commercial priority setting of the pharmaceutical industry, Michael Kirby, former Justice of the High Court of Australia and a member of the High-Level Panel as mentioned in the introductory chapter, during a session of the UN Human Rights Council on 8 March 2017, stressed on the dangers facing millions, including women and children, who are left to beg for charity for patented medicines.[212] He warned of the urgent need for action geared towards realising Goal 3 (on the right to health) of the UN 2030 Agenda for Sustainable Development, otherwise millions of people will be left behind, millions will die.[213]

Before the TRIPS Agreement, i.e. pre-1995, 'the patenting of essential goods such as medicines and foods was long considered an act against the public interest'.[214] Governments reserved the right to adapt their patent laws to advance public health objectives.[215] In the event of a public health crisis, this flexibility enabled them to adopt measures that allowed the copying of patented medicines and offering them at much

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[209] Marijn Dekkers, CEO of Bayer, 'Keynote on Panel 'Buffering Pharma Brand: Restoring Reputation, Rebuilding Trust'' (London: Financial Times Global Pharmaceutical Conference: New Businesses New Markets, 2013) <https://www.keionline.org/node/1910> 27 July 2017.
[210] ibid.
[211] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 2.
[212] Saez, 'UN High-Level Panel on Access to Medicines Takes Next Step at Human Rights Council' (n 2).
[213] ibid.
[214] 't Hoen, *Private Patents and Public Health* (n 5); see also Cullet, 'Patents and Health in Developing Countries' (n 98).
[215] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 21.

lower prices.[216] For example, partly concerned by high prices of medicines, the Indian government passed a Patent Act in 1970 that excluded pharmaceutical products from patent protection.[217] This measure reduced the number of patents by as much as 75 per cent.[218] It equally paved the way for Indian generic companies to flourish, which resulted in the scaling-up of HIV treatment in India due to the production of generic antiretroviral medicines.[219] Also, between 1969 and 1992, Canada regularly utilised compulsory licences to promote the local production of essential pharmaceuticals, culminating in 'some of the lowest consumer prices for medicines' in the industrialised world.[220] However, the emergence of the TRIPS Agreement led to gradual globalisation of an incentive system that does not cater for health needs considered to be unprofitable and that has created significant challenges in accessing medicines that do exist but are marketed beyond the means of the poor in developing and least-developed countries.[221]

The TRIPS Agreement globalised this incentive system by obligating 162 member states of the World Trade Organization (WTO) to provide a minimum standard of intellectual property protection relating to copyright, trademarks, geographical indications, industrial designs, layout designs, confidential information, prevention of some anti-competitive licencing practices and patents.[222] TRIPS was among the set of international treaties negotiated at the Uruguay Round of Multilateral Trade Negotiations held under the aegis of the General Agreement on Tariffs and Trade (GATT), which was eventually replaced by the WTO at the end of negotiations.[223] That is to say, TRIPS is administered under the purview of the WTO.[224] It requires state parties to enforce intellectual property rights

[216] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 21; see also Ellen F M 't Hoen, 'Indian Hepatitis C Drug Patent Decision Shakes Public Health Community' (2016) *The Lancet* <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30656-0/fulltext?elsca1=etoc> accessed 4 June 2016.
[217] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[218] ibid.
[219] 't Hoen, 'Indian Hepatitis C Drug Patent Decision Shakes Public Health Community' (n 216).
[220] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[221] 't Hoen, Private Patents and Public Health (n 5) 6.
[222] World Trade Organization, The Legal Texts: The Results of The Uruguay Round of Multilateral Trade Negotiations 320 (Cambridge University Press 1999) 1869; see also Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press 2011) 57; and Frankel and Gervais (n 6) 28-29.
[223] Frankel and Gervais (n 6) 9-10.
[224] ibid 29.

through national courts, administrative agencies and customs authorities.[225] The implication of the minimum standard of protection required by TRIPS is that parties are at liberty to provide a more extensive standard of protection if they so choose.[226] This creates diversity in laws[227] of WTO member states such that a minimum standard may exist in one state and a higher one in another. However, the TRIPS Agreement does not leave this discretion unfettered; a state that opts to provide for intellectual property rights beyond the minimum standard must ensure not to contravene other provisions of the Agreement, particularly the provisions on national treatment and the most-favoured-nation principles.[228] This is aimed at ensuring that the differing standards of intellectual property protection do not result in discrimination against WTO member states.[229]

This intellectual property protection mandated by the TRIPS Agreement is usually rationalised as a way the law provides incentives for the creation of new inventions and works of expression.[230] While the incentives for creators of original expressive works are provided through copyright protection, providing incentives for new inventions usually falls within the realm of patent rights.[231] TRIPS requires its state parties to grant patent rights for an invention in a field of technology. While it does not define what constitutes 'an invention in a field of technology', TRIPS provides that an invention includes both product and processes, and member states cannot discriminate against inventions in a specific field of technology.[232] What this translates into is that members must grant patents to inventions in *all* fields of technology,[233] which includes pharmaceuticals. Thus, for jurisdictions such as India that excluded patent rights over pharmaceutical products, the emergence of the TRIPS Agreement with its 'minimum' intellectual property standards meant that they had to amend their patent laws to meet their obligations under the Agreement. India amended its patent law in 2005 due to a clause in the TRIPS

[225] ibid.
[226] TRIPS 1994, art 1(1).
[227] Ho, Access to Medicine in the Global Economy (n 222) 57.
[228] Frankel and Gervais (n 6) 29.
[229] ibid.
[230] Aaron Perzanowski and Jason Schultz, *The End of Ownership: Personal Property in the Digital Economy* (The MIT Press 2016) 11; see also Cullet, 'Patents and Health in Developing Countries' (n 98).
[231] Perzanowski and Schultz (n 230) 18; see also Esparaza (n 123) 205.
[232] TRIPS 1994, art 27(1).
[233] ibid.

Agreement which allowed developing countries a grace period to delay the implementation of patents on medicines.[234]

For inventors to benefit from this patent protection, TRIPS requires their invention to be new, involve an inventive step (i.e. non-obvious to a person knowledgeable in the same field), and be capable of industrial application.[235] If the invention meets these criteria, TRIPS confers on the inventor the right to exclude other persons from using, making, offering for sale, selling or importing the patented product[236] for a minimum of 20 years from the date of filing the patent application.[237] In exchange for this right, the public derives the right to utilise such scientific advancement.[238] Regarding pharmaceuticals, the award of this market monopoly incentivises the pharmaceutical industry to invest in R&D of new medicines. Bringing a new medicine to the market requires a large amount of investment, which a 2016 study conducted by the industry-funded Tufts Centre for the Study of Drug Development, pegged at US$ 2.56 billion to US$ 2.87 billion (although this figure is contested by not-for-profit organisations, who estimate the cost to be between US$ 130 million to US$ 195 million).[239]

Having exclusive rights to this new medicine enables pharmaceutical companies to recover the substantial cost invested in R&D, and to generate profits as well by charging a high price for this product.[240] This incentive model is currently central to innovation, as even shareholders who invest in these pharmaceutical companies do so with the expectation of generating a return on investment.[241] In the absence of these exclusive rights vested in the inventor, third parties would freely exploit new scientific innovations. And because inventing something new requires the investment of time, effort and a large amount of money, not being able to recover investment plus a reasonable profit would dissuade most people from innovating:[242] '[in] a world where creating new works is

[234] 't Hoen, Private Patents and Public Health (n 5) 9.
[235] TRIPS 1994, art 27(1).
[236] ibid art 28(1).
[237] ibid art 33.
[238] 't Hoen, Private Patents and Public Health (n 5) 4.
[239] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 29.
[240] ibid.
[241] ibid.
[242] Perzanowski and Schultz (n 230) 19.

expensive and copying them is cheap and easy for the public, poets will be become accountants, and inventors will become plumbers'.[243] Thus, patent monopolies encourage innovative investments by prohibiting free-riding of patented inventions and allowing inventors to collect monopoly rents.

However, there is a problem with using the patent system to incentivise the pharmaceutical industry to innovate: pharmaceutical companies, enabled by patent rights, charge exorbitant prices for medicines to recoup cost sunk in R&D and to garner profits.[244] When medicines are marketed at high prices, access to life-saving medications is restricted to those who can afford it, thereby excluding the poor in developing and least-developed countries who live on under US$1 or US$2 per day.[245] Further complicating this, is the fact that (as noted in Chapter one) some developing and least-developed countries, particularly in the African continent, heavily depend on out-of-pocket payments for health services rather than through insurance and social security.[246] Consequently, individuals pay out-of-pocket for the cost of health services at the point when they seek treatment.[247] The result is that poor people who cannot afford to pay the expensive cost of medicines are denied access to essential treatments. In addition to high pricing, because of the incentives of investment recovery and profit generation, pharmaceutical companies wilfully neglect to invest in diseases that do not promise high returns – especially those that afflict the poor in developing and least-developed countries.[248] This was the gist of Bayer's former chief executive officer's statement that sorafenib was developed for Western patients who can afford it, as cancer predominantly affects people in developed countries.[249]

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[243] ibid.
[244] Carlos M Correa, 'TRIPS and Access to Drugs: Toward a Solution for Developing Countries Without Manufacturing Capacity' (2003) 17 *Emory International Law Review* 390; see also Smith et al. (n 183) 686.
[245] Anup Shah, 'Poverty Facts and Stats' (*Global Issues* 7 January 2013).
[246] Kaseje (n 126) 4; see also 't Hoen, *Private Patents and Public Health* (n 5) 4.
[247] World Health Organization, 'The World Health Report 2000: Health Systems: Improving Performance' (World Health Organization 2000) 97.
[248] Maxwell Morgan, 'Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment' (2006) 64 *University of Toronto Faculty of Law Review* 48, 54; see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7); and 't Hoen, *Private Patents and Public Health* (n 5).
[249] David Ellis, 'Study Reports Higher Rate of Cancer in Developed Countries' (*Medical press*, 6 October 2017) <https://medicalxpress.com/news/2017-10-higher-cancer-countries.html> accessed 23 November 2017.

Further exemplifying the issue with the patent-based incentive system, when Burroughs Wellcome (BW), a British pharmaceutical company, obtained a patent for the use of azidothymidine (AZT) for treating AIDS, they set its retail price at US$10,000 for a year's supply per patient. Justifying such a high price, the company cited the cost of R&D, synthesising and marketing, and maximisation of profit (before the emergence of other drugs that cure the same illness).[250] Even worse is the case of Gilead's hepatitis C drug, sofosbuvir (brand name 'sovaldi'). Gilead Sciences, an American pharmaceutical company, charges US$1000 per pill for sofosbuvir.[251] Sofosbuvir is a hepatitis C drug that cures people with the disease in 12 weeks, costing US$84,000.[252] Globally, there are an estimated 150 million cases of hepatitis C, with 700,000 deaths resulting each year.[253] The company rationalised this excessive price tag on grounds of the cost of R&D, and the value provided by the drug.[254] One clear consequence of these expensive price tags is that because they lack the purchasing power, poor members of society would be deprived of the benefit of these scientific advancements. In February 2016, Gilead's patent application to the Indian Patent Office was challenged by a pre-grant opposition filed by the Initiative for Medicines, Access and Knowledge (I-MAK) and Delhi Network of Positive People (DNP+) – a group of humanitarian organisations in India.[255] They argued that sofosbuvir was old science and did not meet the patent standard of India.[256] These organisations accused Gilead of charging excessive prices in many countries while using patents to prevent people in other countries from purchasing low-cost and equally effective versions of this medicine.[257] (More on the pre-grant opposition later.)

[250] Holger Hestermeyer, Human Rights and WTO: The Case of Patents and Access to Medicines (Oxford University Press 2008) 4-5.
[251] Médecins Sans Frontières, 'Access: Patent Challenge Hearing on Gilead Hepatitis C Drug Sofosbuvir Starts in India' (*Medecins San Frontieres,* 26 February 2016) <http://www.msf.org/article/access-patent-challenge-hearing-gilead-hepatitis-c-drug-sofosbuvir-starts-india> accessed 1 March 2016; note that hepatitis C is a contagious liver infection caused by hepatitis C virus (HCV) – see San Francisco Department of Public Health, 'Hepatitis C' (*Communicable Disease Control and Prevention*) <http://www.sfcdcp.org/hepatitisc.html> accessed 7 December 2017.
[252] ibid.
[253] ibid.
[254] ibid.
[255] ibid.
[256] ibid.
[257] ibid.

Preventing the purchase of low-cost versions of patented drugs is possible due to the territorial nature of intellectual property rights.[258] That an inventor has obtained patent protection for his invention in 'country A' does not mean that he enjoys such protection in 'countries B and C'. To receive protection in 'countries B and C', the inventor must seek protection under the patent laws of each of these countries.[259] As already mentioned, this protection excludes other persons from using, making, offering for sale, selling or importing the patented product. The effect in international trade is that country B cannot import a chemical entity that is patented under its law from country A, whether or not the chemical entity is protected under country A's patent law because patent rights exclude importation.[260] Likewise, a blocking patent in country C can restrict access to a chemical entity for other countries that rely on country C's exports, irrespective of whether or not there is a patent on the chemical entity in the importing country.[261]

For instance, prior to providing patents on pharmaceuticals under the Indian Patent Act, procurement agencies such as the United Nations Children's Fund (UNICEF), the International Dispensary Association (IDA), and non-governmental organisations (NGOs) such as Médecins Sans Frontières (MSF), purchased generic versions of antiretroviral drugs at lower prices from Indian generic manufacturers, which they distributed to countries that lacked access to these drugs.[262] However, existing patents in some of the importing countries, such as South Africa, blocked access to these low-cost generics.[263] In the case of the exporting country, India, implementing patents on pharmaceuticals in compliance with TRIPS in 2005 meant closing the windows for many generic manufacturers who were heavily relied upon by other developing and least-developed countries as primary suppliers of low-cost medicines.[264] While it was still possible to manufacture those generic drugs brought to the market before TRIPS, newer and better-tolerated treatments recommended by the World Health Organization (WHO) were excluded from copying by patents.[265]

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[258] Frankel and Gervais (n 6) 42; see also 't Hoen, *Private Patents and Public Health* (n 5) 147.
[259] 't Hoen, Private Patents and Public Health (n 5) 147.
[260] 't Hoen, Private Patents and Public Health (n 5) 147.
[261] ibid.
[262] ibid 7.
[263] FXB Centre for Health and Human Rights (n 133); see also 't Hoen, *Private Patents and Public Health* (n 5) 7.
[264] 't Hoen, Private Patents and Public Health (n 5) 10.
[265] ibid.

More so, the pharmaceutical industry does not hesitate in enforcing its monopoly rights to frustrate measures adopted by governments of developing and least-developed countries to access medicines at low cost. When South Africa enacted the Medicines and Related Substances Control (Amendment) Act in 1997 to ensure access to affordable medicines due to the proliferation of diseases and increase in medicine prices,[266] pharmaceutical companies sued the government. This action was predicated on the fact that the Act authorised the Minister of Health to use:

a) Parallel imports to import drugs from markets where the patent holder placed the medicine at a lower price; and

b) Compulsory licences to authorise the manufacturing of patented drugs or to import from markets where a manufacturer other than the patent holder placed the drugs at a lower price.[267]

The pharmaceutical industry argued that these powers conferred on the Minister were inconsistent with the provisions of the TRIPS Agreement[268] because they infringed their patent rights.[269] However, the industry discontinued the suit after much pressure and criticisms from NGOs, and upon the intervention of the UN.[270] Nevertheless, this case epitomises how pharmaceutical companies, backed by patent rights, aggressively safeguard their investments and financial advantages by preventing access to low-cost drugs.

Evidence suggests that adopting a loose patent regime could promote access to medicines. For instance, as part of its efforts to enhance access to medicines, the Brazilian government included a strong compulsory licencing regime in its patent law.[271] In 2007,

[266] R L Ostergard, 'The Political Economy of South Africa – United States Patent Dispute' (1999) 2 *Journal World Intellectual Property* 875.
[267] Medicines and Related Substances Control Act 1997 (South Africa), s 15C.
[268] TRIPS 1994, art 27.
[269] Hestermeyer (n 250) 11.
[270] ibid 12.
[271] Monirul Azam, Intellectual Property and Public Health in the Developing World (Open Book Publishers 2016).

the government issued a compulsory licence on the grounds of public non-commercial use to allow the purchase of an HIV drug Efavirenz, produced by an American pharmaceutical company and one of the largest in the world, Merck & Co, from rival generic suppliers in India.[272] This was done to compel Merck & Co to lower the price of the antiretroviral drug for HIV patients. However, while health activists extolled the government for this bold action, the pharmaceutical industry was displeased with this development. [273] Demonstrating the industry's readiness to aggressively protect its investments, Merck's former vice president for corporate responsibility, Jeffery Sturchio, warned that if Brazil expropriated Merck's intellectual property, pharmaceutical companies would discontinue research on diseases that plagued developing and least-developed countries. [274] Likewise, before the TRIPS Agreement required patent protection for inventions in all fields of technology for a term of 20 years, the Republic of Korea, although a developed country, excluded chemicals and pharmaceuticals from patentability and allowed only 12 years of patent protection on other fields of technology.[275] This was aimed at advancing public health objectives[276] and is similar to the exclusion of patents on pharmaceuticals in India during the pre-TRIPS era, which enabled the production of generic versions of new medicines to enhance access to HIV treatment in the developing world. Nonetheless, the Indian generic industry was stifled following the revision of its patent law to include patents on pharmaceuticals,[277] thereby lending credence to the assertion that patents impede access to essential medicines.

As noted in Chapter one, claims that patent monopolies block access to medicines, limit R&D, and disadvantage generic manufacturers in developing and least-developed countries are vigorously challenged by the pharmaceutical industry. It argues that, on the contrary, this system of financially rewarding investments has resulted in the

[272] Andrew Jack and Richard Lapper, 'Brazil Overrides Merck's Patent on HIV Drug' (*Global Economy*, 4 May 2007); see also Patricia Covarrubia, 'Compulsory License and Parallel Import: What is Happening in Latin America?' (*IP Tango*, 26 August 2016).
[273] Jack and Lapper (n 272).
[274] Jack and Lapper (n 272).
[275] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[276] ibid.
[277] 't Hoen, 'Indian Hepatitis C Drug Patent Decision Shakes Public Health Community' (n 216); see also Jae Sundaram, 'India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and other Developing Countries?' (2014) *Information & Communications Technology Law* 1, 5-6.

development of revolutionary drugs that have saved millions of lives, including those in developing and least-developed countries.[278] A typical example is Glaxo Wellcome's[279] investment in the R&D of Zidovudine in 1987, which was administered to decelerate the advancement of HIV, in spite of the majority of HIV patients being situated in developing and least-developed countries and being the highest consumers of antiretroviral drugs.[280] Essentially, this argument attempts to debunk claims that the pharmaceutical industry does not invest in diseases that mostly affect unprofitable markets. That said, whether it is sustainable, given the admission by Marijn Dekkers Bayer's former chief executive officer, is addressed subsequently.

The industry further claims that even in the face of strong patent protection since the advent of TRIPS in 1994, it has continued to invest in drugs that have radically altered the global health landscape.[281] A frequently cited example is the development of HAART (Highly Active Anti-Retroviral Therapy) in 1996.[282] This ground-breaking innovation prolonged the lives of approximately 16 million HIV patients.[283] A 2016 study in the *American Economic Review*, a peer-reviewed general-interest economics journal published in the US since 1911,[284] concluded that stronger intellectual property protection has resulted in more medicines for citizens of developing and least-developed countries.[285] This means that the incentive system of financially rewarding investment in drug R&D has increased the availability of medicines in developing and least-developed countries. In truth, this does not match the present day reality.

Another reason proffered to exonerate patents as a barrier to access to medicines in developing and least-developed countries is that 95 per cent of drugs on the WHO

[278] Glassman and Temin (n 130); see also Cullet, 'Patents and Health in Developing Countries' (n 98).
[279] Now GlaxoSmithKline after a merger with SmithKline Beecham since 2000 – see Bernardo Bátiz-Lazo, 'GSK – A Merger of Equals?' in Gerry Johnson and Kevan Scholes (eds), *Exploring Corporate Strategy: Texts and Cases* (6th edn, Harlow, England; New York: Financial Times Prentice Hall 2002) 956-967.
[280] Adelman and Norris (n 18) 13-14.
[281] Adelman and Norris (n 18) 4.
[282] ibid.
[283] ibid.
[284] American Economic Association, 'American Economic Review' <https://www.aeaweb.org/journals/aer> accessed 3 May 2017.
[285] Cockburn et al. (n 130) 136-164.

Essential Medicines List (EML) are already off-patent.[286] The EML is maintained by the WHO, which enumerates important medicines that should be available and affordable to communities and people that need them.[287] In 2001, Attaran and Gillespie-White investigated the effect of patents on access to antiretroviral drugs for the 25 million people infected with HIV in Africa.[288] Having examined the patent status of 15 HIV drugs in 53 African countries, they concluded that patents were not a barrier to access to essential HIV treatments.[289] In 2004, Attaran further opined that pharmaceutical companies usually did not apply for patents in developing and least-developed countries and therefore, patents rarely determined access to essential medicines.[290] In fact, based on an African survey, there were only 1.4 existing patents and patent applications.[291] The relevant question given these facts presented by Attaran and Gillespie-White is whether it is necessary for patents on essential medicines to exist in African countries before they can impede access. As already mentioned, a patent on an essential medicine in an exporting country can restrict access for other countries that rely on its exports, whether or not a corresponding patent exists in the importing country. This means that a patent on a medicine in India or Brazil, which are renowned for trade in low-cost generic medicines,[292] can hinder either of these countries from exporting to Nigeria (which lacks sufficient manufacturing capacity, as an example), irrespective of whether or not a patent on that medicine exists in Nigeria. On this note, the question would most likely be resolved in the negative and the conclusion that patents do not play a major role in lack of access to essential medicines rendered untenable.

As for whether patents limit research and disadvantage drug manufacturers in developing and least-developed countries, research-based companies are said to have issued 165 voluntary licences aimed at incentivising local manufacturers in developing countries to produce antimalarials, tuberculosis drugs and antiretrovirals for their populations and

[286] Reed F Beall, 'Patents and the WHO Model List of Essential Medicines: Clarifying the Debate on IP and Access' (Geneva: World Intellectual Property Organization 2016) 1.
[287] 't Hoen, Private Patents and Public Health (n 5) 146.
[288] Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa' (2001) 286(15) *Journal of American Medical Association* 1886-1892.
[289] ibid.
[290] Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries' (2004) 23(3) *Health Affairs* 155-166.
[291] ibid.
[292] Sundaram (n 277) 5-6.

export to other developing and least-developed countries.[293] For instance, Merck issued five royalty-free licences for its antiretroviral Efavirenz to South African generic manufacturers.[294] Merck has also extended such royalty-free licences to pharmaceutical companies in India.[295] In addition, these research-based companies have participated in the Medicines Patent Pool (MPP) which was founded by the UN to enhance access to medicines by creating a partnership with patent holders in patent pools.[296] However, it would appear that, as opposed to incentivising local generic manufacturers to produce medicines, the motivation behind issuing voluntary licences is to control competition. For instance, Gilead licenced 11 Indian generic drug makers to develop and market its hepatitis C drug, sofosbuvir, at US$335 per 12-week treatment, which it originally sold for US$84,000 for 12 weeks' treatment.[297] This implied that only the 11 licenced generic companies were authorised to produce the drug. Without this authorisation, other unlicenced generic manufacturers could not produce sofosbuvir as that would be infringing Gilead's rights. In effect, this licence excluded legitimate competition from other generic producers who had the manufacturing capacity to make the drug perhaps for even less than US$335.[298] What is more, this licence precluded exportation to other developing and least-developed countries.[299] This meant that the populations of those other developing and least-developed countries were left without access to sofosbuvir.[300]

Indeed, the market-driven system, aided by patent rights, has yielded transformative advancements that have significantly improved global health. Over 13 million people worldwide now receive antiretroviral treatment, as first-line antiretroviral drugs have become more affordable and available in recent years.[301] According to UNAIDS, 87 per

[293] Medecins Sans Frontieres, Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries (15th edn, Geneva: MSF 2012) 91.
[294] Drugs for Neglected Diseases Initiative, 'Merck & Co., Inc. and Drugs for Neglected Diseases Initiative Collaborate to Find Treatments for World's Most Neglected Tropical Diseases' (DND*i*, 22 June 2009) <https://www.dndi.org/2009/media-centre/press-releases/merck-a-co-inc-and-drugs-for-neglected-diseases-initiative-collaborate-to-find-treatments/> accessed 3 May 2016.
[295] ibid.
[296] Medecins Sans Frontieres, Untangling the Web of Price Reductions (n 293).
[297] Patralekha Chatterjee, 'Gilead Sovaldi Case Reveals Patent-Health Fissures in India' (*Intellectual Property Watch*, 9 March 2016) <http://www.ip-watch.org/2016/03/09/gilead-solvaldi-case-reveals-patent-health-fissures-in-india/> accessed 2 May 2016.
[298] ibid.
[299] ibid.
[300] ibid.
[301] 't Hoen, *Private Patents and Public Health* (n 5) 10; see also Wise (n 135) 337-424.

cent of people with HIV in sub-Saharan Africa receive antiretrovirals, and nearly 76 per cent have achieved viral suppression.[302] Also, pharmaceutical companies have entered into public-private partnerships, usually in collaboration with WHO, to generate scientific data and develop new and improved treatments for malaria, tuberculosis and neglected tropical diseases.[303] Based on these developments, one could conclude that the grant of patent rights spurs innovation. However, this would not be entirely true: there remain considerable gaps in innovation and access.[304] Access to essential medicines continues to pose a major problem for populations of developing and least-developed countries as pharmaceutical companies have persisted with the practice of systematically underinvesting in diseases that would not deliver high returns, especially those mainly affecting the developing world; and the few newer medicines remain prohibitively expensive for the poor.[305] Despite its arguments to the contrary, industry has never equivocated in admitting unwillingness to pursue unprofitable investments – for example, as recently noted by Andrew Hollingsworth, policy manager of the Association of the British Pharmaceutical Industry, '[u]nfortunately, the standard economic model for drug development, in which industry takes all of the risk in [R&D] and gets a return on investment from successful products, does not work for diseases that primarily impact low-income [countries] and developing healthcare systems'.[306]

This situation of underinvestment remains true for the so-called type II and type III diseases that disproportionately affect people who lack purchasing power. Type II diseases are those that disproportionately, but not exclusively affect developing and least-developed countries, such as malaria, tuberculosis, HIV/AIDS, and dengue, which have received some, but not enough R&D.[307] Whereas, type III diseases are those that exclusively affect the developing world – the 'most neglected diseases' – which receive

[302] ibid.
[303] Joseph A DiMasi, Ronald W Hansen, and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs' (2003) 22(2) *Journal of Health Economics* 151-85; see also Adelman and Norris (n 18) 16.
[304] World Health Organization, 'World Health Statistics 2016: Monitoring Health for the SDGs Sustainable Development Goals' (World Health Organization, 2016) 78.
[305] World Health Organization, 'World Health Statistics 2016' (n 304); see also 't Hoen, *Private Patents and Public Health* (n 5).
[306] Julia Kollewe, 'Ebola is in America – and, Finally, Within Range of Big Pharma' *The Guardian* (5 October 2014) <https://www.theguardian.com/business/2014/oct/05/ebola-america-range-big-pharma> accessed 10 August 2015.
[307] 't Hoen, Private Patents and Public Health (n 5) 121.

little or no R&D, such as neglected tropical diseases.[308] For instance, a survey by Médecins Sans Frontières (MSF) (popularly known as Doctors Without Borders), an international humanitarian NGO known for its activities in war-torn regions and developing countries affected by endemic diseases,[309] revealed that there were no medicines for neglected diseases in the R&D pipelines for 20 pharmaceutical companies in the US, Europe and Japan.[310]

There is also a lack of paediatric formulations for the 3.2 million children living with HIV, mostly in sub-Saharan Africa.[311] From a profit-making stance, R&D of paediatric formulations is expensive and laborious, and the markets are usually small and fragmented.[312] Because of the unpleasant taste of antiretrovirals, pharmaceutical companies would need to develop a child-friendly formulation that tastes better, and that could be adjusted depending on the size of the child.[313] What is more, the scaling-up of treatments for mothers with HIV has significantly reduced mother-to-child transmission in the profitable markets of developed countries but has not had a similar impact in the developing world.[314] As a result of these, pharmaceutical companies perceive children with HIV in developing and least-developed countries as 'uninteresting' and 'an economically underprivileged and shrinking market'.[315] Against these facts, how can pharmaceutical companies successfully debunk allegations of not investing in unprofitable diseases? In the case of malaria, parasites have become resistant to Artemisinin combination therapies, which is the frontline treatment for the deadliest malaria parasites, and this has spread beyond the developing world.[316] For example, there were four failed malaria treatments in the UK in early 2017.[317] Thus, it is crucial from a

[308] ibid.
[309] 'Who we are: We are Médecins Sans Frontières' (*Médecins Sans Frontières*) <https://www.msf.org/who-we-are> accessed 30 December 2018.
[310] 't Hoen, Private Patents and Public Health (n 5) 121.
[311] ibid; see also Morgan (n 248) 55.
[312] 't Hoen, Private Patents and Public Health (n 5) 120.
[313] 't Hoen, Private Patents and Public Health (n 5) 120.
[314] ibid; see also Michael Kremer, 'Public Policies to Stimulate Development of Vaccines and Drugs for the Neglected Diseases' in Abhijit Vinayak Banerjee, Roland Bénabou, and Dilip Mookherjee (eds), *Understanding Poverty* (Oxford University Press 2006), noting that research for HIV vaccine centred on HIV strains common in the developed world.
[315] 't Hoen, Private Patents and Public Health (n 5) 120.
[316] HC Deb 20 April 2017, vol. 624, 'Tackling Infectious Diseases' <https://hansard.parliament.uk/commons/2017-04-20/debates/AC8A5B8C-C45C-4105-8E75-F3E11BC58881/TacklingInfectiousDiseases> accessed 14 July 2017.
[317] ibid.

public health perspective to develop newer and more effective single-day malaria treatments.[318]

Besides parasites, viruses, bacteria, and fungi have also become drug-resistant. According to projections in 2017, antimicrobial resistance was likely to cause 700,000 deaths,[319] and the number is expected to rise to 10 million by 2050.[320] What is urgently required is the development of newer antibiotics, the use of which would be controlled in order to break the resistance cycle. However, as drug resistance to antibiotics grows, pharmaceutical companies are pulling out of antibiotics R&D. This is because mitigating the spread of antimicrobial resistance requires treatment preservation and lower consumption; whereas market-driven innovation favours high levels of antibiotics use and aggressive marketing.[321] In essence, treatment preservation and lower consumption mean reduced sales and lower profit margins; therefore, pharmaceutical companies have little incentive to invest in newer and more effective antibiotics.[322] For instance, except bedaquiline, which was approved in 2012 to treat multi-drug-resistant tuberculosis, only one new class of antibiotics has been developed in the last 40 years.[323]

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[318] Veronika J Wirtz, Hans V Hogerzeil, Andrew L Gray, Maryam Bigdeli, Cornelis P de Joncheere, Margaret A Ewen, Martha Gyansa-Lutterodt, Sun Jing, Vera L Luiza, Regina M Mbindyo, Helene Möller, Corrina Moucheraud, Bernard Pécoul, Lembit Rägo, Arash Rashidian, Dennis Ross-Degnan, Peter N Stephens, Yot Teerawattananon, Ellen F M 't Hoen, Anita K Wagner, Prashant Yadav and Michael R Reich, 'Essential Medicine for Universal Coverage' (2017) 389(10067) *The Lancet* 403-476; see also Catherine Saez, 'Lancet Report on Essential Medicines Takes Aim at Access and Affordability' (*Intellectual Property Watch*, 8 November 2016) <https://www.ip-watch.org/2016/11/08/lancet-report-essential-medicines-takes-aim-access-affordability/> accessed 13 July 2017.

[319] HC Deb 20 April 2017 (n 316).

[320] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 13-14; see also Jim O'Neill, 'Tackling Drug-Resistant Infections Globally: An Overview of Our Work' (Review on Anti-Microbial Resistance 2016) <https://amr-review.org/sites/default/files/Tackling%20drug-resistant%20infections%20-%20An%20overview%20of%20our%20work_IncHealth_LR_NO%20CROPS.pdf> accessed 4 August 2017.

[321] Charles Clift, Unni Gopinathan, Chantal Morel, Kevin Outterson, John-Arne Røttingen and Anthony So, 'Towards a New Global Business Model for Antibiotics: Delinking Revenues from Sales. Report from the Chatham House Working Group on New Antibiotic Business Model' (Chatham House, the Royal Institute of International Affairs 2015); see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).

[322] ibid.

[323] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 13-14.

In addition, the poor in developing and least-developed countries still cannot afford much needed medications. A case in point is a 23-year-old South African named Phumeza Tisile who was prescribed linezolid, among other drugs, by her doctors after a diagnosis of multi-drug-resistant tuberculosis in 2010.[324] It was a two-year treatment priced at £27,760 per patient (£38 per pill) and was well beyond her means.[325] Although a generic version of linezolid was available through the Global Fund – a financing institution providing support to countries in response to malaria, tuberculosis and HIV/AIDS[326] – at a lower price, this version was not accessible as linezolid was patented in South Africa.[327] It was not until 2013 that Phumeza began receiving treatment through Médicins Sans Frontières, whereas many like her did not survive.[328] While pharmaceutical companies may insist that 95 per cent of essential medicines on the WHO EML are already off-patent, cases such as this and more recent evidence suggest otherwise. For example, there are existing patents on important medicines for tuberculosis on the WHO EML including bedaquiline and delamanid till 2023 and terizidone till 2024; and patents on treatments for hepatitis C, sofosbuvir till 2024, daclatasvir till 2027 and ledispavir till 2030.[329] This situation does not look promising for access to these medicines for making progress towards sustainable development by 2030.

The role of patent rights in preventing access to medicines has resulted in questions about the extension of intellectual property protection to developing countries. As already mentioned, developing countries did not provide patent protection for pharmaceuticals before the TRIPS Agreement entered into force on 1 January 1995, but were required to comply with its provisions within 10 years post-TRIPS.[330] Whereas, least-developed countries are exempted from providing patent or data protection in general until 1 July

[324] Phumeza Tisile, 'Meet the 23-year-old TB Survivor taking on South Africa's Patent Laws' *The Guardian* (Khayelitsha, 7 June 2014) <https://www.theguardian.com/global-development-professionals-network/2014/jul/07/tb-south-africa-patents-drug-resistance-phumeza-tisile-medicins-sans-frontieres> accessed 10 August 2015.
[325] ibid.
[326] 'Overview' (*The Global Fund*) <https://www.theglobalfund.org/en/> accessed 10 August 2015.
[327] Tisile (n 324).
[328] ibid.
[329] 't Hoen, Private Patents and Public Health (n 5) 101.
[330] The delayed patent protection for pharmaceutical products, including agricultural chemicals was possible due to the provision of TRIPS art 65.4 that allowed developing countries that did not provide product patent in a particular field of technology when the TRIPS Agreement came into force, the privilege of 10 years to introduce protection. See TRIPS 1994, art 65.4; and Peter-Tobias Stoll and Frank Schorkopf, *WTO: World Economic Order, World Trade Law* (Martinus Nijhoff Publishers 2006) 222.

2021 and are required not to grant or enforce patent or data protection on pharmaceuticals until 1 January 2033.[331] However, this exemption does not shield least-developed countries from patent's constraining effect on access to medicine: as noted earlier, a patent in India can restrict access to a drug for Sudan, which relies on India's generic exports, notwithstanding that Sudan does not provide patents for pharmaceuticals being a least-developed country. The argument for providing protection in developing countries is that global protection of intellectual property rights will increase the reward to innovators, thereby inspiring greater amounts of innovation, which will ultimately benefit everyone.[332]

This argument is flawed for three reasons: First, if global intellectual property protection would increase the reward to innovators, why do pharmaceutical companies underinvest in diseases endemic to developing countries? As already noted, the unlikelihood of making a profit because of the small size of the market discourages the pharmaceutical industry from investing in diseases that are predominant in developing countries. This means that innovators are well aware that this market is unprofitable; at best, they only stand to make marginal gains. Secondly, it is incorrect that every innovation benefits everyone. In terms of pharmaceuticals, poor people in developing countries do not enjoy the full benefits of scientific advancements due to limited access to essential medicines, even though these countries protect intellectual property rights. Thirdly, high rewards do not translate into increased innovation. For instance, irrespective of the high prices charged by pharmaceutical companies, Ellen 't Hoen notes that *La Revue Prescrire* – a French medical journal which covers developments in diseases, medications, and in medical techniques and technologies – conducted an examination of 1,432 new drug approvals in Europe between 2000 and 2014 which disclosed that there were no real transformative innovations; only 9 per cent of the new medicines offered actual advancement.[333] More than half (51 per cent) of the new medicines were simply modified

[331] Council for Trade-Related Aspects of Intellectual Property Rights, 'Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council of TRIPS of 6 November 2015' (World Trade Organization 2015) Doc No IP/C/73.
[332] Michael J Trebilcock and Robert Howse, *The Regulation of International Trade* (2nd edn, New York: Routledge 1999) 310.
[333] 't Hoen, *Private Patents and Public Health* (n 5) 126; see also Ellen 't Hoen, 'Patents and Innovation – Does it Deliver?' in Astrid Berner-Rodoreda, Maike Lukow and Luise Steinwachs (eds), *Medicines,*

versions of existing medicines, 20 per cent were adjudged 'possibly helpful', and 14 per cent were declared unacceptable.[334] In light of these, it has been argued that where the highest level of innovation has already been achieved or exceeded through incentives from sales in the markets of developed countries, increased intellectual property protection in developing countries may 'cause a global misallocation of productive resources toward [R&D]'.[335] What is more, the marginal increase in profits accruing to innovators through sales in developing countries are less likely to contribute significantly to global R&D incentives, whereas the social costs of limited access can be profound.[336]

Moreover, claims that research institutions bear the whole financial burden of R&D of new medicines is an overstatement. While it is a fact that R&D is necessary for developing new medicines, in actuality a substantial part of this research is publicly funded.[337] For instance, human rights advocates have referred to the development of many antiretrovirals in publicly funded laboratories.[338] Again, sofosbuvir, which is sold for US$84,000 for 12 weeks' treatment of hepatitis C, was developed with public funding.[339] This fact invites an obvious question: Why do research institutions patent products developed with public funds. This practice had its genesis in the introduction of the 1980 Bayh-Dole Act (Patent Rights in Inventions Made with Federal Assistance)[340] in the US. The policies on R&D of the US, being the linchpin of health technology innovation, shape other actors in the industry, including public and private foundations and donors, and significantly influence global access to the benefits of technology.[341] With this in mind, the establishment of the 1980 Act revolutionised academic research by

Patents, Access and Innovation: The Growing Challenges for People in Low and Middle-Income Countries to Access New Medicines (Bread for the World – Protestant Development Service, 2016) 7.
[334] ibid.
[335] Trebilcock and Howse, *The Regulation of International Trade* (n 332); see also Morgan (n 248) 58-59.
[336] Trebilcock and Howse, *The Regulation of International Trade* (n 332) 311-312; and Morgan, (n 248) 59.
[337] Paul Farmer, *Pathologies of Power: Health, Human Rights, and the New War on the Poor* (University of California Press 2013) 317; see also FXB Centre for Health and Human Rights (n 133).
[338] FXB Centre for Health and Human Rights (n 133); see also The Commission on Intellectual Property Rights, Innovation and Public Health, 'Public Health, Innovation and Intellectual Property Rights' (Geneva: World Health Organization 2006).
[339] FXB Centre for Health and Human Rights (n 133); see also The Commission on Intellectual Property Rights, Innovation and Public Health (n 338).
[340] The Bayh-Dole Act of 1980 (Patent Rights in Inventions Made with Federal Assistance). 35 U.S.C. § 200-212; 37 C.F.R. Part 401.
[341] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 8.

permitting universities and public institutions to patent the results of federally funded research.[342] The social ramification of this is that the public is forced to pay a second time for the fruits of publicly funded research when it pays exorbitantly for new medicines.[343] And the exorbitant prices limit access to these new medicines for those who cannot afford to pay for them.

This raises very significant human rights issues. As already noted in Chapter one, the right to health is a fundamental human right guaranteed by a host of international instruments, notably the Charter of the United Nations 1945, the Universal Declaration on Human Rights 1948, the Constitution of the World Health Organization (WHO)1948, the International Covenant on Economic, Social and Cultural Rights 1966 and many other international treaties, declarations and even national constitutions. For instance, the Universal Declaration on Human Rights (UDHR) states that '[e]veryone has a right to a standard of living adequate for health and well-being of himself and his family, including food, clothing, housing and *medical care*…'[344] (emphasis added.) Similarly, the United Nations International Covenant on Economic, Social and Cultural Rights (UN ICESCR) mandates its state parties to '…recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[345]

In clarifying the meaning of 'the highest attainable standard of physical and mental health', the United Nations Committee on Economic, Social and Cultural Rights (CESCR) explained that it is not limited to health care, but embraces factors that enable the realisation of the right to health, such as access to affordable treatment and essential medicines.[346] In other words, access, in terms of availability and affordability of essential medicines, is essential to the enjoyment of the right to health. In the same vein, Article 15 of the ICESCR affirms the right of *everyone* to enjoy the benefits of scientific progress and its application.[347] The purport of this provision is that both rich and poor are entitled

[342] ibid.
[343] ibid.
[344] Universal Declaration of Human Rights 1948, art 45.
[345] International Covenant on Economic, Social and Cultural Rights 1966, art 12.
[346] Duncan Matthews, 'Intellectual Property Rights, Human Rights and the Right to Health' (2009) Queen Mary University London, School of Law, Legal Studies Research Paper No 24/2009 7; see also Cullet, 'Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health' (n 120) 139-160.
[347] International Covenant on Economic, Social and Cultural Rights 1966, art 15.

to access new health technologies, which include medicines. Mindful of these provisions, any system that limits access to essential medicines derogates the rights to health and the enjoyment of scientific progress. It then means that the market-driven model of the pharmaceutical industry, facilitated by patent monopolies, is in clear conflict with human rights.

Furthermore, both state and non-state actors, such as pharmaceutical companies have a fundamental obligation to make new medicines 'as available as possible'.[348] States have the responsibility to respect, protect and take steps to realise the right to health.[349] Nested in this responsibility is the duty to ensure that medicines are available, accessible, culturally acceptable and of good quality.[350] As set out in the United Nations CESCR, General Comment 14, states should also prioritise the right to health, and ensure that their international obligations do not have an adverse impact on the right to health.[351] Thus, developing and least-developed countries neglect these human rights obligations by prioritising economic and political benefits over the right to health when they implement higher intellectual property protections, for instance, as a condition for accession to the WTO or agreeing to FTAs that contain TRIPS-plus provisions (as will be seen later). Also, states' human rights duties extend to protecting the right to health against abuse by third parties[352] such as pharmaceutical companies. It then means that developing and least-developed countries fail to protect the right to health when, for example, they do not issue compulsory licences to arrest anticompetitive practices of pharmaceutical companies due to threats of retaliation by governments of developed countries (notably the US) in which these companies are domiciled (more on this later).

Along similar lines, pharmaceutical companies are tasked with human rights obligations under the United Nations Guiding Principles on Business and Human Rights, endorsed

[348] Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2008) (n 136).
[349] Stephen P Marks, 'Access to Essential Medicines as a Component of the Right to Health' in Clapham A and Robinson M (eds), *Realizing the Right to Health* (Rüfer and Rub 2009) 82-101.
[350] ibid.
[351] Committee on Economic, Social and Cultural Rights, 'General Comment 14: The Right to the Highest Attainable Standard of Health (Article 12)' (2000) Office of the High Commissioner for Human Rights para 9, 12(a), (b), (d).
[352] John Ruggie, 'Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises: Protect, Respect and Remedy: A Framework for Business and Human Rights' (2008) A/HRC/8/5.

by the Human Rights Council of the United Nations in 2011, to provide 'an authoritative global standard for preventing and addressing the risk of adverse human rights impacts linked to business activities' (as will be seen in Chapter six).[353] In this connection, pharmaceutical companies bear a responsibility to protect, respect and remedy.[354] This means that companies are obligated to avoid causing or contributing to human rights violations through their activities, and address such violations when they occur.[355] Even when they have not played a part in such violations, they bear a responsibility to prevent or mitigate insofar as the violations are linked to their operations, products or services by their business relationships.[356] Concerning the right to health, pharmaceutical companies have a responsibility to take necessary steps to ensure that medicines are 'as accessible as possible' once they have been placed in the market, particularly to those who cannot afford them.[357] Consequently, when demanding high prices for drugs resulting in their inaccessibility to the poor, and by pulling out of research into diseases that plague developing and least-developed countries, pharmaceutical companies breach their internationally recognised obligations to respect and protect human rights. To remedy this violation, pharmaceutical companies would need to embark on price reduction of essential medicines, undertake vigorous research into diseases that afflict developing and least-developed countries in order to develop new and effective medicines, as well as taking other steps to ensure that medicines are 'as available as possible' to the populations of these countries.

Thus far, it has been established that the interaction between patent monopolies (guaranteed by the TRIPS Agreement), international human rights, and public health is problematic and thus, presents a complex challenge. While the justification for awarding patent rights is to incentivise innovation by allowing an inventor to exercise monopoly rights over the patented invention in return for sharing the technology with society, the

[353] Office of the High Commissioner for Human Rights, 'Guiding Principles for Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework' (New York and Geneva: United Nations 2011); see also FXB Centre for Health and Human Rights (n 133).
[354] Ruggie (n 352).
[355] ibid.
[356] ibid; see also The UN Global Compact Office and the OECD Secretariat, 'The UN Global Compact and the OECD Guidelines for Multinational Enterprises: Complementarities and Distinctive Contributions' (Paris, France: OECD Investment Division 2005) <http://www.oecd.org/investment/mne/34873731.pdf> accessed 9 August 2017.
[357] Hunt and Khosla, 'Are Drug Companies Living up to their Human Rights Responsibilities? (n 141).

inefficiencies and abuse resulting from monopoly market power have outweighed social gains, in the context of access to life-saving medicines. As admitted here and in Chapter one, there are multiple barriers to access to medicines. However, the extreme complexity of the impact of the patent system on public health places it at the centre stage of international discussions on access to medicines. In this light, both the UN 2030 Agenda for Sustainable Development and the High-Level Panel on Access to Medicines have proposed the use of TRIPS flexibilities by developing and least-developed countries to promote access to affordable medicines and universal health coverage in order to achieve sustainable development by 2030. However, prior to this, the Doha Declaration on the TRIPS Agreement and Public Health had confirmed the right of WTO member states to use the policy spaces contained in the Agreement to further public health objectives.[358] This came about after the African Group in concert with other developing and least-developed countries invited the Council of TRIPS (the governing body of the TRIPS Agreement) to consider the relationship between TRIPS and access to medicines in view of the tension between patent rights and public health.[359] The outcome was the adoption of the Declaration of TRIPS Agreement and Public Health at the 4th WTO Ministerial Conference in Doha on 14 November 2001 (popularly referred to as 'the Doha Declaration'),[360] which is discussed next.

2.2. The Doha Declaration on the TRIPS Agreement and Public Health

In confirming the policy spaces contained in the TRIPS Agreement, the Doha Declaration acknowledged the existence of public health crises in developing and least-developed countries, caused by malaria, tuberculosis and HIV/AIDS among others, as well as the effect of patent monopolies on the prices of drugs needed to battle these diseases.[361] As opposed to being a problem, parties to the Declaration perceived the need for TRIPS to be part of the solution to address the issue of access to medicines.[362] According to them, the objective of TRIPS is not to prevent member states from taking actions to solve public

[358] Chang-Fa Lo, 'Compulsory Licensing: Threats, Use and Recent Trends' in Bryan Mercurio and Daria Kim (eds), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options* (Taylor & Francis 2017) 144, 146.
[359] ibid.
[360] ibid.
[361] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001.
[362] ibid.

health crises.[363] As a result, while reaffirming commitment to the Agreement, the Declaration stated that TRIPS should be interpreted and implemented in a manner that permits member states to take measures to protect public health and promote access to medicine.[364] Such measures include utilising the policy spaces ('flexibilities') that form part of the TRIPS Agreement.[365] By providing these flexibilities in national legislation, member states can ameliorate the adverse impact of patents on the right to health.[366] These TRIPS flexibilities include: the right of member states to determine patentability criteria (which can exclude patents on trivial developments);[367] the right of states to issue compulsory licences to permit the state or a third party to manufacture a generic version of a patented drug;[368] parallel importation of patented drugs sold in another country at a lower price without the consent of the patent holder;[369] and protecting test data against unfair commercial use (and not granting it a period of exclusivity).[370]

This declaration that countries are entitled to utilise the flexibilities contained in TRIPS implies that any pressure to deter their use applied by any developed country on developing and least-developed countries is contrary to the intents and purposes of the TRIPS Agreement.[371] While this is an obvious political implication, it is doubtful whether the Doha Declaration can be legally enforced against any party attempting to deter another from utilising TRIPS policy spaces. This is because a Declaration has no legal status under the framework of the WTO.[372] Therefore, the Doha Declaration is not an authoritative interpretation of the TRIPS Agreement.[373] However, in the event of disputes initiated under the WTO Dispute Settlement Mechanism, members can rely on the content

[363] ibid.
[364] ibid.
[365] ibid; see also Jillian Clare Cohen-Kohler, 'The Renovation of Institutions to Support Drug Access: Is it Enough?' in Andrew F Cooper (ed), *Innovation in Global Health Governance: Critical Cases* (Routledge 2016) 186.
[366] Jillian Clare Cohen-Kohler, 'The Renovation of Institutions to Support Drug Access: Is it Enough?' in Andrew F Cooper (ed), *Innovation in Global Health Governance: Critical Cases* (Routledge 2016) 186.
[367] Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 181) 392.
[368] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 2; see also Lo (n 358) 144.
[369] Smith et al. (n 183) 684.
[370] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to health' (n 184) 10.
[371] Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 181) 392.
[372] Carlos M Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' (World Health Organization 2002) 44.
[373] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to health' (n 184) 18.

of the Declaration to assert their right to health.[374] Also, Panellists and the Appellate Body can look to the Declaration for guidance in interpreting the provisions of TRIPS when dealing with cases involving public health issues.[375] Therefore, the Declaration is a part of the context of TRIPS according to the rules of treaty interpretation,[376] since it consists of the views and intentions of parties to the TRIPS Agreement, although it does not affect their rights and obligations under the Agreement.[377]

A brief examination to demonstrate how these TRIPS flexibilities can be used to protect public health and enhance access to medicines, as recommended for achieving sustainable development, is necessary:

2.2.1. Interpreting and implementing the TRIPS Agreement in a manner that permits countries to take steps to protect public health and promote access to medicines

The Doha Declaration confirmed that each provision of the TRIPS Agreement should be read in the light of its object and purpose, in accordance with the customary rules of interpretation.[378] The law of treaty interpretation requires a consideration of a treaty in its context, and in view of its object and purpose in order to ascertain its plain and ordinary meaning.[379] If after the contextual consideration its meaning is still obscure, absurd, or there is a need to confirm the interpretation derived from the contextual approach, then the relevant approach is to consider other supplementary means of interpretation, such as the preparatory work of the treaty,[380] subsequent agreements between parties to the treaty (the Doha Declaration being a good example of one of such agreement), [381] and subsequent practices. [382] From Article 7 of TRIPS, its objective is to promote technological innovation and the transfer and dissemination of technology by protecting

[374] European Commission, 'WTO Ministerial Declaration on the TRIPS Agreement and Public Health' (Brussels: European Commission 2001) 2.
[375] ibid.
[376] Vienna Convention on the Law of Treaties 1963, art 33(1).
[377] European Commission, 'WTO Ministerial Declaration on the TRIPS Agreement and Public Health' (n 374) 2.
[378] Doha Declaration para 5(a).
[379] Vienna Convention 1963, art 31(1).
[380] Vienna Convention 1963, art 32.
[381] ibid art 32(3).
[382] Phoebe Li, Health Technologies and International Intellectual Property – A Precautionary Approach (Routledge 2015) 13.

and enforcing intellectual property rights.[383] In other words, the aim of granting, protecting and enforcing intellectual property rights such as patents, is to incentivise innovation.

Nevertheless, TRIPS envisages that the pursuit of this objective should be in a manner conducive and advantageous to the social and economic welfare of users and inventors, and one that balances their rights and obligations.[384] Also, TRIPS Article 8 allows member states to adopt measures to protect public health and promote socio-economic and technological development that are of public interest.[385] When read together, the implication of Articles 7 and 8 of the Agreement is that inasmuch as TRIPS aims to incentivise innovation and development by protecting and enforcing the intellectual property rights of inventors, the protection envisaged is not absolute. It takes into consideration public interest in health and socio-economic development. Thus, the proper interpretation of TRIPS is one that balances the justifiable rights and obligations of inventors and public interest. Taking into account the complex conflict between patents and the right to health, this manner of interpretation means that countries can adopt measures to protect public health insofar as those measures are consistent with the provisions of TRIPS.[386]

2.2.2. Defining what is patentable

As earlier stated, the TRIPS Agreement provides for minimum standards of protection, which member states can choose whether or not to exceed when formulating national legislation. TRIPS is also silent on the definition of some of these standards,[387] and this space presents an opportunity for members to adopt measures to promote access to medicines. From the provisions of TRIPS, member states are required to grant patent protection to products that constitute 'an invention in a field of technology'.[388] Such protection should apply to both products and processes without discrimination against

[383] TRIPS 1994, art 7.
[384] ibid.
[385] ibid art 8.
[386] ibid.
[387] Ho, Access to Medicine in the Global Economy (n 222) 65.
[388] TRIPS 1994, art 27(1).

any field of technology.[389] What this means with regard to pharmaceuticals is that members are required to provide patent for the chemical entity, as well as its manufacturing process.[390] To qualify for protection, TRIPS requires an invention (in this case pharmaceuticals) to be *'new'*,[391] yet it does not clarify whether or not new uses of an existing compound meet the new requirement.[392] Pharmaceutical companies utilise this space by adapting their research to finding new uses and making minor chemical variations to existing drugs, which are the subject matter of patents. These companies first obtain patents on their blockbuster drugs, and then apply for (secondary) patents on minor variations (so-called 'me too drugs'), such as a change in the dosage or slight alteration of the chemical formulation of such drugs, shortly before the expiration of the first patent.[393] For instance, of all the drugs approved by the US Food and Drug Administration (FDA), two-thirds are minor variations of previously approved drugs.[394] While 'evergreening' (as this tactic is known) has made important therapeutic contributions by, for instance, changing existing medicines to enable patients to better tolerate the medicine, or developing safer, less toxic and more effective medicines, it has equally enabled pharmaceutical companies to retain market exclusivity and minimise the cost of R&D, while keeping the income stream generated by these drugs open.[395]

In fact, it is possible for patent holders to file multiple secondary applications for the same invention, thus creating 'a dense web of overlapping' patent rights.[396] This web is known

[389] ibid.
[390] Joe J Wills, Contesting World Order? Socio-economic Rights and Global Justice Movements (Cambridge University Press 2017) 156.
[391] TRIPS 1994, art 27(1).
[392] Ho, Access to Medicine in the Global Economy (n 222) 64.
[393] Cynthia M Ho, 'Should all Drugs be Patentable? A Comparative Perspective' (2015) 17(2) *Vanderbilt Journal of Entertainment & Technology Law* 295, 313-316.
[394] Congress of the United States of America, Congressional Budget Office, 'Research and Development in the Pharmaceutical Industry' (2006) Publication No 2589 14-15 <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf> accessed 26 August 2015.
[395] Esparaza (n 123) 206.
[396] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting' in Adam B Jaffe, Josh Lerner and Scott Stern (eds), *Innovation Policy and the Economy* (MIT Press, 2001); see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 22.

as 'patent thickets'[397] or 'patent clusters'[398] or 'patent floods'.[399] For instance, a pharmaceutical company can have a patent on a chemical compound, then a patent on the method of producing it, then acquires a third patent on a second medical indication, a fourth on new formulations, and so on.[400] Based on a patent landscape analysis of 2011, Lopinavir/ritonavir (an antiretroviral drug) was found to be protected by 805 patent families held by the originator and other research-based companies.[401] This system is used by pharmaceutical companies to prolong market monopoly, thereby preventing competing generic versions from entering the market.[402] Patent thickets also have the effect of creating legal uncertainty regarding the patent status of a pharmaceutical product, which in turn disincentivises generic manufacturers for fear of patent infringement.[403] At the same time, pharmaceutical companies maintain high prices, thereby impeding patient access to medicines.[404] However, developing and least-developed countries can curtail this practice by equally exploiting the absence of a definition of the 'new' criteria for patentability in TRIPS as pharmaceutical companies do. This can be accomplished by defining 'new' to exclude new uses of existing compounds. For example, under the Indian Patent Act, improvements or incremental changes to existing pharmaceutical products are only patentable if demonstrated to be *more efficacious* than the previous product.[405] This means that merely discovering a new use or new form of a known substance is not patentable.[406] This provision was aimed at preventing evergreening in order to promote access to low-cost drugs for its population.[407]

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[397] Shapiro (n 396); see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 22.
[398] European Commission, 'Pharmaceutical Sector Inquiry: Preliminary Report' (2008) DG Competition Staff Working Paper 9 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf> accessed 11 August 2017.
[399] Mattias Ganslandt, 'Intellectual Property Rights or Competition Policy' (2008) 762 IFN Working Paper 12; see also Keith E Maskus, Hamid Beladi and Kwan Choi, *Intellectual Property, Growth and Trade. (Frontiers of Economics and Globalization.)* (Emerald Group Publishing Limited 2008).
[400] 'What is Patent Thicket' (*Intellectual Property Law Forum*) <http://www.intelproplaw.com/ip_forum/index.php?topic=15329.0> accessed 11 August 2017.
[401] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[402] 'What is Patent Thicket' (n 400).
[403] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).
[404] ibid.
[405] Patents (Amendment) Act 2005 (India), s 3(d).
[406] ibid.
[407] Esparaza (n 123) 206.

Nonetheless, a point of criticism against this law was that it failed to define 'efficacy', until 2013 when it was interpreted by the Supreme Court of India in denying Novartis a patent in *Novartis v Union of India*.[408] Novartis filed an application for a patent on an anticancer drug Imatinib mesylate in beta crystalline form, which was a variation of its Imatinib free base (Zimmerman patent).[409] The application disclosed that the Imatinib mesylate in beta crystalline form had more bioavailability (i.e. the medicine's rate of absorption) than the Imatinib free base.[410] The court in finding that Novartis had not met the efficacy requirement under Section 3(d) of India's Patent Act held that 'efficacy should be interpreted to mean therapeutic'.[411] Accordingly, a newly discovered use or a new form of a known substance is patentable in India only if it is proven to be an enhancement of the known substance that will advance its healing effect on patients.[412] Is this provision compatible with the TRIPS Agreement?

Recall that in interpreting and implementing the TRIPS Agreement, Article 8 suggests that countries can adopt measures to protect public health on the condition that such measures are consistent with the provisions of TRIPS.[413] This issue was raised before the Madras High Court in the *Novartis* case before it went to the Supreme Court but was not resolved because the court declined jurisdiction to determine it.[414] Section 3(d) appears to be compatible with TRIPS for the simple reason that TRIPS does not clarify what is 'new' to qualify an invention for patent.[415] As a result, India (and any other member) is at liberty to define its standard *provided it does not discriminate against a field of technology*.[416] This presents another issue: whether Section 3(d) discriminates against pharmaceutical patents by requiring a stringent standard of patentability.

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[408] (2013) 6 SCC 1 96.
[409] ibid.
[410] ibid.
[411] ibid.
[412] Frederick M Abbott, 'Inside Views: The Judgment in Novartis v India: What the Supreme Court of India Said' (*Intellectual Property Watch*, 2013) <http://www.ipwatch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said> accessed 1 August 2015.
[413] TRIPS 1994, art 8.
[414] Shamnad Basheer and Prashant Reddy, '"Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)' (2008) 20(2) *National Law School of India Review* 131-155.
[415] Ho, Access to Medicine in the Global Economy (n 222) 95.
[416] ibid; see also Esparaza (n 123) 215.

Under the TRIPS Agreement, the requirement of non-discrimination against a field of technology does not proscribe differential treatment 'to deal with problems that may exist in certain product areas'.[417] This was the position taken in 2000 by a WTO panel in a complaint by European Communities (now European Union (EU)) and their member states against the protection of inventions in the area of pharmaceuticals under Canada's Patent Act.[418] In the case of India, the problem existing in the pharmaceutical product area is evergreening, and Section 3(d) is only a treatment to address it.[419] Thus, it is difficult to see how Section 3(d) conflicts with India's obligations under TRIPS. Just like India, other developing and least-developed countries could take advantage of this TRIPS flexibility to ensure access to low-cost generics to address the public health situation in their territories.

2.2.3. Pre-grant and post-grant challenges to patent applications and patents

An inventor wishing to patent his invention is required to submit a patent application to a patent office. The duty of the patent office following application is to examine the invention to ascertain whether or not it is new, involves an inventive step and is capable of industrial application. To reach this conclusion, patent examiners search the prior art for a similar invention; however, not all information in the prior art is accessible or known to patent examiners.[420] For this reason, some countries allow third parties to submit evidence of a similar invention existing in the prior art which was not considered by the patent examiners in order to oppose the grant of the patent application (pre-grant opposition) or the issued patent (post-grant opposition).[421] Although the TRIPS Agreement does not require such objection, it allows member states the discretion to adopt such procedures.[422] By the provisions of TRIPS, a member who adopts such a procedure must ensure that it is fair, equitable, not complicated and costly, and without undue delay.[423] Member states are also free to determine the grounds for making such

[417] Panel Report, 'Canada – Patent Protection of Pharmaceutical Product' (WT/DS114/R 2000).
[418] ibid.
[419] Ho, Access to Medicine in the Global Economy (n 222) 96.
[420] ibid 99.
[421] ibid.
[422] ibid.
[423] TRIPS 1994, art 62(4).

objections, and the appropriate persons entitled to object to patent applications and issued patents.[424]

Notwithstanding that this policy space was not identified by the Doha Declaration, it represents an opportunity in the TRIPS Agreement that could be exploited by developing and least-developed countries to enhance access to medicines. Generic companies (which are peers of pharmaceutical companies and have access to the relevant prior art in the pharmaceutical field) could object to the grant of a patent application or an issued patent on medicine on the grounds that it did not meet the patentability requirements. If such objection succeeds, the generic companies would be able to copy and offer such medicine at a low price. For example, the Indian Patent Act entitles *any person* to challenge a pending patent application before it is granted on the grounds that it is not new, lacks an inventive step or does not comply with Section 3(d).[425] Generic competitors and organisations interested in the affairs of cancer and HIV patients are such persons that can lodge a pre-grant objection.[426] In the case of post-grant oppositions, the law allows *an interested party* to challenge a patent after it has been granted, but within the first year of issuance.[427] Such an interested party will rely on the same grounds as the person in the pre-grant. However, regarding who can initiate a post-grant opposition, the law limits it to only *an interested party*, as opposed to *any person*, as is the case with pre-grant oppositions. An example of an interested party would be those who belong to the same field as the inventor, including researchers.[428]

A pre-grant opposition has been successfully employed to make a treatment for HIV available in India. The Initiative for Medicines, Access and Knowledge (I-MAK), a US-

[424] Ho, Access to Medicine in the Global Economy (n 222) 66.
[425] Patents (Amendment) Act 2005 (India), s 25(1).
[426] MSF & Lawyers Collective, 'Novartis Challenges the Indian Patent Law: Cancer Patients and Health Groups Demand Withdrawal of Cases' (India: MSF & Lawyers Collective, 10 September 2006) <http://www.phmovement.org/en/node/264> accessed 10 July 2015; see also Medécins Sans Frontières (MSF), 'ABIA and SAHARA Joint Press Release on Patent Opposition for Tenofovir, Campaign for Access to Essential Medicine' (*MSF*, 26 June 2008) <https://www.msfaccess.org/content/abia-and-sahara-joint-press-release-patent-opposition-tenofovir> accessed 10 July 2015; and Peter Ollier, 'Roche Loses Patent Opposition in India' (*Managing Intellectual Property*, 1 June 2010) <http://www.managingip.com/Article/2483734/Roche-loses-patent-opposition-in-India.html> accessed 15 July 2015.
[427] Patents (Amendment) Act 2005 (India), s 25(2).
[428] Ho, Access to Medicine in the Global Economy (n 222) 102.

based not-for-profit group working to increase access to medicines globally,[429] lodged an objection with the Indian Patent Office challenging a patent application filed by Abbott Laboratories (now AbbVie Inc.) for Lopinavir/ritonavir (sold under the brand name Kaletra in developed countries and Aluvia in developing and least-developed countries).[430] This drug is the classic example of the abuse perpetrated by pharmaceutical companies using the patent system: between 1992 when Abbott was awarded the first patent on ritonavir, and 2011, it had 75 patents on this drug.[431] Also, recall that between Abbott and other research-based companies there are 805 patents on ritonavir. The company has continued to make minor variations to the drug in order to maintain its market monopoly, and it was on the basis of one of such variations that it sought this patent in India. Abbott's application requested patent protection for a method of preparing a heat-stable form of ritonavir.[432] Against this, I-MAK argued that Abbott's patent claim was based on the mere addition of known substances such as polymer PVP to the old drug combination of ritonavir, using previously patented technology, Meltrex (or melt-extrusion).[433] Accordingly, the heat-stable ritonavir did not involve an inventive step to make it eligible for patent protection.[434] The patent office concurred with I-MAK's submission and refused Abbott's application.[435] The corollary of this decision was that Indian generic manufacturers could continue producing and exporting ritonavir to other developing and least-developed countries that are acutely affected by the HIV epidemic without fear of infringing any patent.[436] Moreover, provided the procedure is fair, equitable, not complicated and costly, and not causing undue delay to the grant of a patent, this system of objecting to a patent, whether pre- or post-grant, is compatible with the TRIPS Agreement.[437]

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[429] 'About' (*I-MAK*) <http://www.i-mak.org/about/> accessed 12 July 2017.
[430] I-MAK, 'Patents and HIV Medications: An Overview' (*I-MAK*, January 2011) <http://static1.1.sqspcdn.com/static/f/129694/10047507/1294018196787/IMAK_FINALOverview+1-1-2011.pdf?token=eeGRHF2L%2BC0WV%2Fbrlxvj%2F9HoEd0%3D> accessed 13 August 2017; see also Lynne Taylor, 'India Rejects Abbott Patent on Kaletra' (*PharmaTimes*, 5 January 2011) <http://www.pharmatimes.com/news/india_rejects_abbott_patent_on_kaletra_979826> accessed 13 August 2017; and I-MAK, 'I-MAK Challenges Patents on Lifesaving HIV Drug Combination in Europe, India' (*I-MAK*, 16 August 2007) <http://www.i-mak.org/news-releases/2007/8/16/i-mak-challenges-patents-on-lifesaving-hiv-drug-combination.html> accessed 13 August 2017.
[431] I-MAK, 'Patents and HIV Medications' (n 430).
[432] Taylor, 'India Rejects Abbott Patent on Kaletra' (n 430).
[433] I-MAK, 'I-MAK Challenges Patents on Lifesaving HIV Drug Combination in Europe, India' (n 430).
[434] ibid.
[435] Taylor, 'India Rejects Abbott Patent on Kaletra' (n 430).
[436] ibid; see also I-MAK, 'Patents and HIV Medications' (n 430).
[437] Ho, Access to Medicine in the Global Economy (n 222) 102.

2.2.4. Issuing compulsory licences

The Doha Declaration identified the grant of compulsory licences as one of the flexibilities in TRIPS through which WTO members can protect public health. The TRIPS Agreement[438] allows members to enact laws that provide for other uses[439] of the subject matter of a patent without the authorisation of the rightsholder. This provision is popularly referred to as 'compulsory licencing', although not expressly named thus in the Agreement. In other words, the compulsory licencing system is one that allows countries to issue licences that permit them or a third party to manufacture a generic version of a patented drug without the authorisation of the rightsholder.[440] To check arbitrariness, TRIPS subjects the grant of compulsory licences to certain conditions: (a) the grant must be for use that will counteract anticompetitive practices; (b) the grant must be authorised if after negotiation with the rightsholder based on reasonable commercial terms and conditions, such negotiation was unsuccessful within a reasonable period; (c) this requirement of prior negotiation can be waived in the event of a national emergency or other cases of extreme urgency or in cases of public non-commercial use; (d) the life of the licence must come to an end when the circumstance that led to its grant ceases to exist and is unlikely to recur; and (e) drugs produced under the licence are only for supply to the domestic market of the country that authorised the licence[441] (essentially, it disallows the export of drugs).[442]

One common myth that must be dispelled about compulsory licences is that the law requires a country to grant compulsory licences only in a situation of national emergency. This idea has been sponsored and publicised by the pharmaceutical industry, especially since some developed countries began developing interest in exploring the use of TRIPS

[438] TRIPS 1994, art 31.
[439] 'Other use' refers to use other than that allowed under TRIPS art 30.
[440] Jerome H Reichman and Catherine Hasenzahl, 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America' (2002) Case Study for UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development.
[441] TRIPS 1994, art 31.
[442] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 73.

flexibilities in combating high costs of medicines,[443] as it is increasingly posing a challenge for developed countries as well.[444] So, does there have to be an emergency? The WTO says: 'not necessarily'.[445] Compulsory licences can be granted provided the proposed user obtains the rightsholder's permission on reasonable commercial terms and conditions.[446] If after a reasonable time, efforts to obtain such authorisation was unsuccessful, it is still compatible with TRIPS if a country granted a compulsory licence.[447] However, this prior authorisation can be waived only in situations of *national emergency* or other cases of extreme urgency or in cases of public non-commercial use.[448] This means that the procedure for compulsory licencing in the case of national emergency is more straightforward because the proposed user need not seek authorisation before issuance.[449] Nonetheless, TRIPS requires that the rightsholder be merely notified 'as soon as reasonably practicable'.[450] Besides, the Doha Declaration confirmed that countries are free to determine the grounds for granting compulsory licences.[451] Thus, it is possible for a country to choose to issue a compulsory licence on grounds other than an emergency.

By inserting a provision on compulsory licences in national legislation, a country can licence a government department or a third party to manufacture an expensive patented drug and offer to the public at low cost. Indeed, some countries have used this flexibility: for example, in Africa, the Patent (Amendment) Act of Zimbabwe 2002 enables the state to use a patented invention during a period of emergency.[452] If it appears expedient to the Minister[453] during a period of emergency, he may authorise a Department of State or any person to make, use, exercise and vend a patented invention for any purpose which will achieve *inter alia*: maintenance of supplies and services essential to the well-being of the

[443] Ellen 't Hoen, 'The Most Common Misunderstanding about Compulsory Licensing' (*Medicines Law & Policy*, 25 May 2017) <https://medicineslawandpolicy.org/2017/05/the-most-common-misunderstanding-about-compulsory-licensing/> accessed 17 July 2017.
[444] 't Hoen, Private Patents and Public Health (n 5) 4.
[445] 't Hoen, 'The Most Common Misunderstanding about Compulsory Licensing' (n 443).
[446] TRIPS 1994, art 31(b).
[447] ibid.
[448] ibid.
[449] 't Hoen, 'The Most Common Misunderstanding about Compulsory Licensing' (n 443).
[450] TRIPS 1994, art 31(b).
[451] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001.
[452] Patent (Amendment) Act 2002 (Zimbabwe), s 35(1).
[453] 'Minister' means Minister of Justice, Legal, and Parliamentary Affairs or any other Minister to whom the President may from time to time assign the administration of the Act – see Patent (Amendment) Act 2002 (Zimbabwe), s 1.

community.[454] Under this provision, a period of emergency means any period declared as such by the Minister through a statutory instrument as beginning and ending on specific dates.[455] In 2002, the government of Zimbabwe sought to promote the manufacturing and importing of low-cost HIV/AIDS drugs. Accordingly, the Minister relied on Section 35 in issuing a notice that declared a six-month period of emergency (which was later extended to 2008).[456] A local generic manufacturer, Varichem, was licenced to produce antiretroviral drugs and supply to the national health institutions.[457] As at 2011, there were some local generic manufacturers licenced by the government to manufacture and import HIV/AIDS medications.[458]

Also, in Southeast Asia, Thailand issued compulsory licences in 2007 for the production of two antiretroviral drugs, efavirenz and lopinavir/ritonavir, to provide these drugs at low cost for its people living with HIV.[459] Likewise in the South American region, Ecuador had granted nine compulsory licences as at 2014 for the production of ritonavir, lamivudine and abacavir.[460] These are antiretroviral drugs, targeted at scaling-up treatment for HIV patients in Ecuador. As regards the compatibility of these uses of compulsory licencing in Ecuador, Thailand and Zimbabwe with the TRIPS Agreement, the Doha Declaration confirmed the right of WTO member states to grant compulsory licences, and their freedom to determine the grounds upon which such licences can be granted.[461] Moreover, the Declaration acknowledges the right of countries to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that HIV/AIDS can represent such situations.[462] Therefore, it is unlikely that an objection to these compulsory licences predicated on non-compliance with TRIPS would have succeeded.

[454] Patent (Amendment) Act 2002 (Zimbabwe), s 35(1).
[455] ibid s 35(2).
[456] Zimbabwe: Declaration of Period of Emergency (HIV/AIDS) Notice 2002, General Notice 240 of 2002 <http://www.wipo.int/wipolex/en/text.jsp?file_id=214688> accessed 12 September 2016.
[457] F Musungu and C Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?' (2005) Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), Study 4, 25.
[458] ibid.
[459] ITPC, 'The Campaign for Use of Compulsory Licensing in Thailand' (n 187).
[460] Covarrubia, 'Compulsory License and Parallel Import' (n 272).
[461] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001.
[462] ibid.

Nonetheless, TRIPS' provision on compulsory licencing has been criticised for two reasons: first, by restricting its predominant use to the supply of the domestic market, it did not consider the circumstances of developing and least-developed countries that lack manufacturing capacity, and bear the major brunt of malaria, tuberculosis and HIV/AIDS.[463] Secondly, it does not clarify the threshold for invoking a national emergency to waive the requirement of prior negotiation with rightsholders.[464] Further aggravating this issue is the inconsistency in interpreting 'emergency' in international law.[465] Resultantly, the pharmaceutical industry and the US threaten sanctions against developing and least-developed countries that seek to utilise the national emergency exception.[466]

Recognising that WTO members with insufficient or lacking manufacturing capacities in the pharmaceutical sector could face difficulties in making use of the compulsory licencing system in view of the bar on exportation, the Doha Declaration mandated the TRIPS Council to find a lasting solution to this problem.[467] The 30th of August 2003 saw WTO members agree on a temporary waiver to allow for the export of drugs using the compulsory licencing system under the TRIPS Agreement. Following this, members agreed on 6 December 2005 to make the waiver permanent by amending TRIPS subject to the acceptance of two-thirds of WTO members.[468] In operation, the waiver would allow a country lacking the capacity to manufacture drugs to issue a compulsory licence to import from a country having the capacity and willingness to assist. Likewise, the latter country would have to issue a compulsory licence of its own to enable it to export drugs to the importing country (back-to-back compulsory licences).[469] The aim was that

[463] Jimcall Pfumorodze, 'WTO TRIPS Agreement and Access to Medicines in Southern Africa' (2011) 13 *University of Botswana Law Journal* 87, 89.
[464] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 73; see also Duncan Matthews, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries' (2006) 2 *Intellectual Property Quarterly* 91.
[465] Li (n 382) 13.
[466] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182); see also Matthews, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS' (n 464) 91.
[467] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001, known as 'the paragraph 6 problem'.
[468] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health' (n 184) 10-11.
[469] Jerome H Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) *Journal of Law, Medicine and Ethics* 3.

through this amendment, the flexibility to protect public health would become an integral part of the TRIPS Agreement and there would be legal certainty that any member is entitled to export an entirety of pharmaceutical products made under a compulsory licence to countries that lack manufacturing capacity.[470]

This amendment was formally included in the TRIPS Agreement after acceptance of the amending protocol by two-thirds of the WTO members and took effect on 23 January 2017 to effectively replace the 2003 waiver for members who have accepted it.[471] Member states who were yet to accept were given until 31 December 2017 to do so.[472] While this amendment is very significant being the first ever amendment to WTO rules and prompted by public health concerns, it does not promise meaningful changes in practice.[473] In spite of being in place for 14 years, the waiver has been used only by Rwanda to import a generic fixed-dose-combination HIV medicine from a Canadian producer in 2009.[474] Efforts to use the regime by Apotex, the generic company, lasted four years before it successfully shipped the drug to Rwanda.[475] Organisations such as MSF and the company, Apotex, criticised the waiver for being unnecessarily rigorous.[476] The TRIPS Council's decisions on applications to use this regime are made on a drug-by-drug, country-by-country and case-by-case basis.[477] This does not create economies of scale and the predictability of market prospects that generic manufacturers need to invest in the development of medicines.[478] Further disincentivising these generic companies is the requirement of back-to-back licences, and the possibility that the patent owner might choose to reduce the prices or donate the drugs required, thus rendering

[470] WTO, 'WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines' (*World Trade Organization*, 23 January 2017) <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> accessed 1 February 2017.
[471] 'Intellectual Property: TRIPS and Public Health, Amendment of the TRIPS Agreement' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 1 February 2017.
[472] ibid.
[473] Ellen 't Hoen, 'Access to Medicines Amendment of the WTO TRIPS Agreement. Hype or hope?' (*Medicines Law & Policy*, 11 April 2017) <https://medicineslawandpolicy.org/2017/04/access-to-medicines-amendment-of-the-wto-trips-agreement-hype-or-hope/> accessed 14 July 2017.
[474] ibid.
[475] ibid; see also Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' (n 469)11.
[476] Wise (n 135) 337-424; see also 't Hoen, 'Access to Medicines Amendment of the WTO TRIPS Agreement. Hype or hope?' (n 473).
[477] ibid.
[478] ibid.

already made efforts futile.[479] More, the prior negotiation with patent holders poses a major obstacle for companies as it is usually a daunting task.[480] Again, the stringent requirements for using the waiver not required by TRIPS, but imposed by national legislation, result in the system being unworkable.[481] For example, the Canadian regime limits drugs produced by compulsory licence to 57.[482] In effect, this limitation restricts treatment for only those diseases curable by the 57 drugs on the list. This is clearly not the intent of the Doha Declaration.[483]

Along similar lines, the requirements of packaging, colouring and shaping of pills in using the waiver could potentially impact on access to medicines in developing and least-developed countries.[484] Undertaking this exercise is an additional financial burden on the generic manufacturing company, which will be less motivated to proceed with the production of the generic drug.[485] However, in the event the generic company decides to produce, there is a likelihood that such additional cost would be reflected in the market price of the drug. This would mean that the cost of the drug would remain high in developing and least-developed countries.[486] Mindful of these challenges in using the waiver, the crucial question becomes whether the system would become more workable having been permanently built into TRIPS. Essentially, the implication of the 2017 amendment was to make the temporary waiver of 2003 permanent and part of the TRIPS Agreement. It does nothing to enhance the operational efficiency of the system; the challenges continue to exist. Thus, there will be a need for WTO to provide technical assistance, especially to developing and least-developed countries to enable the effective enactment of the waiver in national legislation. In this regard, it would be helpful to

[479] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health' (n 184) 22.
[480] ibid.
[481] Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions' (n 469)11.
[482] ibid.
[483] ibid.
[484] Simon Lester, Bryan Mercurio and Arwel Davies, *World Trade Law: Text, Materials and Commentary* (Bloomsbury Publishing 2018) 854; see also Duncan Matthews, 'Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation' (2004) 1 *Law, Social Justice & Global Development Journal* (LGD).
[485] Matthews, 'Is History Repeating Itself? (n 484).
[486] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 83.

formulate efficient model legislation based on which developing and least-developed countries can craft their national legislation.

Also, it is important to promote capacity-building and organise workshops to create awareness on how the waiver can be utilised. Since there appears to be more work to be done to use the waiver efficiently, it has been suggested that a straightforward exception under TRIPS Article 30 (which provides exceptions to rights conferred) to supply medicines to a country that has issued a compulsory licence would have been closer to Doha's expectation of an expeditious solution.[487] It is noteworthy that as of 31 March 2018, developing and least-developed countries have been slow to implement the amendment through national legislation, except China and India.[488] Equally, their developed counterparts possessing manufacturing capacity are reluctant to pass legislation which would allow their pharmaceutical industries to supply countries seeking to utilise the provision, except Canada, the Netherlands and Switzerland.[489] Connected with this, it has been suggested that other developed countries may be simply uninterested in operationalising the amendment agreement.[490] Notwithstanding, the waiver system provides an important option for regional economic blocks that house the majority of developing and least-developed members (e.g. the Economic Community of West African States (ECOWAS), as members can collectively request medicine supplies for the entire region.[491] It is in view of this possibility that the system gives some hope.[492]

Regarding the criticism that the TRIPS Agreement does not clarify the threshold for invoking national emergency to waive the requirement of prior negotiation with rightsholders, the Doha Declaration provided illumination in confirming the right of each member state to determine what constitutes a national emergency or other circumstances of extreme urgency.[493] In doing so, it noted that pandemics such as malaria, tuberculosis and HIV/AIDS could give rise to a national emergency or other circumstances of extreme

[487] 't Hoen, 'Access to Medicines Amendment of the WTO TRIPS Agreement. Hype or hope?' (n 473).
[488] Lester et al. (n 484) 854.
[489] Lester et al. (n 484) 854.
[490] ibid 855.
[491] 't Hoen, 'Access to Medicines Amendment of the WTO TRIPS Agreement. Hype or hope?' (n 473).
[492] ibid.
[493] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001.

urgency.[494] In other words, any developing or least-developed country can issue a compulsory licence for the production of patented medicines for malaria, tuberculosis and HIV/AIDS or other diseases without first obtaining authorisation from the patent holder, as long as the country determines that the disease is such that it constitutes a national emergency or a circumstance of extreme urgency that cannot endure protracted negotiations with rightsholders.[495] In view of this, the issue of inconsistency in interpreting 'emergency' in international law pales into insignificance.

Questions also arise as to the use of compulsory licence in preparation for the outbreak of a disease. The 2007 decision 60.28 of the World Health Assembly (WHA), the decision-making body of the WHO, to develop a new framework for virus sharing in cases of global pandemic influenza viruses, requires states to stockpile medications for an impending pandemic, particularly when such pandemic is capable of transmission.[496] The issue then is whether compulsory licences can be legally granted before the actual outbreak of the pandemic to secure medication in preparation.[497] A careful reading of TRIPS Article 31 will reveal that issuing compulsory licences is not restricted to the actual existence of a public health crisis. So, it may be correct to say that the grant of a compulsory licence depends on the identification of a public health crisis[498] – whether actual or imminent. In view of this, it is not illegal within the context of the provision to grant the licence in preparation for a pandemic outbreak. However, the legality of the practice of stockpiling medication in view of TRIPS Article 30 is a different issue.[499]

Other than compulsory licencing, TRIPS Article 30 allows member states to provide for 'limited' exceptions to the exclusive rights conferred by a patent.[500] Such exceptions must satisfy three requirements: (a) they must be a narrow deviation from the usual patent rights; (b) they must not unreasonably conflict with the normal exploitation of the patent;

[494] ibid para 5(c); see also Lo (n 358) 152.
[495] Lo (n 358) 152.
[496] WHA 60.28, 'Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits' (Sixtieth World Health Assembly Agenda Item 12.1 2007); see also Elisa Morgera and Kati Kulovesi, *Research Handbook on International Law and Natural Resources* (Edward Elgar Publishing 2016) 232.
[497] Li (n 382) 17.
[498] ibid.
[499] TRIPS 1994, art 30.
[500] ibid.

and (c) they must not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.[501]Although TRIPS does not go further to define these requirements,[502] a WTO panel addressed them while analysing a stockpiling exception under the Canadian Patent Law.[503] Canada allowed generic manufacturers who obtained regulatory approval to sell generic versions of the patented drug after patent expiry, to produce and stockpile an *unlimited quantity* of the patented drug during the last six months of the patent term.[504] This exception was significant because it ensured that generic drugs existed at the expiry date of the patent.[505] Otherwise, generic versions would not be available to consumers for several months after patent expiration, which would be the normal time for generic manufacturers to commence production.[506]

The WTO panel found that the stockpiling exception was not appropriately limited and thus impermissible.[507] Particularly, the provision did not limit the quantity of drugs a generic manufacturer could make during the patent term. The panel was of the view that a 'limited exception' entailed a narrow derogation from the range of rights conferred on the patent holder.[508] Therefore by permitting the manufacturing of an *unlimited quantity* of generic drugs during the patent term, the exception constituted a substantial curtailment of the exclusionary rights conferred on the patent holder, to such an extent that it did not qualify as a limited exception.[509] However, the panel did not say that stockpiling of generic versions was generally not permissible.[510] What seemed to be important was that the stockpiling exception did not comply with the requirements of limited exceptions prescribed by TRIPS. It is inferable that supposing the stockpiling exception of the Canadian Law provided that generic manufacturers made a *limited quantity* of generic versions of patented drugs, then it would have been permissible. Thus, it would not

[501] ibid.
[502] Ho, Access to Medicine in the Global Economy (n 222) 71.
[503] Patent Law (RSC, 1985, c.P-4) Canada, s 55.2(2).
[504] Panel Report, 'Canada – Patent Protection of Pharmaceutical Product' (n 417).
[505] Ho, Access to Medicine in the Global Economy (n 222) 73.
[506] ibid.
[507] Ho, Access to Medicine in the Global Economy (n 222) 73.
[508] Frederick M Abbott, 'TRIPS Dispute Settlement Decisions' (2009) ICTSD <http://www.ictsd.org/downloads/2009/10/abbott_trips_dsu.pdf> accessed 28 April 2016.
[509] ibid; see also 'DS114: Canada – Patent Protection of Pharmaceutical Products' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed 28 April 2016.
[510] Ho, Access to Medicine in the Global Economy (n 222) 73.

contravene the TRIPS Agreement if any developing or least-developed country issued compulsory licences to stockpile medicines in preparation for an outbreak, insofar as the manufacturing of the generic version of the patented drug complies with the three requirements of limited exceptions (as they are cumulative[511]).

2.2.5. Parallel importation of patented drugs

The Doha Declaration recognises that TRIPS permits each WTO member to establish its regime of exhaustion of intellectual property rights, which is not challengeable under the WTO Dispute Settlement System.[512] Nonetheless, any country exercising this right shall do so subject to the Most Favoured Nation (MFN) and National Treatment provisions of TRIPS Articles 3 and 4.[513] The exhaustion principle is the idea that an intellectual property rightsholder surrenders some of his monopolies once he sells or gives the product to a new owner.[514] In so doing, the sale exhausts those intellectual property rights because the rightsholder will not be able to control many of the ways in which the new owner may use the product.[515] In relation to patents, this means that after the first sale of a product a patent holder cannot prevent its use or resale.[516] The first sale exhausts his exclusive rights to use, sell and offer for sale. Consequently, the exhaustion of these rights allows for parallel importation of the product from the market in which it was placed by the patent owner or a third party whom he authorised.[517] In other words, exhaustion of rights is also an exception to the patent holder's right to exclude importation.[518] Under the TRIPS Agreement, a member may adopt an international, regional or national exhaustion of rights regime: an international regime enables a country to explore the option of parallel import from any other country; regional regimes limit importation to

[511] Panel Report, 'Canada – Patent Protection of Pharmaceutical Product' (n 417). As will be seen in Chapter six, however, the possibility of amending the TRIPS Agreement to clarify issues of this nature is very remote, given the difficulty in amending WTO rules.
[512] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001, para 5(d).
[513] TRIPS 1994, art 6.
[514] Perzanowski and Schultz (n 230) 25.
[515] ibid.
[516] Ho, Access to Medicine in the Global Economy (n 222) 107-108.
[517] WIPO, 'International Exhaustion and Parallel Importation' (*World Intellectual Property Organization*) <http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm> accessed 16 August 2017; see also Ho, *Access to Medicine in the Global Economy* (n 222) 107.
[518] Ho, Access to Medicine in the Global Economy (n 222) 107.

products originating from members of a regional or economic agreement; while national exhaustion excludes parallel importation.[519]

According to the Doha Declaration, the use of this policy space can advance the interest of developing and least-developed countries in accessing low-cost medicines.[520] For example, Zimbabwe has an international exhaustion of patent rights regime.[521] A Zimbabwean pharmaceutical company, Datlabs, imports zidovudine from India using this provision that permits parallel importation of patented products.[522] This has remarkably enhanced access to low-cost medicines in Zimbabwe.[523] Essentially, any developing or least-developed country that has an international exhaustion regime can rely on it to import pharmaceuticals from any country where the patent owner has sold them, and where they are cheap and affordable. However, there is a fundamental concern that drugs supplied to developing and least-developed countries at preferential prices may surface in markets of developed countries through parallel export.[524] This may discourage pharmaceutical companies from supplying developing and least-developed countries with drugs at lower prices, or supplying at all.[525] In view of this, it would be in the interest of developing and least-developed countries to craft measures that will prevent parallel exports of medicines imported at low cost.[526]

2.2.6. Protection of clinical data against unfair commercial use

[519] Duncan Matthews and Viviana Munoz-Tellez, 'Parallel Trade: A User's Guide' in Anatole Krattiger, Richard Nelsen Mahoney, Lita Nelsen, Jennifer A Thomson, Alan B Bennett, Kanikaram Satyanarayana, Gregory D Graff, Carlos Fernandez and Stanley P Kowalski (eds), *Intellectual Property Management in Health and Agriculture Innovation: A Handbook of Best Practices* (MIHR-USA 2007) 1429.
[520] F. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner in WTO' (2002) 5 *Journal of International Economic Law* 497.
[521] Patent (Amendment) Act 2002 (Zimbabwe), s 24A.
[522] Pfumorodze (n 463) 98-99.
[523] ibid.
[524] Elizabeth Siew Kuan, 'Balancing Patents and Access to Medicine' (2009) 21 *Singapore Academy Law Journal* 469.
[525] F M Scherer and Jayashree Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' (2002) 5 *Journal of International Economic Law* 913.
[526] For policy recommendations on how developing and least-developed countries can prevent parallel exports, see Keith E Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries' (2001) Report presented to the WIPO under terms of Special Service Agreement; Scherer and Watal (n 525) 913; and Mattias Ganslandt and Keith E Maskus, 'Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union' (2004) 23 *Journal of Health Economics* 1035-1057.

Before a regulatory authority grants a pharmaceutical company marketing approval for a new drug, the company is required to provide evidence of the safety, efficacy, and quality of the drug in the form of clinical data.[527] Usually, the clinical data include tests conducted during the manufacturing process, the chemical composition of the drug, and pre-clinical and clinical drug trials.[528] These clinical data cost pharmaceutical companies a substantial amount of money to generate.[529] Upon satisfaction with the data presented, the agency approves the drug and is under a duty to keep the data and not disclose their content.[530] In the interest of access to low-cost medicines, the regulatory authority can allow a generic company seeking approval for the generic version of the new drug to rely on the clinical data submitted by the originator pharmaceutical company based on bioequivalence.[531] This means that the generic company will be excused from generating fresh clinical evidence to prove the safety, efficacy and quality of the generic drug, but will be allowed to use the clinical data submitted by the originator company to discharge this burden of proof on the basis that for all intents and purposes, the new drug and its generic version are the same.[532] This provides an incentive for generic companies to produce, as they are spared from bearing the considerable cost of generating clinical data.[533]

In view of the substantial cost spent on generating clinical data, pharmaceutical companies consider it an unfair advantage that generic companies are allowed to rely on submitted data without cost.[534] As a result, they use data exclusivity to prevent generic companies from obtaining marketing approval by referring to the original clinical data.[535] Data exclusivity is a form of intellectual property protection and refers to the period

[527] Gerald J Mossinghoff, 'Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process' (1999) 54 *Food and Drug Law Journal* 187–194.
[528] Olasupo A. Owoeye, 'Data Exclusivity and Public Health under the TRIPS Agreement' (2014) 23(2) *Journal of Law, Information and Science* 109.
[529] Srividhya Ragavan, 'The Significance of the Data Exclusivity and Its Impact on Generic Drugs' (2017) 1(1) *Journal of Intellectual Property Studies* 133, 133-136.
[530] ibid; see also Mossinghoff (n 527) 187–194.
[531] Ragavan (n 529) 133-136.
[532] Ho, Access to Medicine in the Global Economy (n 222) 76-83.
[533] Owoeye (n 528) 109.
[534] Priapantja Priapantja, 'Trade Secret: How Does This Apply to Drug Registration Data?' (2000) ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, Department of Health and World Health Organization; see also Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva, Switzerland: South Centre 2002) 6-7.
[535] Ragavan (n 529) 133-136.

during which the clinical data submitted to a drug regulatory authority are under protection.[536] For the duration of this protection, generic companies are not permitted to rely on the protected clinical data in their applications for marketing approval.[537] This provides pharmaceutical companies with a form of marketing exclusivity, as no generic versions are likely to be placed in the market within the period of protection.[538] This situation enables pharmaceutical companies to recover the cost expended in generating data used in obtaining marketing authorisation.[539] Because generic companies are barred from referring to previously submitted clinical data, they are disincentivised from producing generic versions of new drugs due to the considerable cost, rigorous and time-consuming process of generating test data. Consequently, data exclusivity hinders generic competition, and adversely affects the availability of low-cost drugs.[540] As will be seen later on, data exclusivity is pushed and advocated for by pharmaceutical companies and the US in FTAs negotiated between developed countries and developing/least-developed countries.[541]

However, under the TRIPS Agreement, countries that request submission of undisclosed test or other data as a condition for gaining marketing approval are required to protect such data against 'unfair commercial use' and not data exclusivity.[542] This TRIPS provision is amorphous for while it demands protection for undisclosed test or other data submitted to regulatory authorities, it does not define what constitutes an 'unfair commercial use' against which the data are protected.[543] As with all other undefined terms in the TRIPS Agreement, members are vested with the discretion to adopt an interpretation that most suits their situation. Developed countries, especially the US and its pharmaceutical companies, have exercised this right by categorising the reliance by generic companies on submitted clinical data as being an 'unfair commercial use' through

[536] European Commission, 'Pharmaceutical Sector Inquiry' (n 398) 17.
[537] ibid.
[538] ibid.
[539] Charles Clift, 'Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals' in Krattiger et al., *Intellectual Property Management in Health and Agriculture Innovation* (n 519) 435.
[540] ibid.
[541] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health' (n 184) 10; see also Morgan (n 248) 68.
[542] TRIPS 1994, art 39(3); see also Ellen F M 't Hoen, Pascal Boulet and Brook B Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A proposal for Greater Coherence in European Pharmaceutical Legislation' (2017) 10(19) *Journal of Pharmaceutical Policy and Practice* 2.
[543] Ho, Access to Medicine in the Global Economy (n 222) 83.

data exclusivity provisions.[544] Likewise, developing and least-developed countries in need of access to affordable medicines can exclude reliance on clinical data as constituting an 'unfair commercial use,' thereby allowing generic companies to refer to previously submitted clinical data in gaining approval for generic drugs.[545] For example, India approves generic substitutes by permitting reliance on clinical data of a previously approved drug on grounds of bioequivalence.[546] While there is no specific statute at the moment prohibiting unfair commercial use of clinical data in India, other existing laws on the law of confidence, tort, equity and contract seem sufficient to comply with the minimum standard required by TRIPS.[547] Thus, this policy space presents a viable tool for enhancing access to medicines in developing and least-developed countries even though it was not identified by the Doha Declaration.

Indeed, access to essential medicines can be enhanced through the use of TRIPS flexibilities. Developing and least-developed countries can insert provisions on these flexibilities in national legislation to provide a legal basis for using them to ameliorate the negative impact of patents on public health. This fact is substantiated by the cited examples of the few countries that have utilised the flexibilities to this end. It is for this reason that the UN 2030 Agenda for Sustainable Development and the High-Level Panel encouraged developing and least-developed countries to exploit these policy spaces to promote access to affordable medicines. However, there are impediments to the use of TRIPS flexibilities by developing and least-developed countries. Developed countries, led by the US, whittle down the possibility of utilising the flexibilities by seeking increased intellectual property protection under the provisions of FTAs.[548] These provisions are popularly known as 'TRIPS-plus' provisions because they require higher standards of patent protection than the TRIPS Agreement.[549] The following section

[544] ibid.
[545] ibid; see also Ragavan (n 529) 133-136.
[546] Ho, Access to Medicine in the Global Economy (n 222) 119.
[547] Vishwas H Devaiah, Tahir Amin, Priti Radhakrishnan and Michael Steffen, 'The Impact of Article 39.3 in India: A Practical Perspective' (2006) *New York: Institute for International Law and Justice, South Asia Dialogue Series*; see also Satwant Reddy and Gurdial Singh Sandhu, 'Report on Steps to be taken by Government of India in the Context of Data Protection Provisions of Article 39.3 of TRIPS Agreement' (Government of India: Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers 2007) 13 <http://chemicals.nic.in./DPBooklet.pdf.> accessed 10 November 2015.
[548] Rudolf V van Puymbroeck, 'Basic Survival Needs and Access to Medicines – Coming to Grips with TRIPS: Conversion + Calculation' (2010) 38 *Journal of Law, Medicine and Ethics* 520, 531-533.
[549] Baird, 'Magic and Hope' (n 190) 111.

discusses these TRIPS-plus provisions and evaluates in what ways they obstruct the use of TRIPS flexibilities.

2.3. TRIPS-Plus Provisions in Free Trade Agreements (FTAs) as Barriers to the Use of TRIPS Flexibilities

For any developing or least-developed country, the motive for negotiating FTAs with a developed counterpart is to gain access to foreign markets, usually for agricultural exports.[550] In the course of negotiating these agreements, developing and least-developed countries agree to provide very stringent intellectual property protections in exchange for trade concessions from developed countries.[551] This practice began long before the TRIPS-plus era. For example, when India signed the TRIPS Agreement, it was in the middle of one of the most severe financial crises in its history.[552] Because of this, India could not avoid ratifying the Agreement as it formed part of a larger economic agreement that could guarantee increased exports.[553] In reality, however, FTAs do not deliver on the promise of attracting investment and increased exports. This was the experience of Jordan (a developing country) in its FTA with the US, in which Jordan acceded to high intellectual property protections in order to attract foreign direct investments (FDIs), and increased exports of goods and services to North America.[554] Nonetheless, empirical evidence has shown that this agreement failed to deliver on its promises.[555] Therefore, FTAs are a means through which developed countries gain more concessions than those obtained under the WTO system[556] without giving anything in return. The consequence for developing and least-developed countries is that the higher intellectual property protections they agree to in these agreements deprive them of the right to use the policy spaces contained in the TRIPS Agreement. Any step to utilise TRIPS flexibilities would be considered a breach of the trade agreement and be met with threats of retaliation from

[550] Smith et al. (n 183) 687.
[551] ibid.
[552] Muria Kruger, 'Harmonizing TRIPS and the CBD: A Proposal from India' (2001) *Minnesota Journal of Global Trade* 175.
[553] ibid.
[554] Hamed El-Said and Mohammed El-Said, 'TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector' (2005) 2 *Manchester Journal of International Economic Law* 71.
[555] ibid.
[556] ibid.

developed countries.[557] Accordingly, TRIPS-plus provisions of FTAs undermine the use of TRIPS flexibilities by developing and least-developed countries to promote access to medicines.[558]

What are these TRIPS-plus provisions and in what manner do they impede the use of TRIPS flexibilities?

2.3.1. Provisions on data exclusivity

As previously noted, the TRIPS Agreement merely requires the protection of clinical data against 'unfair commercial use' – a term it left undefined. This affords WTO members the freedom to define the term to suit their circumstances. In effect, countries in need of access to low-cost drugs can exclude reliance on data previously generated by originator companies from acts that constitute 'unfair commercial use'. Conversely, countries seeking higher intellectual property standards can classify 'reliance' as unfair commercial use. In FTAs, developed countries impose this latter position on developing and least-developed countries through data exclusivity provisions so that for the period of protection of the clinical data generated by originator companies, national regulatory authorities will not allow generic companies to rely on those data to obtain approval for cheaper versions of drugs, even when they are off patent.[559] This can be explained by the fact that pharmaceutical companies perceive it as an unfair commercial use when generic companies rely on previously submitted clinical data to secure marketing authorisation.[560] As a consequence, generic companies are discouraged from introducing cheaper drugs after patent expiration because of the substantial cost involved in generating new clinical data.[561] However, if they decide to undertake the financial burden, the cost of generating clinical data will be reflected in the pricing of the generic drug.[562]

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[557] Arup (n 191) 9.
[558] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Armed TRIPS Provisions' (2007) 10 *Journal of International Economics & Law* 921, 962-963; see also Cynthia M Ho, 'A New World Order for Addressing Patent Rights and Public Health' (2007) 82 *Chicago-Kent Law Review* 1469, 1497-502.
[559] Smith et al. (n 183) 687.
[560] Priapantja (n 534); see also Correa, Protection of Data Submitted for the Registration of Pharmaceuticals (n534) 6-7.
[561] Ragavan (n 529) 133-136.
[562] ibid.

FTAs concluded by the US are notorious for including data exclusivity provisions. They prohibit generic competitors from relying on clinical data for five to 15 years following the first regulatory approval of new medicines.[563] A 2007 study disclosed that out of 103 drugs, which were not subject to patent, almost 80 per cent had no generic versions.[564] Generic producers attributed this lack of competition to the stringent data exclusivity provision contained in the US-Jordan FTA.[565] This provision is also responsible for the increased cost of pharmaceuticals and lack of access to medications in Jordan.[566] Thus, data exclusivity provisions enable pharmaceutical companies to extend their monopoly[567] and exploit profit by preventing competition.[568]

2.3.2. Provisions on patent linkage

Patent linkage refers to the system or process of establishing a relationship between an application for marketing approval of a generic drug and the patent status of the originator drug in order to prevent the regulatory authorities from granting approval for the generic version while the originator drug is protected by patent.[569] This means that without patent linkage provisions, the patent status of the originator drug is irrelevant to the process of obtaining marketing approval.[570] Under the TRIPS Agreement, regulatory authorities are not required to link drug approval to patents.[571] In fact, the provision on the protection of clinical data is the only TRIPS provision that addresses what a regulatory authority should

[563] Laura Chung, 'Use of Paragraph 6 System for Access to Medicine' (2010) 36 *North Carolina Journal of International Law & Commercial Regulation* 137.
[564] Rohit Malpani, 'All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the U.S. – Jordan FTA Affects Access to Medicines' (2007) *Oxfam International* 9.
[565] ibid 2.
[566] ibid.
[567] Susan K Sell, 'TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP' (2011) 18 *Journal of Intellectual Property Law* 447.
[568] Jerome H Reichman, 'Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective' (UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning 2004) 2 <http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf> accessed 30 November 2015; see also Chung (n 563) 180-82 (discussing FTAs with Chile, Jordan, and Morocco).
[569] Bryan Mercurio, 'Patent Linkage Regulations: The Importance of Context and of Balancing Competing Interests' in Mercurio and Kim (eds), *Contemporary Issues in Pharmaceutical Patent Law* (n 358) 98.
[570] Mercurio, 'Patent Linkage Regulations: The Importance of Context and of Balancing Competing Interests' (n 569) 98.
[571] Ho, Access to Medicine in the Global Economy (n 222) 120-21.

do.[572] However, TRIPS-plus provisions in FTAs require drug regulatory authorities to deny marketing approval to generic substitutes prior to patent expiration except with the consent of the rightsholder.[573] Thus, where this linkage provision exists in an FTA entered into by any developing or least-developed country, national regulatory authorities cannot approve, for example, patented drugs that have been produced under a compulsory licence, without the authorisation of the rightsholder to address a situation of national emergency or other circumstance of extreme urgency.[574] That compulsory licence would have been issued in futility.[575] This sort of provision is mostly included in US FTAs to prohibit generic competition.[576]

2.3.3. Provisions limiting the use of compulsory licences

As already mentioned, the Doha Declaration confirmed, as a flexibility in TRIPS, the right of WTO members to determine the grounds upon which to grant compulsory licences.[577] However, FTAs dispossess developing and least-developed countries of this right by limiting the grounds upon which they could invoke compulsory licences.[578] Notably, these provisions prohibit the grant of compulsory licences for export purposes, thereby sabotaging the waiver framework for supplying generic medicines to countries that lack manufacturing capacity.[579] More so, in the US-Vietnam (a developing country in transition) FTA, for example, parties are only permitted to grant compulsory licences in emergency situations, as an antitrust remedy, or for public non-commercial use.[580] Again, in the US-Singapore (a developing country) FTA, parties are required to pay 'reasonable and entire' remuneration to the patent holder as opposed to 'adequate

[572] ibid.
[573] Carlos M Correa, 'Implications of Bilateral Free Trade Agreement on Access to Medicines' (2006) 84(5) *Bulletin of World Health Organization* 399, 401-02.
[574] Frederick M Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' (2004) Quaker United Nations Office, Occasional Paper 14, 1,12; see also Médecins Sans Frontières, 'Access to Medicines at Risk Across the Globe: What to Watch Out for in Free Trade Agreements with the United States' (2004) Geneva: Médecins Sans Frontières.
[575] Médecins Sans Frontières, 'Access to Medicines at Risk Across the Globe' (n 574).
[576] Correa, 'Implications of Bilateral Free Trade Agreement on Access to Medicines' (n 573) 401-02.
[577] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001, para 5(b).
[578] Baird, 'Magic and Hope' (n 190) 124.
[579] Morgan (n 248) 97.
[580] Pedro Roffe and Christoph Spennemann, 'The Impacts of FTAs on Public Health Policies and TRIPS Flexibilities' (2006) 1(1/2) *International Journal of Intellectual Property Management* 75, 80.

remuneration' stipulated by TRIPS.[581] While the TRIPS Agreement allows members to provide for intellectual property protections that are higher than its minimum standard, the reality is that provisions of this nature constrict the use of TRIPS flexibilities to promote access to much needed medicines in developing and least-developed countries.[582]

2.3.4. Provisions precluding parallel importation

As earlier stated, the TRIPS Agreement allows each member state to adopt its exhaustion regime. This will enable countries access low-cost drugs through parallel importation once they have been placed in the market by the patent holder. However, FTAs provide patent holders with an exclusive right to bar parallel importation, thereby blocking the use of this all-important flexibility.[583] For example, each party is required in the US FTAs with Singapore and Morocco to grant patent holders exclusive rights to bar parallel importation; more so in cases where there are contractual restrictions on distribution.[584] Under Article 16(7)(2) of the US-Singapore FTA, each party is required to provide a cause of action to prevent or redress the procurement of patented pharmaceutical products in breach of a contract between the patent holder and a licencee, irrespective of whether such breach occurs within or beyond its territory.[585] This means that pharmaceutical companies can, through a contract, preclude the distribution via parallel imports of low-cost essential medicines.[586]

2.3.5. Provisions extending patent term

Under the TRIPS Agreement, the term of protection for a patent shall not end before the period of 20 years counted from the date of filing.[587] However, US FTAs for instance, require an extension of this term for pharmaceutical companies purportedly to account

[581] Baird, 'Magic and Hope' (n 190) 124.
[582] Roffe and Spennemann, 'The Impacts of FTAs on Public Health Policies and TRIPS Flexibilities' (n 580) 75.
[583] Ho, 'A New World Order for Addressing Patent Rights and Public Health' (n 558) 1501-02; see also Smith et al. (n 183) 687.
[584] Ho, 'A New World Order for Addressing Patent Rights and Public Health' (n 558) 1501-02; see also Ho, *Access to Medicine in the Global Economy* (n 222) 240-241.
[585] United States-Singapore Free Trade Agreement 2003, art 16(7)(2).
[586] Ho, Access to Medicine in the Global Economy (n 222) 240-241.
[587] TRIPS, art 33.

for delays in patent assessment and regulatory delays.[588] Added to this, these agreements do not stipulate a maximum time for the extension.[589] Consequently, patent term extension provisions prolong the period during which generic competition is excluded, thereby keeping affordable medicines out of the reach of the poor in developing and least-developed countries.[590]

Without doubt, the higher intellectual property protection demanded by these TRIPS-plus provisions in FTAs obliterates the possibility of using TRIPS flexibilities to enhance access to medicines.[591] This poses a critical concern for the future, as FTAs of this nature are bound to proliferate due to the economic and political motivations of countries that prompt the negotiation of these agreements. Supposing one were to argue that future FTAs would not insist on higher intellectual property standards, having realised their implications for public health, the reality is that existing agreements already demand higher standards and these continue to fuel the problem of access to medicines.[592] Besides, such argument would be unsustainable in light of the intellectual property standards contained in new FTAs, such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) (formerly the Trans-Pacific Partnership Agreement), as will be discussed shortly. Despite these, the UN Sustainable Development Agenda 2030 and the High-Level Panel hinged the realisation of the health-related goal on the utilisation of TRIPS flexibilities by developing and least-developed countries to promote universal health coverage and access to affordable medicines.[593]

As previously mentioned, the Agenda and the High-Level Panel further recommended the negotiation of a binding drug R&D Convention that would delink the costs of R&D from the end prices of medicines, and redirect R&D to pressing public health needs, such

[588] Correa, 'Implications of Bilateral Free Trade Agreement on Access to Medicines' (n 573) 400; see also Smith et al. (n 183) 687; and Baird, 'Magic and Hope' (n 190) 122.
[589] ibid.
[590] Smith et al. (n 183) 687.
[591] Sell, 'TRIPS Was Never Enough' (n 567) 454.
[592] Ho, Access to Medicine in the Global Economy (n 222).
[593] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3); see also High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7).

as neglected tropical diseases and antimicrobial resistance.[594] The principle of delinkage is based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided, but not through the price of products.[595] This would mean, for example, creating prize funds for the development of medicines, thereby providing an incentive for R&D without allowing a monopoly on the sales of the product.[596] An instance is the US$80 billion proposed by the US senator, Bernard Sanders, for the development of new but low priced treatments for cancer and HIV.[597] Thus, the notion of delinkage 'is not about taking money away from drug development…[but] making sure needed [R&D] takes place and the results…are available to all'.[598] Nevertheless, can these strategies be trusted to promote universal health coverage and deliver timely access to medicines in developing and least-developed countries to eradicate malaria, tuberculosis, and HIV/AIDS by 2030?

2.4. The Reinforcement of TRIPS Flexibilities to Promote Universal Health Coverage and Access to Medicines

While the calls for the greater use of TRIPS flexibilities by developing and least-developed countries to promote universal health coverage and access to affordable medicines may appear good in theory, in practice the feasibility is marred by economic and political realities. Any developing or least-developed country can adopt higher protection for intellectual property rights without a positive obligation to do so.[599] The inducement is usually the possibility of attracting foreign investment or political or other support from developed countries.[600] Such adoption would normally be encouraged by the science, technology and trade industries, and through technical assistance provided by the World Intellectual Property Organization (WIPO) – one amongst 17 specialised

[594] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7); see also FXB Centre for Health and Human Rights (n 133).
[595] World Health Organization, World Intellectual Property Organization and World Trade Organization, *Promoting Access to Medical Technologies and Innovations* (n 179).
[596] Ellen 't Hoen, 'UN High-Level Panel on Access to Medicines Calls for Stronger Public Leadership in Innovation and Access to Medicines' (*Medicines Law & Policy*, 15 September 2016) <https://medicineslawandpolicy.org/2016/09/un-high-level-panel-on-access-to-medicines-calls-for-stronger-public-leadership-in-innovation-and-access-to-medicines/> accessed 14 July 2017.
[597] ibid.
[598] ibid.
[599] Smith et al. (n 183) 688.
[600] Assafa Endeshaw, 'Asian Perspectives on Post-TRIPS Issues in Intellectual Property' (2005) 8 *Journal of World Intellectual Property* 211-12; see also Smith et al. (n 183) 688.

agencies of the UN created in 1967 to encourage creative activity and to promote the protection of intellectual property throughout the world[601] with a membership of 191 states[602] – and patent offices in jurisdictions such as the US, Australia and Europe.[603] A clear example is the influence of the European Patent Office (EPO) on the policies of Chinese and Vietnamese patent offices in granting patent for second indications.[604] This suggests that developing and least-developed countries are, in many cases, not compelled by FTAs to provide increased intellectual property protection. Mindful of this, the issue is not as simple as encouraging developing and least-developed countries to vehemently refuse TRIPS-plus provisions when negotiating FTAs or remove TRIPS-plus languages where they exist in order to use TRIPS flexibilities to promote access to medicines, as often advocated by commentators.[605] In actuality, developing and least-developed countries can voluntarily adopt higher intellectual property protection for economic or political gains.

Furthermore, the High-Level Panel urged developing and least-developed countries in its report to make a complaint to the WTO Secretariat during Trade Policy Review of member states regarding instances of threats and undue pressure from developed countries or the private sector, that occur when they seek to use the TRIPS flexibilities, and that such acts should be met with punitive measures.[606] However, the WTO may not be inclined to discourage higher intellectual property standards, and quite understandably so, since its TRIPS Agreement merely sets a minimum standard of intellectual property protection, thereby allowing member states to adopt higher standards. As a matter of fact, a country wishing to become a member of WTO is expected to adopt TRIPS-plus provisions either as part of its commitments or as part of the demands imposed during negotiation.[607] This is aimed at satisfying existing members so that any of them can veto the country's application.[608] For these reasons, China and Jordan, for instance, committed

[601] Convention Establishing the World Intellectual Property Organization (Stockholm: 14 July 1967, as amended on 28 September 1979), 2nd preambular citation.
[602] 'Member States' (*WIPO*) <http://www.wipo.int/members/en/> accessed 18 March 2018.
[603] Smith et al. (n 183) 688.
[604] Nguyen Dzung, 'Vietnam Patent Law: Substantive Law Provisions and Existing Uncertainties' (2007) 6 *Chicago-Kent Journal of Intellectual Property* 138-56; see also Smith et al. (n 183) 688.
[605] Correa and Matthews, 'The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health' (n 184) 114.
[606] FXB Centre for Health and Human Rights (n 133).
[607] Smith et al. (n 183) 688.
[608] ibid.

to protecting clinical data under exclusive rights for a period of six years, while Cambodia and Saudi Arabia agreed to five years' exclusive protection for clinical data and to link drug approval to patents.[609] Moreover, one of the influential members of the WTO, the US, is well-known for coercing developing and least-developed countries to adopt stronger intellectual property rights through threats of trade sanctions using its Section 301 law, yet the WTO has not been known to oppose this approach except to state that the use of Section 301 must strictly follow WTO rules.[610]

Under section 301 of the US Trade Act of 1974 (as amended), the Office of the United States' Trade Representative (USTR) is mandated to prepare an annual report identifying trade barriers to American companies and persons due to intellectual property laws of other countries.[611] This report identifies countries that do not provide 'adequate and effective' protection of intellectual property rights or 'fair and equitable market access to [American] persons that rely upon intellectual property rights'.[612] Countries found to have inadequate intellectual property protections are subjected to sanctions. The report also contains a 'Priority Watch List' to monitor countries whose intellectual property regimes are deemed of concern.[613] The fear of the special 301 Section of the US Trade Act has resulted in countries adopting TRIPS-plus provisions. Australia, for instance, adopted data exclusivity as a result of a complaint by the US.[614] China is on the 301-priority watch list because it narrows the scope of what is patentable to exclude methods of treatment and diagnosis.[615] Interestingly, China is not obligated to protect such information under the TRIPS Agreement.[616]

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[609] F Abbott and C Correa, 'World Trade Organization Accession Agreements: Intellectual Property Issues' (2007) Geneva: QUNO <http://www.quno.org/geneva/pdf/economic/issues/WTO-IP-English.pdf> accessed 15 August 2015.
[610] Delegation of the European Commission to the United States, 'WTO Report on US Section 301Law: A Good Result for the European Union and the Multilateral System' (1999) Brussels: Press Release No 86/89 (IP/99/1051) <http://trade.ec.europa.eu/doclib/docs/2003/november/tradoc_114823.pdf> accessed 4 April 2018.
[611] Shayera Ilias Akhtar and Ian F Fergusson, *Intellectual Property Rights and International Trade* (Createspace Independent Pub 2014).
[612] ibid.
[613] ibid.
[614] Priapantja (n 534); see also Smith et al. (n 183) 688.
[615] USTR, 'Special 301 Report' (2007) Washington DC: Office of the United States Trade Representative <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf> accessed 16 August 2015.
[616] ibid.

India presents a special case: in 2016, the US Chamber of Commerce, in a document filed with the US Trade Representative, stated that the Indian government had 'privately' reassured the pharmaceutical industry that it would not issue compulsory licences for commercial purposes.[617] The industry had long been concerned about the laws and court decisions in India that permitted generic competitors to market generic versions of their medicines.[618] Actually, India has been the world's tourist centre for generic drugs, as many generic manufacturers are based in India.[619] However, this appears to be changing. Consumer groups have argued that the pharmaceutical industry, with the support of the US government, is pressurising India to tighten its patent law over the fear of competition.[620]

Stronger evidence that confirms that an agreement was reached between the Indian government and the pharmaceutical industry has emerged. In April 2016, two Indian generic drug companies, BDR Pharmaceuticals and Lee Pharma, announced their withdrawal from the pursuit of compulsory licences that would have allowed the production and marketing of low-cost versions of drugs made by Bristol-Myers Squibb (a US pharmaceutical company) and AstraZeneca (an Anglo-Swedish pharmaceutical company).[621] For a long time, these generic companies had appealed against the rejection of the licence applications by the Indian government. Lee Pharma applied to sell a version of the Onglyza diabetes medicine made by AstraZeneca, while BDR sought to sell a version of the Sprycel cancer medicine from Bristol-Myers Squibb.[622] The generic companies claimed that the government succumbed to the pressure from the industry because it desired to boost FDI.[623] More, the US Trade Representative had regularly placed India on its priority watch list for countries that failed to adequately protect and enforce patent rights.[624] This was because the industry believed the Indian government to be lenient towards protecting and enforcing intellectual property rights in order to favour

[617] Ed Silverman, 'India Agrees to Restrict Generic Drug Licenses, Business Group Say' (*STAT,* 9 March 2016).
[618] ibid.
[619] ibid.
[620] ibid.
[621] Ed Silverman, 'Two Drug Makers Complain India is Thwarting Licenses for Selling Generics' (*STAT,* 13 April 2016).
[622] ibid.
[623] ibid.
[624] ibid.

its domestic drug makers that sell generics.[625] Particularly, they had remained unhappy about a court decision in 2013 rejecting a patent for the Gleevec cancer medicine sold by Novartis.[626] Thus, these circumstances caused the Indian government to finally accede to pressure.

However, there was a view that the rejection of the licence applications did not mean that the Indian government had succumbed to enforcing stronger intellectual property policies. The view was that the companies did not meet the requirements for the grant of a compulsory licence under Indian Patent Law.[627] In particular, Lee Pharma failed to convince the patent officials that the AstraZeneca drug or others like it, for example, were not meeting patients' needs.[628] Added to this, there were similar drugs already in the market, including a generic version sold at a lower price at the time the companies applied for the licences.[629] Thus, the patent office determined that they had not made a good case for the grant of a compulsory licence.[630] However, this view pales into insignificance in light of the recent grant of the application for a patent on sofosbuvir, Gilead's hepatitis C drug, by the Indian patent office, in spite of the pre-grant oppositions and public protest against the application. Initially, the patent office rejected the application in January of 2015 on the grounds that Gilead failed to demonstrate that the drug was new and involved an inventive step sufficient to grant the application.[631] In order not to lose the market, Gilead granted licences to 11 generic manufacturers in India to make the drug available at a lower price (US$335 per 12-week treatment).[632] This was a shrewd strategy because these licences had the effect of preventing legitimate competition from generic manufacturers who could produce and offer the drug[633] at an even lower price.

Meanwhile, the US Trade Representative in April 2016 placed India on its annual priority watch list of countries it singled out for enforcing intellectual property rights

[625] ibid.
[626] Silverman, 'Two Drug Makers Complain India is Thwarting Licenses for Selling Generics' (n 621).
[627] ibid.
[628] ibid.
[629] ibid.
[630] ibid.
[631] Marko, 'India Grants Patent for Sovaldi – Is the Indian Hepatitis C Tourism Over?' (*FixHepC,* 11 May 2016) <https://fixhepc.com/blog/item/69-india-grants-patent-sovaldi.html> accessed 4 June 2016.
[632] ibid; see also Médecins Sans Frontières, 'Access: Patent Challenge Hearing on Gilead Hepatitis C Drug Sofosbuvir Starts in India' (n 251).
[633] Chatterjee, 'Gilead Sovaldi Case Reveals Patent-Health Fissures in India' (n 297).

unfavourable to US companies.[634] At this time, many patient groups perceived this as an effort by the US government to pressure India to change its approach to patent law.[635] This perception was substantiated when on 9 May 2016, the Indian patent office in 'direct contradiction' to its previous decision, granted Gilead a patent for sofosbuvir.[636] The patent office justified this decision on the basis that the claimed compounds met the patentability requirements under the Indian Patent Law.[637] Leena Menghaney, head of South Asia MSF, noted that there had been extreme pressure on the Indian government to interfere with the independence of the patent office to ensure that patents are granted easily to US companies.[638] She stated that this explained why the patent office disregarded proceedings against Gilead in the US in which the same application was found to infringe two of Merck's patents, thereby defeating Gilead's claim that the drug was novel.[639] Also, the Co-Founder and Director of I-MAK explained that the patent office had dealt with excessive external influences, particularly since the initial decision of 2013 rejecting the patent application.[640] He reasoned that the decision was not based on law and consisted of many discrepancies, and the organisation was inclined to appeal the decision.[641]

Besides India, Colombia is another developing country whose experience demonstrates the degree of pressure applied by the US on developing and least-developed countries to enforce higher intellectual property standards. In February 2016, the US government offered to assist Colombia with over US$450 million to support the peace initiatives with the Marxist rebels, against whom it waged a long-running battle.[642] This initiative was called 'Paz Colombia'.[643] In April 2016, a Colombian Embassy official in the US notified

[634] Ed Silverman, 'Gilead Gets a Big Win as India Upholds a Sovaldi Patent, After All' (*STAT,* 10 May 2016) <https://www.statnews.com/pharmalot/2016/05/10/gilead-hepatitis-patents-drug-pricing/> accessed 4 June 2016.
[635] Silverman, 'Gilead Gets a Big Win as India Upholds a Sovaldi Patent, After All' (n 634).
[636] Marko (n 631).
[637] ibid.
[638] ibid.
[639] ibid.
[640] ibid; see also Vidya Krishnan, 'Gilead Gets Patent for Hepatitis C Drug Sovaldi' *The Hindu* (10 May 2016) <http://www.thehindu.com/news/national/gilead-gets-patent-for-hepatitis-c-drug-solvadi/article8577060.ece> accessed 4 June 2016.
[641] Marko (n 631).
[642] Ed Silverman, 'US Pressure Colombia Over Plan to Sidestep Patent for A Novartis Drug' (*STAT,* 11 May 2016).
[643] ibid.

his government that the support of the US for the peace initiative might suffer if the Colombian health minister proceeded with plans to grant a compulsory licence for a Novartis drug.[644] Prior to this, the health minister had stated that he might issue a compulsory licence to enable a generic company make a low-cost version of the Gleevec leukaemia treatment.[645] This action would have saved Colombia about US$12 million annually.[646] This plan infuriated Novartis, which as explained by the Colombian official, had a direct link to prominent members of the US Congress.[647] The official stated that the situation was prone to escalate to the point that it could undermine the approval of the financing of the new initiative.[648] More so, the damage could extend to the free trade treaty between the two countries, in which Colombia was obligated to comply with various international trade laws.[649] Added to this, the health minister's plan might weaken support for bringing Colombia into the CPTPP, which was subject to Congress' approval.[650] These views parallel the situation described earlier where countries wishing to become part of the WTO adopt higher intellectual property standards as part of their commitments in order to attract the veto of existing members.

In this case, Colombia wished to become a member of the CPTPP, and this was subject to the approval of the US Congress. Thus, the official considered it in Colombia's interest not to utilise TRIPS' compulsory licence flexibility to make low-cost leukaemia treatment available to its population. This illustrates how the prospects of economic or political benefits from a developed country can entice any developing or least-developed country to adopt stringent intellectual property rights. It is equally important to point out that Colombia was on the US Trade Representative's watch list of countries that failed to 'sufficiently' enforce intellectual property rights.[651] However, Colombia seemed unperturbed by the impending consequence of sidestepping Novartis' patent. The Colombian Health Minister, Alejandro Gaviria, expressed the intention to unilaterally reduce the price that government would pay for the medicine, having failed to reach an

[644] ibid.
[645] Silverman, 'US Pressure Colombia Over Plan to Sidestep Patent for A Novartis Drug' (n 642).
[646] ibid.
[647] ibid.
[648] ibid.
[649] ibid.
[650] ibid.
[651] ibid.

agreement with Novartis.[652] This was amidst heavy criticism from the pharmaceutical industry.[653] Reacting to Colombia's situation, an advocacy group expressed the view that it was disgraceful to link actions targeted at a country's health needs, to a promise to support a process of peace and reconciliation in a country that had faced horrendous violence.[654] Yet the US planned to do this.[655]

The US government's disposition towards patent protection and enforcement can be described in no better way than 'hypocritical'. The case of the anthrax scare and Bayer's patent on Cipro gives weight to this claim. Shortly after the tragedy of the terrorist attacks of 11 September 2001 on the US, letters containing anthrax were sent to significant US personalities.[656] At the time, Bayer produced the only medication approved in the US for treating anthrax, which was the Cipro antibiotic.[657] As expected, there was an instant increase in the demand for the drug as people in the US prepared for major biological terror attacks. The US government wanted to purchase a quantity to cover 12 million people for 60 days.[658] In spite of Bayer's increase in production, the demand outweighed the supply.[659] Ironically, Cipla – an Indian generic manufacturer that had been producing the generic version of the drug, and marketed it for a fraction of the cost of the brand name drug – volunteered to supply the US with Cipro, even though it was under patent protection.[660] Initially, the US government appeared to want to continue clutching at its pro-patent position because Bayer had announced that it would triple Cipro production to 200 million tablets over three months.[661]

[652] Covarrubia, 'Compulsory License and Parallel Import' (n 272); see also Ed Silverman, 'Colombia Plans to Proceed with Price Cut on Novartis Cancer Drug' (*STAT*, 16 September 2016).
[653] ibid.
[654] This view was expressed by Andrew Goldman – the legal affairs and policy counsel at Knowledge Ecology International – see Silverman, 'Colombia Plans to Proceed with Price Cut on Novartis Cancer Drug' (n 652).
[655] Silverman, 'Colombia Plans to Proceed with Price Cut on Novartis Cancer Drug' (n 652).
[656] Hestermeyer (n 250) 14.
[657] ibid.
[658] ibid.
[659] ibid.
[660] V Shridhar, 'Perilous Patent' *Frontline* (24 November 2001); see also Hestermeyer (n 250) 14.
[661] M Fleischer-Black, 'The Cipro Dilemma – In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?' *The American Lawyer* (January 2002); see also S Vedantam and T Chea, 'Drug Firm Plays Defense in Anthrax Scare' *Washington Post* (20 October 2001); and Hestermeyer (n 250) 14.

However, the US government's posture changed when it learnt that Canada intended purchasing a generic version of Cipro that was half the price Bayer would have charged.[662] When Bayer threatened legal action, the US and Canada agreed to respect the patent on the condition that Bayer would deliver the medicine at US$1.30 as against its usual government price of US$1.83.[663] Despite this agreement, the US government threatened to purchase a generic version of Cipro if Bayer failed to make a further price concession.[664] It went as far as backing the threat with an Executive Order authorising the Department of Health to contract with a competitor to purchase Cipro.[665] Bayer, left with no choice, agreed to supply 100 million tablets of Cipro for US$0.95.[666] Added to this, the US was also able to secure an additional 200 million tablets.[667] The point being made is that the US government was willing to disregard Bayer's patent on Cipro and encourage the production of a generic version to meet the health needs of its population, whereas it adopts various coercive tactics to deter other countries from using TRIPS flexibilities to meet their public health demands, as demonstrated by the examples discussed.

Further impairing the practicality of the use of TRIPS flexibilities to promote universal health coverage and timely access to affordable medicines is the growing number of trade agreements that enshrine TRIP-plus provisions. For instance, the CPTPP Agreement was signed on 4 February 2016 after seven years of secret negotiations, without the opportunity for public review.[668] This is a trade agreement that was originally negotiated between the US and 11 other Pacific Rim countries, namely: Australia, Brunei

[662] Fleischer-Black (n 661).
[663] Hestermeyer (n 250) 14.
[664] Hestermeyer (n 250) 14; see also S Vedantam and DL Brown, 'US Seeks Price Cut from Cipro Maker' *Washington Post* (24 October 2001); and K Bradsher and El Andrews, 'US Says Bayer Will Cut Cost of its Anthrax Drug' *NY Times* (24 October 2001).
[665] Hestermeyer (n 250) 14; see also The White House, 'Executive Order No 13232, Further Amendment to Executive Order 10789, as Amended, To Authorize the Department of Health and Human Services to Exercise Certain Contracting Authority in Connection with National Defense Functions' (2001) 66 FR 53941.
[666] Hestermeyer (n 250) 14.
[667] ibid; see also Dominic White, 'Bayer to Agree Cipro Deal with Anxious US' *The Telegraph* (25 October 2001) <https://www.telegraph.co.uk/finance/2739021/Bayer-to-agree-Cipro-deal-with-anxious-US.html> accessed 5 December 2015; and Department of Health and Human Services (HHS), 'Bayer Agree to Cipro Purchase' (24 October 2001) <http://avalon.law.yale.edu/sept11/hhs_013.asp> accessed 5 December 2015.
[668] Ian F Fergusson and Brock R Williams, 'The Trans-Pacific Partnership (TPP): Key Provisions and Issues for Congress' (2016) (CRS Report R44489) Washington, DC: Congressional Research Service; see also George H Pike, 'Trans-Pacific Partnership: The Devil in the Details' 33(1) *Information Today* (January/February 2016) <http://www.infotoday.com/IT/jan16/Pike--Trans-Pacific-Partnership--The-Devil-in-the-Details.shtml> accessed 4 June 2016.

Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.[669] However, the US withdrew from this Agreement on 23 January 2017 based on the apprehension that the CPTPP would be unfavourable to the US manufacturing industry.[670] In spite of this, other parties, led by Japan, agreed to proceed with the Agreement without the US.[671] The CPTPP has been described as a model agreement not just for countries in the Asia-Pacific region, but the world over as its parties aim to access one another's ports with little or no tariffs or other restrictions by 2030.[672] Contrary to this view, many have expressed the fear that the agreement contains 'dangerous provisions' that would negatively impact on public health safeguards enshrined in international law and restrict access to low-cost generic medicines for millions of people.[673] This is because while it was a party to the Agreement, the US pushed policies in the CPTPP that impose aggressive intellectual property standards that favour commercial interests and prejudice public health.[674]

For example, the CPTPP provides for lower patentability standards, thereby creating new patent monopolies for existing medicines. It requires parties 'to grant secondary patents' on modifications of existing medicines for at least one of the following: new uses, methods of use or new processes of a known product.[675] This provision aims to prevent parties from using public health safeguards such as the TRIPS flexibilities, in their national patent laws and judicial decisions that limit patent evergreening.[676] In effect, this provision would keep prices high by delaying the entrance of cheap generic drugs into the market. Again, the CPTPP contains provisions on patent term extension. The

[669] Médicins Sans Frontières (MSF) Access Campaign, 'Trans-Pacific Partnership Agreement' (*MSF*, January 2016) <http://www.msfaccess.org/spotlight-on/trans-pacific-partnership-agreement> accessed 4 June 2016.
[670] Adam Davidson, 'What the Death of the T.P.P. Means for America' *The New Yorker* (23 January 2017) <http://www.newyorker.com/business/adam-davidson/what-the-death-of-the-t-p-p-means-for-america> accessed 21 July 2017.
[671] Sri Jegarajah, Craig Dale and Leslie Shaffer, 'TPP Nations Agree to Pursue Trade Deal Without the US' *CNBC* (20 May 2017) <https://www.cnbc.com/2017/05/20/tpp-nations-agree-to-pursue-trade-deal-without-us.html> accessed 20 August 2017.
[672] Médicins Sans Frontières (MSF) Access Campaign, 'Trans-Pacific Partnership Agreement' (n 669); see also Davidson (n 670).
[673] Médicins Sans Frontières (MSF) Access Campaign, 'Trans-Pacific Partnership Agreement' (n 669).
[674] ibid.
[675] Text of the Trans-Pacific Partnership Agreement, art 18.37(2) <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text accessed> 4 June 2016.
[676] MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (*MSF*, 4 February 2016) <http://www.msfaccess.org/content/msf-open-letter-asean-governments-dont-trade-away-health> accessed 4 June 2016.

Agreement enjoins parties to extend the patent term to compensate for unreasonable delays caused by the length of time spent on obtaining marketing approvals for pharmaceuticals.[677] Currently, patents on drugs in most countries last for 20 years from the date of filing. This required adjustment to the usual patent term would allow the patent holder to maintain monopoly without competition and continue to charge high prices for the drug.[678] Also, this trade agreement provides for data exclusivity. It prevents regulatory authorities from approving any generic or biosimilar drug formulation that relies on already generated clinical data during the period of exclusivity.[679] The CPTPP requires parties to protect clinical data with a period of market exclusivity for at least five years for small molecules and at least three years for modifications to existing drugs, or five years for combinations.[680] This provision encourages abusive data evergreening.[681]

There is a novel provision on data protection in the CPTPP: the Agreement prescribes data protection obligations for biologics. Biologics refer to 'any virus, therapeutic serum, toxin, antitoxin, hormone or protein, including monoclonal antibodies or similar products used to diagnose, prevent, treat or cure a disease or condition'.[682] The protection required is eight years for market exclusivity or five years with other measures that provide a comparable outcome.[683] In practice, these provisions offer separate protection to pharmaceuticals even after the expiration of the normal patent term.[684] Consequently, medicines remain costly and competition to challenge such prices is delayed. Also noteworthy is the fact that the CPTPP requires new forms of intellectual property enforcement. It grants customs' officials new powers to detain medicines and provides for mandatory injunctions for alleged intellectual property infringements, as well as increases damages payable.[685] This trade agreement contains an array of obligations that could increase unjustified interruptions and delays in legitimate trade in generic medicines, and restrict the functions of countries' judicial systems of balancing

[677] TTP Agreement, art 18.48; see also art 18.46.
[678] MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (n 676).
[679] TPP Agreement, arts 18.46, 18.48.
[680] TPP Agreement, arts 18.46, 18.48; see also MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (n 676).
[681] MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (n 676).
[682] High-Level Panel on Access to Health Technologies, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (n 7) 5.
[683] MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (n 676).
[684] ibid.
[685] ibid.

commercial and public health interests in disputes regarding intellectual property.[686] By implication, countries are denied the right to define their own enforcement provisions as guaranteed by international law.[687]

For pharmaceutical companies, these stronger intellectual property rights guaranteed by the CPTPP mean extended monopolies and delayed generic competition.[688] In contrast, the TRIPS-plus provisions translate into higher prices for patients who need medicines in developing and least-developed countries where health insurance schemes do not exist, and patients are expected to pay for medicines out-of-pocket.[689] Indeed, some countries would be inclined to ratify this agreement perhaps due to the prospects of boosting exports and economic growth.[690] For instance, China and the Philippines have indicated interest in joining.[691] Also, efforts are being made to encourage other countries to join the CPTPP, but without these countries afforded the opportunity to make any input to the Agreement.[692] Remarkably, the consequences of the CPTPP will have a ripple effect: they will not only affect developing and least-developed countries but also some of the developed ones.[693] Canada, for example, will also face extended patent provisions and increased cost of medicines.[694] Moreover, the CPTPP is more likely to give pharmaceutical companies leverage over governments of both developed and developing/least-developed countries, as shown by the US$500 million lawsuit instituted by Eli Lilly against the Canadian government for the rejection of two drug patents and for allowing competitors to enter the market.[695] This should not be the case; '[a]ccess to medicine cannot be reduced to simple economics'.[696] For every calculation of demand and supply of drugs, there is a life attached.[697] As a result, a patient pays the ultimate

[686] ibid.
[687] ibid.
[688] Médicins Sans Frontières (MSF) Access Campaign, 'Trans-Pacific Partnership Agreement' (n 669).
[689] Médicins Sans Frontières (MSF) Access Campaign, 'Trans-Pacific Partnership Agreement' (n 669).
[690] Kimberly Amadeo, 'Trans-Pacific Partnership Summary, Pros and Cons' (*the balance*, 14 June 2017) <https://www.thebalance.com/what-is-the-trans-pacific-partnership-3305581> accessed 17 June 2017.
[691] ibid.
[692] MSF, 'Open Letter to ASEAN Governments: Don't Trade Away Health' (n 676).
[693] Heather Culbert, 'Why the TPP Trade Deal is a Threat to Public Health' *The Globe and Mail* (17 July 2015) <http://www.theglobeandmail.com/opinion/why-the-tpp-trade-deal-is-a-threat-to-public-health/article25548162/> accessed 4 June 2016 – Heather Culbert is the President of Médicins Sans Frontières (MSF) Canada.
[694] ibid.
[695] ibid.
[696] ibid.
[697] ibid.

price for any vaccine not administered or any antiretroviral that is costly.[698] The current situation is that many people in developing and least-developed countries lack access to lifesaving medication, and trade agreements of this kind play a major role in bringing about this situation.[699]

2.5. The Problem with Negotiating a Convention on Drug Research and Development for Realising Sustainable Development by 2030

Having established that the full use of TRIPS flexibilities is marred by economic and political realities, would negotiating a binding convention aimed at delinking the costs of drug R&D from end product prices and redirecting R&D to pressing public health needs promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030? Probably, if it is at all feasible to conclude a binding convention in time to realise the sustainable development target of eradicating malaria, tuberculosis, HIV/AIDS and other communicable and noncommunicable diseases by 2030. This pessimism is grounded on the fact that besides the bureaucracy associated with international law negotiations, they are usually complex and long-winded.[700] In part, this can be imputed to the presence of multiple stakeholders with divergent, and in many instances, conflicting interests, which ultimately affect not only the timely and successful completion of such negotiations, but also the workability of the end product. For example, the negotiation of the international regime, the Nagoya Protocol 2010, to implement the access and benefit-sharing provisions of the Convention on Biological Diversity 1992 – a multilateral treaty directed at the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources[701] – was a complex and prolonged process that lasted almost 10 years.[702]

Because the world's biological diversity (biodiversity) was rapidly diminishing, particularly as a result of overexploitation by human beings, efforts to conserve living

[698] ibid.
[699] ibid.
[700] Paul Meerts, 'Challenges to Diplomatic Negotiations' (2015) PIN Policy Brief 3.
[701] Convention on Biological Diversity 1992, art 1.
[702] Ryo Kohsaka, 'The Negotiating History of the Nagoya Protocol on ABS: Perspective from Japan' (2012) 9(1) *IPAJ* 56-66, 56.

resources and to use its genetic components in a sustainable manner became important.[703] For this to be achieved, there was an urgent need to develop an international regime that would establish more predictable conditions for access to genetic resources; and importantly, to ensure benefit-sharing with developing and least-developed countries and the indigenous and local communities within their territories that provide the genetic resources, thereby creating incentives to conserve and sustainably use biodiversity.[704] As will be seen in Chapter four, since traditional medicine is derived from the use of plants, animals and their genetic components, the threat of loss of biodiversity could affect access to it. This is why the Convention on Biological Diversity 1992 and its Nagoya Protocol 2010 are relevant for ensuring that traditional medicines are available and accessible for health care: they demand the conservation and sustainable use of biodiversity, and the preservation of the traditional knowledge implicated in its use, as well as the sharing of benefits derived from such utilisation with the knowledge and resource holders. This is further assessed in Chapter six.

The complex and protracted turn that the Nagoya negotiations took has been attributed to two main reasons: first, the proliferation of international instruments and fora related to genetic resources since the Convention on Biological Diversity 1992 came into force in 1993 complicated negotiations.[705] According to Drahos and Tansey in 2008, '…there are more international fora than ever before to negotiate food, biodiversity and intellectual property rights…and there are more actors, coalitions and networks participating and exercising some kind of influence in those negotiations…'[706] These international instruments include the TRIPS Agreement, the Antarctic Treaty System, the International Treaty on Plant Genetic Resources for Food and Agriculture 2001 (Plant Genetic Resources Treaty 2001), the United Nations Law of the Sea Convention (LOSC) 1982,

[703] H E Mr Joseph Deiss, 'Statement at the Opening of the High-Level Meeting of the General Assembly as a Contribution to the International Year of Biodiversity' (*General Assembly of the United Nations President of the 65th Session*, 22 September 2010) <http://www.un.org/en/ga/president/65/statements/biodiversity220910.shtml> accessed 3 December 2017.
[704] 'About the Nagoya Protocol' (*Convention on Biological Diversity*) <https://www.cbd.int/abs/about/default.shtml> accessed 3 December 2017.
[705] Achmad Gusman Siswandi, 'The Nagoya Protocol: Unfinished Business Remains Unfinished' in Matthew Rimmer (ed), *Indigenous Intellectual Property: A Handbook of Contemporary Research* (Edward Elgar Publishing 2015) 334-364, 342.
[706] Peter Drahos and Geoff Tansey, 'Postcards from International Negotiations' in Geoff Tansey and Tasmin Rajotte (eds), *The Future Control of Food* (London: Earthscan 2008) 197-211, 197, 199.

and the International Convention for the Protection of New Varieties of Plants, while the fora include the WTO, WHO, WIPO, the Commission on Genetic Resources for Food and Agriculture, and the Food and Agriculture Organization. The point is that the interaction between these instruments and fora on one hand and the negotiations of the Nagoya Protocol, on the other hand, gave rise to some contentious issues that needed to be addressed, but which at various points resulted in a meltdown in negotiations.[707]

A typical example is the relationship between the TRIPS Agreement 1994 and the WTO, and the Nagoya Protocol 2010. Successful negotiations were constantly impeded because of debates concerning whether the Protocol should include provisions requiring inventors to disclose all information relating to genetic resources and associated traditional knowledge used in their inventions when applying for patent protection provided by the TRIPS Agreement.[708] While developing countries and their indigenous peoples that house the majority of the world's biodiversity pushed for the disclosure requirement to be included in the final draft of the Nagoya Protocol 2010, the biotechnology and pharmaceutical industries, supported by developed countries, vehemently opposed this inclusion.[709] Because they relied heavily on genetic resources for developing their commercial products, the biotechnology and pharmaceutical industries feared that disclosure of the use of genetic resources and associated traditional knowledge would hinder their chances of securing patent protection.[710] This conflict of interest between stakeholders was the second reason for the complications in the Nagoya negotiations.

There were competing interests between multiple stakeholders in the field of genetic resources and associated traditional knowledge utilisation: each stakeholder sought to protect its interest through the provisions of the Nagoya Protocol 2010, and this engendered difficulty in reaching compromises at times.[711] These competing stakeholders included: the developing countries; the indigenous and local communities; NGOs; developed countries; the biotechnology and pharmaceutical industries; and researchers. For the developing countries, the objective was to stop 'biopiracy' (appropriation of

[707] Siswandi (n 705) 343.
[708] Siswandi (n 705) 343.
[709] ibid 349.
[710] ibid.
[711] ibid.

genetic materials and associated traditional knowledge without compensation to the community from which they originate) by asserting their sovereign rights over genetic resources in accordance with the Convention on Biological Diversity 1992 and demanding to share in benefits arising out of their commercial exploitation.[712] The indigenous and local communities principally pushed for stronger recognition of their rights, particularly with regard to traditional knowledge associated with genetic resources.[713] This group suspected that if the Protocol failed to meet 'internationally accepted rights of indigenous people', it would 'facilitate the misappropriation of genetic resources from indigenous lands and territories, and alienate the traditional knowledge implicated in benefit sharing schemes'.[714] In the case of NGOs, an international regime that provided strong compliance measures that would not permit biopiracy by developed countries, and ensured restitution for wrongs done to developing and least-developed countries, indigenous peoples and local communities were their main targets.[715]

The developed countries (especially the industrialised ones, who were firmly criticised as the major obstruction to the adoption process of the Nagoya Protocol 2010), were intent on ensuring that any legal measures taken would not jeopardise their biotechnology and pharmaceutical sectors, which are of immense value to their economies.[716] On their part, the biotechnology and pharmaceutical industries (who depended heavily on the use of genetic resources for R&D of commercial products, and whose interests have been supported by the developed countries) were keen to ensure that their patent rights were not constrained by requirements of disclosure.[717] Lastly, researchers sought to ensure that the Nagoya Protocol 2010 would not impede their ability to use genetic materials in the field of basic research.[718] Finally, even though negotiations finally concluded, this clash

[712] ibid; see also Merle Alexander, 'Inside Views: A Rights-Poor Protocol for Biodiversity Access and Benefit-Sharing' (*Intellectual Property Watch*, 8 October 2010) <https://www.ip-watch.org/2010/10/08/inside-views-a-rights-poor-protocol-for-biodiversity-access-benefit-sharing/> accessed 4 December 2017; and Convention on Biological Diversity 1992, art 3.
[713] Siswandi (n 705) 351.
[714] Japan, 'Indigenous Peoples Press Conference Summary at COP 10' (*Indigenous Peoples Issues and Resources*, 28 October 2010).
[715] Berne Declaration, ECOROPA, EED and TWN, 'What We Need – and What We Don't Need for a Credible and Effective ABS Protocol' (2010) 35(7) *ECO* 1 <http://www.ukabc.org/eco@cop10-7.pdf> accessed 4 December 2017; see also Siswandi (n 705) 350.
[716] Siswandi (n 705) 347; see also David E Schindel, 'Biotechnology Without Borders' (2010) 467 *Nature* 779-781.
[717] Siswandi (n 705) 349.
[718] ibid.

of interests culminated in the workability of the resulting Nagoya Protocol 2010 being marred by weak, recurring discretionary and ambiguous provisions, as will be seen in Chapter six.[719]

Ensuring coherence between the competing interests of these multiple stakeholders in the context of the interaction between intellectual property, genetic resources and associated traditional knowledge has remained a complex and highly debated issue and maintained a prominent position in discussions held within international trade and intellectual property frameworks.[720] The concerns of developing and least-developed countries, including indigenous and local communities over the protection of biotechnology inventions derived from genetic patrimony and associated traditional knowledge prompted the ongoing negotiations within the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) which has been established since 2000 to develop an international legal instrument or instruments that would 'provide effective protection of traditional cultural expressions/folklore, traditional knowledge (including traditional medical knowledge), and address the [intellectual property] aspects of access to and benefit-sharing of genetic resources'.[721] Nonetheless, it has been observed that negotiations among stakeholders have progressed 'along opportunistic, ideological and political lines all of them bearing the hallmarks of North-South geopolitical power relations as an obvious and enduring undercurrent'.[722] This has resulted in important disagreements, and it increasingly appears that a few powerful developed countries, such as Canada, Japan, South Korea, the US and in certain respects, the EU, are committed to ensuring that no good outcome will result from WIPO-IGC negotiations.[723]

[719] Siswandi (n 705) 342, 344.
[720] Ricardo Mélendez-Ortiz, 'Foreword: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore' in Daniel F Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017).
[721] WIPO, 'Intellectual Property and Traditional Medical Knowledge: Background Brief - No 6' (2016).
[722] Chidi Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' in Robinson, Abdel-Latif and Roffe (eds), *Protecting Traditional Knowledge* (n 720).
[723] ibid.

As will be seen in Chapter six, delegates in the WIPO-IGC continue to disagree over what definition is to be given to 'misappropriation', as there seems to be an aversion to 'biopiracy' because of its perceived political undertone.[724] As well, delegates still argue the question of whether to include the disclosure requirement in patent applications, and what scope it should be afforded – whether disclosure of source and/or origin of genetic resources and traditional knowledge.[725] In this regard, the strong opposition by developed countries to the proposal by developing and least-developed countries, as well as indigenous and local communities for a pragmatic readjustment of the patent system to address the misappropriation of genetic resources and associated traditional knowledge, continues to intensify existing mistrust over 'the sincerity of [developed countries] in nurturing the development agenda within and outside the WIPO committee processes'.[726] As a result, almost 18 years and 35 sessions later, no concrete agreement has been reached and such a prospect progressively appears unlikely.[727]

Based on these lessons from the history of the Nagoya Protocol 2010 and the ongoing negotiations at the WIPO-IGC, this research envisages that the process of negotiating a convention on drug R&D would be a complex and protracted one that could potentially redound to a stalemate. In addition to the bureaucracy that treaty negotiations are typically known for, this research argues that two main factors will prove major challenges to the timely and successful conclusion of the convention: first, there will be competing interests resulting from the presence of multiple stakeholder groups; and secondly, the interface between two important instruments in the field of R&D of medicines – the TRIPS Agreement and the United States' 1980 Bayh-Dole Act – on the one hand, and the negotiated convention on drug R&D on the other hand, will give rise to very contentious issues that must be addressed, but which also have the potential to lead to a breakdown of negotiations.

[724] ibid.
[725] ibid; see also Margo A Bagley, 'Of Disclosure 'Straws' and IP 'Camels': Patents, Innovation, and the Disclosure of Origin Requirement' in Robinson, Abdel-Latif and Roffe (eds), *Protecting Traditional Knowledge* (n 720) 85.
[726] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 722).
[727] Graham Dutfield, 'TK Unlimited: The Emerging but Incoherent International Law of Traditional Knowledge Protection' (2017) 20 *Journal of World Intellectual Property* 144-159, 146.

On the first matter, the competing stakeholders will include developed countries, the pharmaceutical industry and other research institutions, developing and least-developed countries, and NGOs. Conceivably led by the US in this arena, developed countries, as in most multilateral negotiations, will wield the bargaining power. Their main objective will be to safeguard their economic interests in research, development and commercialisation of medicines. To achieve this, they will seek to ensure that whatever measures are prescribed by the convention will not be disadvantageous to the pharmaceutical industry and other research institutions, as the commercial activities of the latter contribute significantly to their economies. For developing and least-developed countries, the aims are straightforward: secure a convention that would result in vigorous R&D for malaria, tuberculosis, HIV/AIDS and other neglected tropical diseases, as well as promote access to the end product at lower prices. In alignment with this interest, NGOs will take the position that the convention should be one to ensure that essential medicines are available and affordable to patients residing in developing and least-developed countries. One critical step that both the developing and least-developed countries, and NGOs will take to achieve their objective of access to affordable medicines, is to oppose patents on medicines developed under the proposed convention fervently.

However, being profit oriented, the pharmaceutical industry and other research institutions will be averse to any measure that will interfere with their profit stream, notably the acquisition of patent rights on the end product of R&D. No doubt, they will have the firm support of developed countries on this issue, especially the US. An offshoot of this conflict of interest will be the legal nature of the international agreement on R&D. Indeed, while the High-Level Panel proposed a binding convention on R&D, it appears unlikely based on the perceived substance of the concerns of the developed countries, and the pharmaceutical industry and other research institutions that hard law would best serve their interests. Consequently, they may be more inclined to an agreement on R&D that is of a ‘soft’ nature. And indeed, parties will be free to negotiate the legal nature of this instrument because, as mentioned in Chapter one, the recommendations of the High-Level Panel are merely advisory. Thus, this thinking presupposes that the legal nature of the international agreement will constitute one of the keenly contested issues during negotiations. In light of these competing interests, the various stakeholder groups would seek to prevent an outcome that would be undesirable to them, or to weaken the final

agreement in such a way that it would be harmless to their interests.[728] Apart from consuming time, this could potentially result in an ineffective agreement on drug R&D – one that is marred by weak, recurring discretionary and ambiguous provisions; more or less the same as the Nagoya Protocol 2010.

On the second factor that may cost the timely and successful conclusion of the convention, recall from earlier that the TRIPS Agreement and the 1980 Bayh-Dole Act both enable pharmaceutical companies and other research institutions to patent the end product of R&D. As already noted, they will be determined to retain this right under the proposed convention on drug R&D. Whether pharmaceutical companies and other research institutions will be allowed to patent products developed under the convention will be another heavily contested issue; more so, as developing and least-developed countries and NGOs will vigorously resist any such attempts. This will be true mainly because it seems that allowing pharmaceutical companies and other research institutions to continue patenting the products of R&D, even under the new convention, will defeat its purpose. The sole reason for this is that patent rights will continue to aid the exercise of the market monopolies that have culminated in high costs of medicines in the first place. What is more, it is difficult to imagine pharmaceutical companies and other research institutions being disposed to forfeiting their market monopolies, as this would mean limiting their profit stream – the developed countries will not stand for this. The suggestion here is that this issue is of such a controversial nature that it could potentially result in a breakdown of negotiations.

In conclusion, the effectiveness of the strategy of the full use of TRIPS flexibilities and the negotiation of a binding convention on drug R&D to promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030 is marred by economic and political realities of these countries, as well as great complexity and uncertainty. For developing and least-developed countries to make considerable progress towards attaining the 2030 Agenda for Sustainable Development, there is a need for governments of developing and least-developed countries to adopt

[728] Meerts (n 700) 3.

other measures to operate alongside this strategy ('a mix of policy initiatives'[729]) to eradicate malaria, tuberculosis, HIV/AIDS and other chronic communicable and noncommunicable diseases. Otherwise, it is difficult to see how Goal 3, which is central to the realisation of all other sustainable development goals, would be reached, thereby leaving millions of people, especially in developing and least-developed countries, behind. It is in this light that Chapter three considers whether traditional medicine can contribute to achieving sustainable development by 2030 through providing treatment for malaria, tuberculosis and HIV/AIDS.

As noted in Chapter one, there is an increased global awareness regarding the role of traditional medicine in meeting health demands in developing and least-developed countries.[730] The traditional medicine system consists of a body of knowledge, skills and practices of indigenous peoples, based on their beliefs, theories and experiences, used to prevent, diagnose and treat physical and mental illnesses.[731] It was in view of its potential for providing health care that the 2008 Beijing Declaration – a non-binding document on traditional medicine adopted by 193 WHO member states – encouraged governments to integrate traditional medicine into their national healthcare systems through formulation of national policies, to develop traditional medicine based on R&D, and to establish systems for the qualification, accreditation and licencing of traditional medicine practitioners (discussed in Chapter five).[732] The idea is that if Chapter three substantiates that traditional medicine consists of curative and palliative remedies for malaria, tuberculosis and HIV/AIDS, then developing and least-developed countries should *appropriately* integrate traditional medicine into their health systems as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D, with the aim of making significant progress towards sustainable development by 2030.

[729] Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (n 182) 73.
[730] Abbott, 'Documenting Traditional Medical Knowledge' (n 195).
[731] WHO, 'Traditional Medicine: Definitions' (2000) WHO/EDM/TRM/2000 <http://www.who.int/medicines/areas/traditional/definitions/en/> accessed 14 September 2015.
[732] The Beijing Declaration, adopted by the WHO Congress on Traditional Medicine 2008; see also Abbott, 'Documenting Traditional Medical Knowledge' (n 195).

CHAPTER THREE

ACCESSIBLE MEDICINE FOR SUSTAINABLE DEVELOPMENT: A CASE FOR TRADITIONAL MEDICINE

Chapter two considered the effectiveness of the strategy of the full use of TRIPS flexibilities and the negotiation of a binding convention on drug research and development (R&D) to promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030 and concluded that it is impaired by the economic and political realities of these countries, as well as great complexity and uncertainty. Consequently, it proposed the integration of traditional medicine into the national health systems of developing and least-developed countries as complementary to the use of TRIPS flexibilities and (probably) a convention on drug R&D if the extant chapter establishes that traditional medicine can contribute to sustainable development. On this note, this chapter explores whether, in fact, traditional medicine can contribute to progress towards the 2030 Agenda for Sustainable Development by providing medicines for malaria, tuberculosis and HIV/AIDS. As explained in Chapter one, ensuring healthy lives and promoting well-being for all at all ages – Goal 3 – is central to realising all other sustainable development goals, since good health is essential to attaining a socially and economically productive life. Therefore, if traditional medicine can maintain health and promote well-being, especially by providing treatment for malaria, tuberculosis and HIV/AIDS, then it would be logical to conclude that it can contribute to sustainable development.

In investigating this hypothesis, this chapter attempts to enable a comprehensive understanding of the traditional medicine system in operation. It verifies whether the traditional system of medicine could provide curative, as well as palliative medicines to further the sustainable development goal of eradicating these diseases by 2030. In relation to this, this chapter notes that traditional medicine has served as a source of health care, most times the only source of essential medicines to some of the world's poorest people, especially those found in developing and least-developed countries. As will be seen, this point has been corroborated by notable international organisations, among others, the United Nations (UN), the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF). This chapter also explores traditional approaches to sickness,

causation and healing in the traditional medicine cosmology; preparation and administration of traditional medicine; including why some people find traditional medicine more appealing than conventional medicine. These discussions are aimed at unearthing the healthcare practices under the traditional medicine system and enabling an understanding of their potential to contribute to realising sustainable development.

3.1. Deciphering Traditional Medicine

The World Health Organization (WHO) adopted a definition for traditional medicine in a WHO Meeting on the Promotion and Development of Traditional Medicine held in Geneva in 1977. This definition originated from a group of experts from the African Region assembled in Brazzaville, the Republic of Congo in 1976 by the WHO Regional Office for Africa.[733] These experts defined traditional medicine as:

> the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing.[734]

Implicit in this definition is the recognition that the traditional approach to treatment is not confined to the physical but also encompasses the consideration of psychosomatic and psychosocial factors. As will be seen in section 3.3, this subtlety stands as one of the reasons patients resort to traditional medicine.

Traditional medicine is a subset of the traditional knowledge of indigenous peoples.[735] As explained by the World Intellectual Property Organization (WIPO), traditional knowledge is:

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[733] AFRO Technical Report Series no 1, *African Traditional Medicine*: *Report of the Expert Committee* (Brazzaville: AFRO, 1976) 3-4.
[734] ibid.
[735] Sungha Kim, Boyoung Kim, Sujeong Mun, Jeong Hwan Park, Min-Kyeoung Kim, Sunmi Choi and Sanghun Lee, 'Development of a Template for the Classification of Traditional Medical Knowledge in Korea' (2016) 178 *Journal of Ethnopharmacology* 82-103; see also Richard Wilder, 'Protection of Traditional Medicine' (2001) CMH Working Paper Series, Paper No WG 4:4.

> knowledge that is created, maintained, and developed by indigenous peoples [and] local communities…and that is linked with, or is an integral part of, the…social identity and/or cultural heritage of indigenous peoples [and] local communities; that is transmitted between or from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms; and which may be dynamic and evolving, and may take the form of know-how, skills, innovations, practices, teachings or learnings.[736]

This traditional know-how, skills, innovations, practices, teachings and learnings relate to various fields, including agriculture, science, technology, ecology, biological diversity and medicines.[737] It is generated from the interaction of the indigenous peoples with their natural environment.[738] This interaction mirrors a *quid pro quo* in which the indigenous peoples sustain and nurture the environment, which in turn, provides them with food, clothing and medicines.[739] Thus, it is from this relationship that the traditional knowledge of the medicinal uses of plants (otherwise called 'traditional medical knowledge') is produced.

The knowledge is qualified by 'traditional' because it stems from the culture of the community. It would be wrong to presume that it is antiquated because it is 'traditional'.[740] On the contrary, it is created every day, as it is a by-product of the continuous interaction between the indigenous peoples and their social and natural environment.[741] What makes it 'traditional' is its characteristic of being 'deeply rooted' in a particular sociocultural milieu, which differs from one community to another.[742] Its

[736] WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, The Protection of Traditional Knowledge: Draft Articles, Geneva: Thirty-Fourth Session 12-16 June 2017, WIPO/GRTKF/IC/34/5, art 2.
[737] WIPO, 'Traditional Knowledge' (*World Intellectual Property Organization*) <http://www.wipo.int/tk/en/tk/> accessed 29 May 2017.
[738] Sithole Jabulani, 'The Challenge Faced by African Libraries and Information Centres in Documenting and Preserving Indigenous Knowledge' (2007) *IFLA Journal*, 17-23.
[739] Backgrounder, 'Indigenous Peoples – Land, Territories and Natural Resources' (2007) United Nations Permanent Forum on Indigenous Issues <http://www.un.org/en/events/indigenousday/pdf/Backgrounder_LTNR_FINAL.pdf > accessed 27 March 2017.
[740] Wilder (n 735); see also WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[741] Wilder (n 735).
[742] Ernest Rukangira, 'Medicinal Plants and Traditional Medicine in Africa: Constraints and Challenges' (2001) Sustainable Development International 180.

creation and practices are fundamental components of the cultural traditions of the community,[743] and it reflects such traditions.[744] Consequently, each community has a peculiar approach to health and diseases, down to perceptions about microorganisms that cause diseases and therapeutic behaviours.[745] It is then arguable that there exist as many traditional medicines as there are indigenous and local communities, giving traditional medicine its diverse and pluralist nature.[746] Put differently, traditional medicine also refers to traditional medical systems that are wide-ranging and diversified.[747]

As can be gleaned from WIPO's definition, traditional knowledge is created and held collectively; it is intergenerational, generally unwritten and sacred. It is considered a collective heritage in the sense that while individual traditional medicine practitioners such as a *shaman* in Latin America (specifically Bolivia) or a *sangoma* in South Africa may themselves innovate, such innovation is based on the community's customs and traditions, and thus regarded as community-held.[748] Generally, traditional medical knowledge is unwritten and exists in the minds of the indigenous peoples.[749] Such knowledge may be sacred in the sense that it is kept a secret, is mystical and based on salient physical symptoms or perceived supernatural forces.[750] In most indigenous communities, it is passed on orally from generation to generation.[751] However, it is possible to find them reduced in writing, regulated, taught openly and practised widely.[752] According to Wilder, there are codified knowledge systems in South Asia which include the Ayurvedic systems of medicine, 'codified in the 54 authoritative books' of the system; the Siddha system, as codified in 29 authoritative books; and the Unani Tibb tradition, which is codified in 13 authoritative books.[753] Traditional Chinese medicine (TCM) is openly practised and publicly taught through specific medical institutions.[754]

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[743] Wilder (n 735).
[744] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[745] Rukangira (n 742).
[746] ibid.
[747] M A Maar and M Shawande, 'Traditional Anishinabe Healing in a Clinical Setting' (2010) 6(1) *Journal of Aboriginal Health* 18-27.
[748] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[749] Jabulani (n 738) 17-23.
[750] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[751] Jabulani (n 738) 17-23.
[752] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[753] Wilder (n 696).
[754] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).

The form in which traditional knowledge exists is a critical issue with regard to its wider application, as will be seen in Chapters four, five and six. Previously, in jurisdictions such as the US, evidence other than documented foreign knowledge was inadmissible to refute claims of novelty in opposition proceedings challenging patents that incorporated traditional medical knowledge.[755] (Recall from Chapter two that an invention must pass the patentability criteria of new, inventive step and industrial application). This created a window of opportunity for anyone capable of replicating traditional knowledge to patent such replication as a new invention,[756] giving rise to biopiracy claims by the indigenous peoples and their countries. Also, because there is the concern of lack of evidence supporting the safety and efficacy of traditional medicine (as will be seen here and in Chapter four), drug regulatory authorities, in Brazil for example, require manufacturers to submit evidence of safety and efficacy of herbal medicines in the form of test data generated through pre-clinical and clinical trials or any literature containing data that validates the safety and efficacy of the herbal medicine.[757]

This gravitation towards valuing documented traditional knowledge over one existing in oral form has culminated in documenting traditional knowledge in digital libraries to constitute evidence supporting the safety and efficacy of traditional medicine and to function as evidence of prior art to destroy novelty claims in illegitimate patents based on traditional knowledge. For instance, see the Traditional Knowledge Digital Library (TKDL) developed under the aegis of India's Council of Scientific and Industrial Research (CSIR) and Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), which embodies existing literature on the four areas of Indian traditional medical knowledge: Ayurveda, Unani, Siddha and Yoga.[758] However, Chapters five and six will show that as important as documentation is for providing evidence of quality, safety and efficacy, and for defensive protection of traditional

[755] This used to be the position of the law under 35 United States Code (U S C), sec 102(a), (b); however, this aspect of the legislation has been changed by the America Invents Act (Bill HR 1249) signed by the US President on 16 September 2011 – see Summary of the America Invents Act <http://www.aipla.org/advocacy/congress/aia/Pages/summary.aspx> accessed 5 August 2016; see also Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-based Biopiracy' (n 192) 241.
[756] ibid 241.
[757] Ana Cecília Bezerra Carvalho, João Paulo Silvério Perfeito, Leandro Viana Costa e Silva, Lívia Santos Ramalho, Robelma France de Oliveira Marques, Dâmaris Silveira, 'Regulation of Herbal Medicines in Brazil: Advances and Perspectives' (2011) 47(3) *Brazilian Journal of Pharmaceutical Science* 467-473.
[758] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).

medical knowledge, it could engender further unlawful exploitation of the traditional knowledge of indigenous peoples by third parties, particularly the biotechnology and pharmaceutical industries.

Under international law, there is no definition of the concept of 'indigenous peoples'[759] who generate traditional medical knowledge. However, they are identified based on generally accepted characteristics, which include:

> self-identification as an indigenous people; the existence of and desire to maintain a special relationship with ancestral territories; distinct social, economic or political systems from mainstream society, which may be reflected in language, culture, beliefs and customary law; and a historically non-dominant position within society.[760]

International human rights law recognises the right of these peoples to self-determination pursuant to the International Covenant on Civil and Political Rights – a multilateral treaty, part of the International Bill of Human Rights comprised of 169 parties; the International Covenant on Economic, Social and Cultural Rights (noted in Chapter one); and the International Convention on the Elimination of All Forms of Racial Discrimination – a UN human rights convention that promotes understanding among all races comprised of 179 parties,[761] by virtue of which indigenous peoples are entitled to pursue their development whether social, cultural or economic.[762]

Furthermore, international law confers the right to own and control traditional medical knowledge on the indigenous peoples in accordance with the principle of self-determination. The 2007 United Nations Declaration on the Rights of Indigenous Peoples

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[759] Vicky Tauli-Corpuz, 'Report of the Special Rapporteur on the Rights of the Indigenous Peoples' (UN General Assembly, 71st session Item 66(a) 2016) 5.
[760] ibid.
[761] 'Parties to the International Convention on the Elimination of all Forms of Racial Discrimination' United Nations Treaty Collection <https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-2&chapter=4&clang=_en> accessed 7 April 2018.
[762] Tauli-Corpuz, 'Report of the Special Rapporteur on the Rights of the Indigenous Peoples' (n 759); see also M. A. Martinez, 'Study on Treaties, Agreements and other Constructive Arrangements Between States and Indigenous Populations: Final Report of the Special Rapporteur' (E/CN.4/Sub.2/1999/20) para 256.

(UNDRIP), which details and interprets indigenous peoples' rights and the 'standard achievement' they hope to pursue,[763] asserts the right of the indigenous peoples over their traditional medicine and the right to maintain traditional health practices, including the conservation of medicinal plants under Article 24(1).[764] Article 31 bestows on the indigenous peoples the right to maintain, protect and develop traditional knowledge, including 'manifestations of sciences, technologies and cultures,' as well as human and genetic resources, seeds, medicines, and knowledge of the properties of plants.[765] Moreover, the Declaration recognises that traditional knowledge is the product of indigenous intellect. This can be inferred from the right it confers on the indigenous peoples to maintain, control, protect and develop their intellectual property rights over traditional knowledge.[766] While the UNDRIP has no force of law, as UN Declarations are not legally binding, it carries with it a considerable moral force.[767] This becomes clearer when the exploitation of traditional medical knowledge without compensation to the indigenous peoples is viewed against the backdrop of these rights affirmed by the Declaration, as will be assessed in Chapter six.

Although the indigenous peoples have proprietary rights over it, traditional medicine is widely used for improving health. In Africa, about 80 per cent of the population relies on traditional medicine to meet their health demands.[768] Due to historical circumstances and cultural beliefs, Asian and Latin American populations depend on traditional medicine for their health care needs as well.[769] In China, traditional medicine caters for about 40 per cent of the entire health care delivered.[770] This situation also applies to developed countries: there is a rapid growth in the use of 'complementary and alternative medicine'

[763] Tauli-Corpuz, 'Report of the Special Rapporteur on the Rights of the Indigenous Peoples' (n 759); see also The United Nations Declaration on the Rights of the Indigenous Peoples (UNDRIP) 2007.
[764] UNDRIP 2007, art 24(1).
[765] ibid art 31.
[766] ibid.
[767] United Nations Permanent Forum on Indigenous Issues, 'Declaration on the Rights of the Indigenous Peoples' <http://www.un.org/esa/socdev/unpfii/documents/faq_drips_en.pdf> accessed 31 May 2017; see also International Work Group for Indigenous Affairs, 'The UN Declaration on the Rights of the Indigenous Peoples' (*IWGIA*) <http://www.iwgia.org/human-rights/international-human-rights-instruments/undeclaration-on-the-rights-of-indigenous-peoples> accessed 31 May 2017.
[768] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[769] ibid.
[770] ibid.

(CAM) in Australia, Belgium, Canada, France and the US.[771] The designation of traditional health practices in these jurisdictions as 'complementary and alternative medicine' is representative of the fact that these practices do not form part of their traditions and are not integrated into their national health systems.[772] In fact, the primary care delivered by the health systems of these countries is predominantly conventional medicine.[773] As previously noted, traditional medicine is 'traditional' because it emanates from the customs and belief systems of an identifiable group where it is the source of primary health care,[774] so that in China and India, Acupuncture and Ayurveda are Chinese and Indian traditional medicines respectively. However, in the European Union (EU) countries such as France and Germany, Ayurveda and Acupuncture are CAMs. Thus, the reference to health practices as complementary and alternative in one jurisdiction does not derogate the fact that it is traditional to another.

The application of traditional medicine consists of various health practices, approaches, knowledge and beliefs that incorporate plant, animal, and mineral-based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as treat, diagnose or prevent illness.[775] WHO categorises traditional medicine as medication and non-medication therapies.[776] While medication therapies consist of the use of herbal medicines, animal parts and minerals, non-medication therapies are carried out essentially without medication, such as in the case of yoga, manual therapies, qigong, tai ji, thermal therapy, acupuncture and other physical, mental, spiritual and mind-body therapies.[777] Regarding medication therapies, herbal medicines are the most widely used. As will be seen in 3.2, herbal remedies exist for treating and improving the quality of life of people who have contracted malaria, tuberculosis and HIV/AIDS. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain plant parts or other plant materials

[771] Ryan B Abbott, Ka-Kit Hui, Ron D Hays, Jess Mandel, Michael Goldstein, Babbi Winegarden, Dale Glaser and Laurence Brunton, 'Medical Student Attitudes Towards Complementary, Alternative and Integrative Medicine' (2011) *Evidence-based Complementary and Alternative Medicine*.
[772] ibid; see also P C Pietroni, 'Beyond the Boundaries: Relationship between General Practice and Complementary Medicine' (1992) 305 *British Medical Journal* 564-566.
[773] Abbott et al., 'Medical Student Attitudes Towards Complementary, Alternative and Integrative Medicine' (n 771).
[774] Pietroni (n 772).
[775] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[776] ibid.
[777] ibid.

or a combination of these as active ingredients.[778] Finished herbal products are commonly referred to as 'modernised traditional medicine' because high-technological machines are used in converting plant materials to soluble granules and tablets in clean and standardised forms.[779] Prior to this, the practice has been to handpick and separate unwanted plant parts before transforming them into a powdery form by grinding.[780]

However, technology has now made it possible to bottle and cork herbal medicines or place them in sachets for purposes of hygiene and preservation.[781] Also, such bottles or sachets are labelled with the name(s) of the manufacturer and the address; preparation, dosage, methods of preservation, and expiry date; an indication that the drug has been registered with regulatory authorities; and treatment claims.[782] These herbal drugs are also researched and documented.[783] This process can be differentiated from the usual trial and error approach to preparing traditional medicine where estimations are made as to the species and its location, what plants are poisonous at what time of the year and the best time to collect such plants, including the method of preparation and dosification.[784] Interestingly, some traditional medicine practitioners assert that they are provided with this information by supernatural forces. Nonetheless, with regard to the new method of researching herbal drugs, the point must be made that it does not meet the standard of conventional medicine owing to the adoption of poor methodologies. According to evidence-based medicine (EBM), the best method for verifying the safety and efficacy of treatment intervention is through randomised controlled trials (RCTs).[785] This presupposes that whatever knowledge generated by any means other than RCTs may not

[778] ibid 1.
[779] Temitope I. Borokini and Ibrahim O Lawal, 'Traditional Medicine Practices Among the Yoruba People of Nigeria: A Historical Perspective' (2014) *Journal of Medicinal Plants Studies* 20-33, 29.
[780] ibid.
[781] Borokini and Lawal (n 779) 20-33, 29.
[782] ibid.
[783] ibid.
[784] Gurdial Nijar, *TRIPS and Biodiversity: The Threat and Responses – A Third World View* (Malaysia: Third World Network 1996) 16; see also Gideon Emcee Christian, 'Digitization, Intellectual Property Rights and Access to Traditional Medicine Knowledge' (2009) A Research Paper Prepared for International Development Research Centre (IDRC) Ottawa, Canada.
[785] J. C. Tilburt and Ted J. Kaptchuk, 'Herbal Medicine Research and Global Health: An Ethical Analysis' (2008) 86(8) *Bulletin of the World Health Organization* 594-9 <https://www.ncbi.nlm.nih.gov/pubmed/18797616> accessed 20 April 2017; see also Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).

be reliable. Consequently, this reasoning has provoked concerns regarding the safety and efficacy of herbal medicines.[786]

The difference in research methodology aside, traditional and conventional medicines are not at odds in terms of what they seek to achieve. The reality is that conventional medicine has kept abreast of scientific and technological developments more than traditional medicine,[787] which is only beginning to modernise its therapies. Differences also lie in the cultures of the people who practise the two systems and the fact that traditional medicine has always been an essential part of human cultures.[788] However, both traditional and conventional medicines are widely used and of importance in health systems. To this extent, both are directed towards the common goal of providing health care, regardless of the setting in time, place and culture.[789] The next section investigates this role of traditional medicine in providing health care, paying particular attention to whether it can provide treatment for malaria, tuberculosis and HIV/AIDS for progress towards sustainable development.

3.2. Traditional Medicine for Malaria, Tuberculosis and HIV/AIDS

Traditional medicine derived from nature has played a vital role in improving human health. It has been used to maintain and restore human health from ancient times.[790] There is no culture that cannot attest to the use of mostly plants as medicine.[791] Documented accounts[792] demonstrate the part played by ancient Graeco-Roman,[793] Hebrew,[794]

[786] These issues are further discussed in Chapters four and five.
[787] World Health Organization, *The Promotion and Development of Traditional Medicine* (Geneva: World Health Organization 1978) 9.
[788] World Health Organization, The Promotion and Development of Traditional Medicine (n 787) 9.
[789] ibid.
[790] Maurice Strong, 'Sustainable Use of Biodiversity' in John Thor Arnason, National Research Council of Canada, Tropical Conservancy (Organization) (eds), *Biodiversity and Health: Focusing Research to Policy: Proceedings of the International Symposium Held in Ottawa, Canada, October 25-28, 2003* (NRC Research Press 2005) 17.
[791] Oguamanam, International Law and Indigenous Knowledge (n 69) 118.
[792] ibid contains the sources of the accounts.
[793] Stanley Krippner and Benjamin Colodzin, 'Folk Healing and Herbal Medicine' in George G Meyer and Kenneth G Cull (eds), *Folk Medicine and Herbal Healing* (Springfield: IL: Charles C Thomas 1981) 16-17.
[794] Richard Lucas, *Nature's Medicines: The Folklore, Romance, and Value of Herbal Remedies* (West Nyack, NY: Parke Publishing 1966) 13; see also Richard L Rubin, 'Healing with Plants in the Jewish Culture' in Meyer and Cull (n 793) 167-168.

Egyptian,[795] Chinese,[796] Arabian, and Aryan[797] civilisations, among others, in the development of modern medicine and associated sciences beginning with herbology.[798] Yet there was a time when the use of traditional medicine was discouraged because it was perceived to be dangerous.[799] However, there has been a change in this way of thinking conceivably due to the realisation of the potential of traditional medicine in providing health care. This can be deduced from the fact that as much as 80 per cent of the world's population uses traditional medicine to meet their health care demands.[800] Health care demands are presently at an increase amongst the populations of developing and least-developed countries as they are disproportionately affected by malaria, even though by WHO's assessments as much as half of the world's population is at risk of contracting malaria.[801] With the increase in resistance to anti-malarial medicines and the inability of the poor in developing and least-developed countries to afford essential medicines, the situation is even more problematic.[802]

In this connection, Goal 3 of the UN Agenda for Sustainable Development is to eradicate malaria by 2030.[803] Traditional medicine can contribute to realising this goal as it has been used for thousands of years to treat malaria.[804] For example, it was discovered in the 17th century in South America that the Peruvian indigenous peoples used the bark of the cinchona tree to treat malaria.[805] In Asia, traditional Chinese medicine traditionally uses

[795] Lucas (n 794); see also Rubin (n 794).
[796] Kenneth R Pelletier, 'Psychosomatic Approaches to Healing' in Meyer and Cull (n 793) 15; see also William McKinley Klein, 'The Role of Botanical Gardens and Arboreta in Traditional Medicine' in Timothy Tomlinson and Olayiwola Akerele (eds), *Medicinal Plants: Their Role in Health and Biodiversity* (Philadelphia: University of Pennsylvania Press 1998).
[797] Krippner and Colodzin (n 793) 16-17.
[798] ibid 15, explaining that 'herbology' is derived from the Latin word *herba* or grass and the Greek word *logos*, meaning description, translating into 'description of grass'; see also Oguamanam, *International Law and Indigenous Knowledge* (n 69) 265.
[799] Strong (n 790).
[800] Strong (n 790).
[801] Roll Back Malaria Partnership, 'Key Facts about Malaria' <http://www.rollbackmalaria.org/about/about-malaria/key-facts> accessed 1 August 2015; see also Roll Back Malaria Partnership, 'Endemic Countries' <http://www.rollbackmalaria.org/countries/endemic-countries-1> accessed 1 August 2015.
[802] Merlin L Wilcox, 'A Clinical Trial of 'AM', a Ugandan Herbal Remedy for Malaria' (1999) 21(3) *Journal of Public Health Medicine* 318-324.
[803] See Chapter one for discussion on this.
[804] Merlin L Wilcox and Gerard Bodeker, 'Traditional Herbal Medicines for Malaria' (2004) 329 *BMJ* 1156-1159, 1157.
[805] Byron Breedlove and Paul M. Arguin, 'Portrait of the Coveted Cinchona' (2015) 21(7) *Emerging Infectious Diseases* 1280-1281.

the plant *Artemisia annua* (sweet wormwood) to treat fevers.[806] In 1998 in Africa, a survey of the WHO Roll Back Malaria Programme – a global action plan to end malaria – in Ghana, Mali, Nigeria and Zambia, revealed that over 60 per cent of children with high fever received treatment at home with herbal medicines.[807] Traditionally called '*konoruku*' in Ghana, traditional healers use Ankama (lemon) leaves, Kunkruma roots and leaves, Adisikankyi roots or barks and dried pepper to treat malaria.[808]

Some cohort studies[809] have been carried out to assess the efficacy of some traditional herbal treatments used by traditional healers in treating malaria. Based on the review of the work done by the Research Initiative on Traditional Antimalarial Methods (RITAM) founded in 1999 with the objective to further research on traditional medicines for malaria, it was discovered that a few of these cohort studies showed complete clearance of the malaria parasite by the seventh day of treatment.[810] A study of the antimalarial effects of *Alocasia macrorrhiza* (giant taro) root decoction showed 100 per cent clearance by day seven without recurrence for the 21 days period of follow-up.[811] Another study showed 100 per cent clearance of the parasite in adults by a leaf extract of *Morinda Lucida* (brimstone tree). However, this was not the situation with infected children as there was no full parasite clearance.[812] This calls attention to the flaws of these studies: while they support the hypothesis that traditional medicine can provide treatment for malaria, cohort studies appear not be the best method for verifying malaria treatment efficacy.

[806] 'Hard to Swallow' (2007) 448(7150) *Nature* 105-106.
[807] Oguamanam, *International Law and Indigenous Knowledge* (n 69) 119; see also 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 13; and Obijiofor Aginam, 'From the Core Peripheries: Multilateral Governance of Malaria in a Multicultural World' (2002) 3 *Chicago Journal of International Law* 87-103.
[808] Abena Dove Osseo-Asare, *Bitter Roots: The Search for Healing Plants in Africa* (University of Chicago Press 2014).
[809] A study design where a group of people who share a common characteristic or experience within a defined period is followed prospectively to record or evaluate their status in relation to disease or outcome – see Jae W Song and Kevin C Chung, 'Observational Studies: Cohort and Case-Control Studies' (2010) 126(6) *Plastic and Reconstructive Surgery* 2234-2242.
[810] Merlin Wilcox and Gerard Bodeker, 'Herbal Remedies for Malaria: An Overview of Clinical Studies' in M Wilcox, P Rasoanaivo, and G Bodeker (eds), *Traditional Medicine, Medicinal Plants and Malaria* (London: Harwood Press 2004); see also Wilcox and Bodeker, 'Traditional Herbal Medicines for Malaria' (n 804).
[811] Gerard Bodeker, 'Medicinal Plant Biodiversity and Local Healthcare: Rural Development and the Potential to Combat Priority Diseases' in B Havercort and S Rist (eds), *Endogenous Development and Bio-Cultural Diversity* (Netherlands: COMPAS Press 2007).
[812] ibid.

A problem with such studies is the potential semi-immunity of the trial population to malaria.[813] This could result in the clearance of the parasite and abatement of the symptoms without effective treatment.[814] This is true for children aged over five years, as seen in the *Morinda Lucida* study, particularly in high endemic areas such as Sub-Saharan Africa because they are said to have good immune responses to malaria.[815] It then means that high clearance rate does not translate into efficacy.[816] Also, when areas that have high malaria transmission are considered, it may not be realistic to achieve complete parasite clearance.[817] In these circumstances, WHO, just like the conventional medical community, has recommended adequate clinical response as a more useful measure to evaluate traditional medicine treatment efficacy.[818] Nevertheless, as will be seen later (in Chapters four and five), the adequacy of clinical trials in verifying the safety and efficacy of traditional therapies that are underpinned by magico-religious beliefs and practices is open to question. The issue centres on how these traditional beliefs and practices, and the influence they have on the efficacy of traditional medicine would be incorporated into clinical trial designs. Some of these magico-religious beliefs and practices are discussed later on in this chapter.

Another flaw of these studies conducted to verify the efficacy of traditional medicine in treating malaria is that very few of them have reported side effects from these herbal preparations.[819] This is extremely important because potential side effects resulting from ingesting these preparations would have an impact on the patient's health. It appears that the reason for the small amount of data is that 'patients were not questioned about adverse effects or new symptoms since starting the treatment'.[820] None of the studies reported serious adverse effects, except three cohort studies and three controlled trials that reported effects on biochemical variables (mostly common liver function tests), and two studies monitored the electrocardiograms.[821] Regarding toxicity, no cases were reported.[822]

[813] Wilcox and Bodeker, 'Traditional Herbal Medicines for Malaria' (n 804).
[814] ibid.
[815] ibid.
[816] ibid.
[817] ibid.
[818] ibid.
[819] Wilcox and Bodeker, 'Traditional Herbal Medicines for Malaria' (n 804).
[820] ibid.
[821] ibid.
[822] ibid.

However, minor side effects have been reported, as they are equally important. Some malaria patients who were being treated at a herbalist's clinic in South-West Uganda were followed to evaluate how they responded to a particular herb, 'AM'.[823] While 88 patients were enrolled, 72 were followed for two days and were questioned about side effects. The outcome was that although there were no major side effects, about 50 per cent experienced minor side effects.[824] These were sufficiently unpleasant in some cases and deterred patients from continuing treatment, for instance, diarrhoea and bitter taste.[825] Nonetheless, it must be pointed out that this does not mean that the treatment was not safe and effective. There were notable symptomatic improvements and a reduction of parasite counts in the patients that took AM,[826] thus validating its efficacy. The issue was that the treatment was not well tolerated by the patients, for example, due to the bitter taste of herbal antimalarial treatments,[827] as opposed to being unsafe. Therefore, while it is conceded that there is need to expand the evidence-base regarding the safety and efficacy of traditional medicine for treating malaria, this fact does not in and of itself refute the proposition that it could provide treatment to aid the eradication of malaria by 2030.

Tuberculosis is another disease that the 2030 Agenda for Sustainable Development seeks to exterminate. This is understandable as tuberculosis is one of the leading causes of death worldwide.[828] As already noted in Chapter one, 1.8 million lives were lost in 2015 on account of this disease with 95 per cent of the deaths occurring in developing and least-developed countries.[829] Tuberculosis continues to leave casualties in its wake, given the fact that it is an opportunistic infection of HIV/AIDS, and a form of tuberculosis is known to be multidrug-resistant.[830] The disease-causing bacterium, *Mycobacterium tuberculosis*, primarily attacks the lungs resulting in pulmonary tuberculosis.[831] It could

[823] Wilcox, 'A Clinical Trial of 'AM' (n 802) 318-324.
[824] ibid.
[825] Wilcox and Bodeker, 'Traditional Herbal Medicines for Malaria' (n 804) 1156-1159.
[826] Wilcox, 'A Clinical Trial of 'AM' (n 802) 318-324.
[827] Wilcox and Bodeker, 'Traditional Herbal Medicines for Malaria' (n 804) 1156-1159.
[828] 'Tuberculosis' (*World Health Organization*, 2017) <http://www.who.int/mediacentre/factsheets/fs104/en/> accessed 8 October 2017.
[829] ibid.
[830] ibid.
[831] World Health Organization, *Global Tuberculosis Control* (World Health Organization 1998); see also PRJ Gangadharam, 'Drug Resistance in Tuberculosis' in LB Reichman and ES Hershfield (eds), *Tuberculosis: A Comprehensive International Approach* (New York: Marcel Dekker 1993) 293-328.

also affect other parts of the body causing extrapulmonary tuberculosis.[832] The common symptoms of the tuberculosis disease include coughing, fever, sneezing, chest pain, weight loss, haemoptysis and fatigue.[833] It is noteworthy that the use of medicinal plants to treat tuberculosis is well documented in the African and Asian continents. Existing literature confirms the presence of antimicrobial properties in the plants used and the commonality of some herbal medicines to both continents for treating tuberculosis.[834] There is also evidence of traditional remedies for tuberculosis in some parts of South America.

In Africa, the VhaVhenda traditional healers of the Limpopo Province in South Africa use *Lippia javanica* (Burm. F.) Spreng and *Carica papaya* (pawpaw) to treat tuberculosis.[835] In Cameroon and Nigeria, *Aframomum melegueta* (grains of paradise) is a well-documented herbal treatment for tuberculosis, cough and chest congestion.[836] The leaf extract of *Artemisia Afra* (African wormwood) is known to be active against *mycobacterium* A+ strain and other bacteria such as *Bacillus cereus*, *Klebsiella pneumonia*, *Staphylococcus aureus*, and *Escherichia coli*.[837] For managing the fever symptom in a tuberculosis patient, the Ugandan AM herb or the roots or barks of Ankama, Kunkruma, Adisikankyi and dried pepper in Ghana could be administered. *Zingiber officinale* (Ginger) is widely used in African, Chinese, Ayurvedic and Tibb-Unani herbal medicines for improving appetite[838] and thus could be used to manage the weight loss

[832] Sebua Silas Semenya and Alfred Maroyi, 'Medicinal Plants Used for the Treatment of Tuberculosis by Bapedi Traditional Healers in Three Districts of the Limpopo Province, South Africa' (2013) 10(2) *African Journal of Traditional, Complementary and Alternative Medicines* 316-323; see also SK Sharma and A Moha, 'Extrapulmonary Tuberculosis' (2004) 120(4) *Indian Journal of Medical Research* 316-353.
[833] Semenya and Maroyi (n 832).
[834] ibid.
[835] E Green, A Samie, CL Obi, PO Bessong and RN Ndip, 'Inhibitory Properties of Selected South African Plants against Mycobacterium Tuberculosis' (2010) 130(1) *Journal of Ethnopharmacology* 151-157 <https://www.ncbi.nlm.nih.gov/pubmed/20447452> accessed 7 June 2017; see also Semenya and Maroyi (n 832).
[836] Jean L Betti, 'An Ethnobotanical Study of Medicinal Plants Among the Baka Pygmies in the Bja Biosphere Reserve, Cameroon' (2004) 25(1) *African Study Monographs* 1-27; see also LS Gill, *Ethnomedical Uses of Plants in Nigeria* (Uniben Press 1992); and Semenya and Maroyi (n 832) 316-323.
[837] Semenya and Maroyi (n 832) 316-323; see also LV Buwa and AJ Afolayan, 'Antimicrobial Activity of Some Medicinal Plants used for the treatment of Tuberculosis in the Eastern Cape Province, South Africa' (2009) 8(23) *African Journal of Biotechnology*, 6683-6687 <http://www.academicjournals.org/article/article1380012521_Buwa%20and%20Afolayan.pdf> accessed 7 June 2017.
[838] 'How to Gain Weight with Natural Herbs and Herbal Supplements' (*The Herbal Resource* 2017) <https://www.herbal-supplement-resource.com/gain-weight-supplements.html> accessed 6 June 2017; see also Badreldin H Ali, Gerald Blunden, Musbah O Tanira and Abderrahim Nemmar, 'Some

symptom. Likewise, the use of *Eriobotrya japonica* (Loquat) as a remedy for tuberculosis and cough is common amongst the Bapedi traditional healers of the Limpopo Province in South Africa, the peoples of Muroto and Susaki in Japan, traditional healers in Korea and traditional Chinese medicine.[839] In South America, the largest group of traditional healers in Bolivia – the Kallawayas – use *Equisetum giganteum* L. (Southern giant horsetail) to treat tuberculosis.[840] For centuries, the native population of Mexico has used *Larrea tridentata* (creosote bush or chaparral) as a treatment for tuberculosis and cold amongst others. However, in 2005, Health Canada – the Federal Department responsible for maintaining and improving health in Canada[841] – issued a warning to consumers to avoid products containing chaparral because of potential damage to the kidneys and liver.[842] Similarly, the US Food and Drug Administration (FDA) warned of the health risks associated with ingesting chaparral.[843]

While these reports suggested that the use of chaparral could be deleterious to health, they did not contradict its long traditional use in treating tuberculosis. In fact, while issuing these warnings, both health agencies corroborated the use of chaparral as a traditional medicine without adverse events.[844] A plausible explanation for the warnings regarding the side effects of chaparral could be that it was used without recourse to its traditional usage. It appears that at the time, health products were manufactured using chaparral as

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Phytochemical, Pharmacological and Toxicological Properties of Ginger (*Zingiber Officinale* Roscoe): A Review of Recent Research' (2007) 46(2) *Food and Chemical Toxicology* 409-420.

[839] Semenya and Maroyi (n 832) 316-323; see also Y Nishioka, S Yoshioka, M Kusunose, T Cui, A Hamada, M Ono, M Miyamura and S Kyotani, 'Effects of Extracts Derived from Eriobotrya Japonica on Liver Function Improvements in Rats' (2002) 25(8) *Biological and Pharmaceutical Bulletin* 1053-1057; H Ito, E Kobayashi, Y Takamatsu, SH Li, T Hatano, H Sakagami, K Kusama, K Satoh, D Sugita, S Shimura, Y Itoh and T Yoshida, 'Polyphenols from Eriobotrya Japonica and their Cytotoxicity against Human Oral Tumor Cell Lines' (2000) 48(5) *Chemical and Pharmaceutical Bulletin* 687-693; and M Parihar, A Chouhan, MS Harsoliya, JK Pathan, S Banerjee, N Khan and VM Patel, 'A Review: Cough and Treatments' (2011*) International Journal of Natural Products Research* 9-18.

[840] Vivian Lunny, 'Traditional Medicine in Bolivia, South America' (*Positive Health Online*, September 1997) <http://www.positivehealth.com/article/herbal-medicine/traditional-herbal-medicine-in-bolivia-south-america> accessed 6 June 2017.

[841] 'About Health Canada' (*Government of Canada*) <https://www.canada.ca/en/health-canada/corporate/about-health-canada.html> accessed 6 June 2017.

[842] Health Canada, 'Health Canada Warns Consumers Not to Take Products Containing Chaparral' (*Government of Canada*, 21 December 2005) <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2005/13575a-eng.php> accessed 6 June 2017.

[843] Mark Blumenthal, 'Herb Industry and FDA Issue Chaparral Warning: Experts Unable to Explain Possible Links to Five Cases of Hepatitis' (*Encognitive.com*) <http://www.encognitive.com/node/14728> accessed 6 June 2017.

[844] Health Canada, 'Health Canada Warns Consumers Not to Take Products Containing Chaparral' (n 842); see also ibid.

an ingredient.[845] One of the reports in the US concerned a woman who suffered from liver and kidney failure after consuming *capsules containing* chaparral for one year.[846] This situation seems akin to the misuse of *Ephedra sinica* in the US (discussed in Chapter four). Under traditional Chinese medicine, *Ephedra* is one of the oldest and widely used herbs for treating asthma, nasal congestion and eczema.[847] Manufacturers of dietary supplements included *Ephedra* in the production of weight-loss and athletic enhancement supplements, which was marketed widely in the US between 1980 and 1990.[848] These supplements resulted in various side effects such as heart attacks, strokes and death, and were eventually banned.[849] The problem here was that the manufacturers did not consider *Ephedra's* traditional use, dosification and contraindications.[850] Practitioners of traditional Chinese medicine were well aware that *Ephedra* was toxic when used in high concentrations. Accordingly, they usually prescribed it in combination with other herbs that had the effect of attenuating its toxicity.[851] This underscores the importance of administering medicinal plants in accordance with traditional knowledge. Thus, inasmuch as chaparral may have side effects, it is an antidote to tuberculosis when used in strict adherence to its traditional usage. It is then clear from this long strand of evidence collected from Africa, Asia and South America that traditional medicines play a vital role in providing treatment for tuberculosis and could contribute to its eradication by 2030 if used appropriately in the health systems of developing and least-developed countries.

Traditional medicine can also aid the realisation of the sustainable development target related to HIV/AIDS by providing affordable palliative care to HIV/AIDS patients. There is evidence that proves that traditional healers have used traditional therapies to not only manage HIV/AIDS opportunistic infections but also to improve the quality of life of

[845] Health Canada, 'Health Canada Warns Consumers Not to Take Products Containing Chaparral' (n 842); see also Blumenthal (n 843).
[846] Blumenthal (n 843).
[847] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9.
[848] Ka Kit Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine (TCM)' (1999) Report for the U.S. Food and Drug Administration 1; see also Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9.
[849] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9; see also 'FDA Notice Prohibiting Sales of Supplements Containing Ephedrine Alkaloids (Ephedra)' (*Herbal Extract Plus*, 12 April 2004) <http://www.herbalextractsplus.com/FDAdocs/04.12.04-supplements-containing-ephedrine.html> accessed 7 June 2017.
[850] Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848).
[851] Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848); see also Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9.

persons living with AIDS. This has been acknowledged by government policies, non-governmental organisations (NGOs) and other institutions, particularly regarding the role of traditional healers in providing counselling and support to AIDS patients.[852] In Asia, India's National AIDS Policy acknowledges that an alternative system lies in the traditional system of medicine to resolve the lack of access to the essential medicines problem caused by high prices of medications.[853] The policy states that in situations where antiretroviral drugs are extremely expensive, there is a need to resort to the indigenous systems, such as Ayurveda, Unani, and Siddha.[854] It recognised that many of the medicines in these systems could potentially reduce the viral load in the body of the patients, thereby ensuring a healthier and longer life despite the infection.[855]

Under the traditional Chinese medicine, 'qian-kun-nin', a herbal formulation believed to have anti-infection, antitumour, antiretroviral and immunomodulatory properties, was evaluated for its efficacy.[856] For a 24-week period, eight HIV-positive patients were given oral qian-kun-nin in a single-blind trial.[857] There was a great reduction in the plasma virus load in contrast to the baseline level at the end of week 12 and week 24.[858] The reduction remained so even four weeks after cessation of the qian-kun-nin treatment.[859] Blood tests to measure the CD4 cells – white blood cells that fight infection[860] – showed a significant increase at the end of week 12 compared to the baseline level.[861] There were also no adverse effects or side effects recorded in any of the patients.[862] Although this seems to

[852] Marlise Ritcher, 'Traditional Healers and Traditional Medicines in South Africa' (2003) Discussion Paper Prepared for the Treatment Action Campaign and AIDS Law Project 9-10.
[853] 'India's National AIDS Policy' <http://www.youth-policy.com/Policies/India%20National%20AIDS%20Policy.pdf> accessed 1 June 2016.
[854] ibid.
[855] ibid.
[856] Lui Zang, Shi-Tao Yue, Yong-Xui Xue, Anoja S Attele and Chun-Su Yuan, 'Effects of Qian-Kun-Nin, A Chinese Herbal Medicine Formulation, on HIV Positive Subjects: A Pilot Study' (2000) 28(3-4) *American Journal of Chinese Medicine* 305-312.
[857] The idea of 'blinding' involves a clinical trial or experiment where only the researchers know which subjects are administered the active medication and which are not, with the aim of eliminating the placebo effect from the test results – see Larry E Miller and Morgan E Stewart, 'The Blind Leading the Blind: Use and Misuse of Blinding in Randomized Controlled Trials' (2011) 32 *Contemporary Clinical Trials* 240-243.
[858] Zang et al., 'Effects of Qian-Kun-Nin, A Chinese Herbal Medicine Formulation, on HIV Positive Subjects' (n 856) 305-312.
[859] ibid.
[860] Jonathan Kaplan, 'CD4 Cells, HIV, and AIDS: Test Results, What They Mean' (*WebMD*, 7 June 2017) <https://www.webmd.com/hiv-aids/cd4-count-what-does-it-mean#1> accessed 7 April 2018.
[861] Zang et al., 'Effects of Qian-Kun-Nin, A Chinese Herbal Medicine Formulation, on HIV Positive Subjects' (n 856) 305-312.
[862] ibid.

suggest that qian-kun-nin could potentially treat HIV-positive patients, the trial design and the sample size make it problematic to draw solid conclusions from this evaluation.[863] The evaluation does, however, demonstrate the therapeutic potential of traditional medicine to treat HIV and calls attention to the need for standard operating procedures for the clinical evaluation of its medicines.[864]

In the South American region, the plant *Baccharis trinervis* (Lam.) Pers. has been used as traditional medicine for centuries in Bolivia, Colombia, Ecuador, Panama and Venezuela.[865] A study conducted by an AIDS research group searching for South American medicinal plants containing antiviral agents found that 'aqueous' extracted from this traditional medicine showed antiviral activity that may prove useful in treating AIDS patients;[866] but this does not end the story. Further studies are required to ascertain the chemical identification of the active constituents in *B. trinervis* and their potential mechanisms of action.[867] Nonetheless, this study is of consequence in that it supports the hypothesis that traditional medicine embodies untapped remedies for HIV/AIDS that could contribute to achieving sustainable development. There is also the use of cat's claw (*Uncaria tomentosa*) in Bolivia as traditional medicine, which is vital to containing the HIV/AIDS pandemic. This plant is a good immunomodulator that prevents HIV from progressing into AIDS.[868] Even so, the exploitation of cat's claw by biotechnology and pharmaceutical companies for its medicinal properties almost resulted in its extinction in Peru.[869] As will be examined in Chapters four and six, over-exploitation of biological diversity either for traditional medicine or by the biotechnology and pharmaceutical industries poses a challenge to access to traditional medicine for treatment. This

[863] Zang et al., 'Effects of Qian-Kun-Nin, A Chinese Herbal Medicine Formulation, on HIV Positive Subjects' (n 856) 305-312.
[864] ibid.
[865] Susan E Freire, Estrella Urtubey and Daniel A. Giuliano, 'Epidermal Characters of Baccharis (Asteraceae) Species used in Traditional Medicine' (2007) 29(1) *Caldasia* 23, 29.
[866] Sonsoles Sanchez Palomino, María José Abad, Luis Miguel Bedoya, Javier García, Eduardo Gonzales, Ximena Chiriboga, Paulina Bermejo and José Alcami, 'Screening of South American Plants against Human Immunodeficiency Virus: Preliminary Fractionation of Aqueous Extract from *Baccharis Trinervis*' (2002) 25(9) *Biological and Pharmaceutical Bulletin* 1147-1150, 1149.
[867] ibid.
[868] Lunny (n 840).
[869] Karen Timmermans, 'Trips, CBD and Traditional Medicines: Concepts and Questions' (Jakarta, Indonesia, WHO: Report of an ASEAN Workshop on the TRIPS Agreement and Traditional Medicine, 2001).

necessitates the conservation of biodiversity and the sustainable use of its components as provided by the Convention on Biological Diversity 1992.

In Africa, traditional medicine has played a major part in providing health solutions for people living with HIV/AIDS. A traditional healer based in Chitungwiza in Zimbabwe – Itai Bakasa – confirmed that they (traditional healers) do not only treat but also offer counselling services.[870] His words were that '[o]ur clients believe in us, and we are helping them fight STIs and HIV/AIDS'.[871] This statement is not without backing; there is evidence not just in Zimbabwe, but also in other developing and least-developed African countries that suggests that traditional healers impact positively on the health of persons living with AIDS through their treatments. In 2001, another Zimbabwean traditional healer named Mutsa Chikede advertised the use of a traditional spell that ensured fidelity, together with the more conventional methods of condoms and abstinence to curb the spread of AIDS.[872] The Tonga ethnic group of Zimbabwe and Zambia had for long used this magic spell to 'lock' their young girls to prevent them from engaging in pre-marital sex, but unlocked them when they got married.[873] According to Chikede, if cast, the spell would magically 'lock women' and 'immobilise men', thereby preventing them from having extra-marital sex, as condoms and abstinence only had a limited impact in stemming the spread of AIDS in Zimbabwe.[874] Traditional herbs were used to cast the spell and could be administered by a healer even in the absence of the subject.[875] This technique became popularly known as 'the locking system' or 'the immobiliser' and was reversible in the event of a partner's death or divorce.[876] At the time it was introduced, about 45 couples locked themselves. However, there is no evidence regarding whether or not more people subscribed to this technique.[877]

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[870] Tendai Chara, 'Traditional Healers Want Stake in Self-testing' *The Sunday Mail* (20 March 2016).
[871] ibid.
[872] Yahoo Groups, 'Central Locking System to Lock AIDS Out?' (15 October 2001) <https://groups.yahoo.com/neo/groups/zimbabwe2/conversations/topics/3725> accessed 29 May 2016.
[873] 'Magic Fidelity Spell for AIDS' *News24* (Harare: 10 October 2001) <http://www.news24.com/xArchive/Archive/Magic-fidelity-spell-for-Aids-20011010> accessed 8 June 2017.
[874] Yahoo Groups, 'Central Locking System to Lock AIDS Out?' (n 872).
[875] ibid.
[876] ibid.
[877] ibid.

What is clear, nonetheless, is that there were divided opinions regarding its utilisation in preventing HIV/AIDS and other sexually transmitted diseases (STDs). The Zimbabwean Minister for Health at the time – Timothy Stamps – described the practice as 'primitive and contrary to every concept of human dignity and rights'.[878] He explained that it was disrespectful to the institution of marriage, as marriage was not a prison. People did not get married expecting to be locked into marriage 'like animals' or 'as if it were a form of slavery'.[879] In his view, the idea was destined to fail 'because people had always found ways to go round locks in the past'.[880] For Carolyn Maposhere of the Women and AIDS Support Network, the lack of evidence regarding the side effects of such practices posed a problem.[881] Moreover, she expressed the belief that casting spells on people was not the proper way to curb HIV/AIDS; 'there [had] to be a voluntary change of behaviour'.[882] On the other side of the divide, other traditional healers such as Chikede thought that the technique was an ingenious measure to prevent HIV/AIDS, and could even frustrate rape attempts.[883]As far as these arguments go, they do not dispute that the magic spell could have potentially prevented the spread of HIV/AIDS and even rape. This is conceivably on account of its success amongst the Tonga minority ethnic group in preserving their girls for marriage. The issues these arguments raise represent the moral stance of their proponents and by no means depreciate the efficacy of the spell. Clearly, the 45 couples that had themselves locked perceived it as an effective measure to guard against diseases, and so did the group of traditional healers. However, the real concern about the spell technique appears to be the lack of evidence as to its side effects, and this concern is one that pervades the use of traditional medicine.

The concern regarding some traditional medicines is not limited to the absence of evidence regarding adverse reactions, but also the limited knowledge regarding their pharmacological effects.[884] A Zimbabwean study conducted by Dr MB Sebit and his colleagues evaluated the quality of life of people living with AIDS by administering herbal medicine to 79 per cent of the participants, whereas 21 per cent received

[878] ibid.
[879] ibid.
[880] ibid.
[881] ibid.
[882] ibid.
[883] ibid.
[884] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).

conventional medical care.[885] The study adopted the WHO Quality of Life Project instrument to determine the quality of life and the measured disease progression. While the data generated from this study substantiated the efficacy of herbal medicines in improving the quality of life of HIV-1 infected patients, their pharmacological effects were unknown.[886] As with the study on *B. trinervis* in South America, this situation demands further research to determine the active chemical ingredients, effects and modes of action of the herbal medicines used. The problem, however, is the arduous nature of research on herbal medicines. Evaluating the pharmacological effects of a herbal medicine prepared by a single medicinal plant involves a complex process, as a plant may comprise hundreds of chemical components.[887] It is even more onerous to assess a multi-component herbal medicine, which could contain three times that number of active ingredients.[888] Thus, the financial exaction of undertaking research to ascertain the potential mechanisms of action of herbal medicines could be prohibitive.[889]

This notwithstanding, the need to expand the knowledge base regarding the pharmacological basis of traditional medicines cannot be overemphasised considering the potential risk of unsafe and ineffective herbal medicines on the health of patients or consumers. The touting of *Sutherlandia frutescens* (cancer bush) as a cure for cancer and HIV/AIDS exemplifies this point. The cancer bush is a legume grown in Southern Africa, which is said to have been used traditionally to treat symptoms of HIV/AIDS such as diarrhoea, tuberculosis, and weight loss and to boost the immune system.[890] Several

[885] MB Sebit, SK Chandiwana, AS Latif, E Gomo, SW Acuda, F Makoni and J Vushe, 'Quality of Life Evaluation in Patients with HIV-1 Infection: The Impact of Traditional Medicine in Zimbabwe' (2000) 46(8) *Central Journal of Medicine* 208-213.
[886] Sebit et al. (n 885).
[887] Ossy M J Kasilo and Jean-Marie Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' *African Health Monitor* (World Health Organization Regional Office for Africa 2013); see also 'WHO Traditional Medicine Strategy 2002-2005' (n 12); and Harry H S Fong, Guido F Pauli, Judy L Bolton, Richard B van Breemen, Suzanne Banuvar, Lee Shulman, Stacie E. Geller and Norman R Farnsworth, 'Evidence-Based Herbal Medicine: Challenges in Efficacy and Safety Assessment' in Ping-Chung Leung, Harry H S Fong and Charlie C. Xue (eds), *Current Review of Chinese Medicine: Quality Control of Herbs and Herbal Materials* (World Scientific 2006) 11.
[888] ibid.
[889] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[890] JA Ojewole, 'Analgesic, Antiinflammatory and Hypoglycemic Effects of Sutherlandia Frutescens R. BR. (variety Incana E. MEY.) [Fabaceae] shoot aqueous extract' (2004) 26(6) *Methods and Findings in Experimental and Clinical Pharmacology* 409-416; see also M Thornley, 'Sutherlandia or Cancer Bush of South Africa Aids in the Treatment of Wasting Diseases' *Natural News* (4 February 2010) <http://www.naturalnews.com/028085_cancer_bush_wasting_diseases.html > accessed 11 June 2017; and Janine Erasmus, 'Latest Study on 'Miracle' HIV Plant' (*Brand South Africa*, 11 February 2011)

studies have been carried out in South Africa to determine the safety and efficacy of *sutherlandia.* Phyto Nova (PTY) Ltd, a South African Company that research, promotes and distributes traditional medicines from indigenous African plants, studied *sutherlandia* and concluded that this traditional medicine had a positive effect on the quality of life of persons living with AIDS.[891] It observed that about 4,000 of their patients who, though not on antiretroviral but used *Sutherlandia*, manifested an improvement in appetite, exercise tolerance, mood, and sense of well-being.[892] Some others exhibited an increase in weight within six weeks of starting the treatment.[893] Likewise, a study conducted by the South African Medical Research Committee (MRC) concluded that the plant was safe to use, as it showed no sign of toxicity.[894] Another study by the South African Herbal Science and Medicine Institute (SAHSMI) at the University of Cape Town equally confirmed the safety and efficacy of *sutherlandia*, as the trial data disclosed a high level of tolerance and no adverse reaction amongst the patients who ingested the plant.[895]

In addition to these studies, the use of *sutherlandia* by traditional healers in treating AIDS patients is widespread in South Africa. For instance, there was a report of a traditional healer who administered the plant to a terminal AIDS patient whose health improved after that.[896] There was also an ethnobotanist and Research Fellow with the Zululand University, Anne Hutchings, who was renowned for treating AIDS patients with *sutherlandia* alongside other herbs at the Ngwelezena Hospital's AIDS clinic in Northern KwaZulu-Natal, South Africa.[897] 176 of her patients are said to have attributed the improvement in their health to *sutherlandia*.[898] While these lend weight to the efficacy of *sutherlandia* in improving the quality of life of persons living with AIDS, there is emerging research that suggests the contrary. A report by the GAIA Research Institute in South Africa noted that *sutherlandia* contains a substantial amount of canavanine, which

<https://www.brandsouthafrica.com/investments-immigration/science-technology/sutherlandia-220211> accessed 11 June 2017.
[891] Ritcher (n 852) 9-10.
[892] ibid.
[893] ibid.
[894] Erasmus (n 890); see also Ritcher (n 852) 9-10.
[895] ibid.
[896] Thornley (n 890).
[897] Thornley (n 890).
[898] ibid.

is a non-proteinogenic amino acid[899] that is capable of inhibiting the activity of the immune system.[900] In effect, when ingested, canavanine suppresses vital immune responses against infections such as the HIV.[901] What this suggests is that *sutherlandia* is not an immune booster, contrary to traditional medicine claims. Since AIDS progressively causes the failure of the human immune system,[902] what is needed to defuse its activity is an immunomodulator, as opposed to an immunosuppressant. Based on this, the report concluded that *sutherlandia* is 'an extremely dangerous substance and ought not to be fraudulently sold as a safe and efficacious panacea'.[903]

Another research from the Stellenbosch University (SU) in South Africa issued a warning to HIV-positive patients against the use of *sutherlandia*. According to this research, HIV causes chronic inflammation of the central nervous system once a person is infected.[904] This neuro-inflammation further progresses into neuro-degeneration and dementia. The appropriate medical action in such a situation would be to administer medicine targeted at limiting the extent of the neuro-inflammation, particularly given that antiretroviral drugs do not perform this function.[905] As opposed to achieving this, the research found that the ingestion of *sutherlandia* increases the neuro-inflammation in the HIV-positive patient.[906] It must be noted, however, that this conclusion does not disprove the traditional use of *sutherlandia* to treat diarrhoea, tuberculosis and weight loss in an HIV-negative patient. Instead, it merely suggests that *sutherlandia's* pharmacological activity changes once a person has contracted HIV.[907] This disagreement regarding the safety and efficacy of *sutherlandia* leaves one with the conclusion that its true pharmacological effects in treating HIV/AIDS are unknown, as the conflicting outcomes of these researches cancel

[899] Pawel Staszek, Leslie A. Weston, Katarzyna Ciacka, Urszula Krasuska and Agnieszka Gniazdowaka, 'L-Canavanine: How Does a Simple Non-Protein Amino Acid Inhibit Cellular Function in a Diverse Living Cell' (2017) 16(6) *Phytochemistry Reviews* 1269-1282.
[900] Stuart Thomson, 'Canavanine Toxicity: Is Sutherlandia a Healthy Herb or Potent(ial) Poison? HIV Positives and AIDS Sufferers Beware: The Remedy may be Worse than the Alleged Disease' (*GAIA Organics*, August 2002) <http://www.gaiaresearch.co.za/sutherlandia.html> accessed 10 June 2017.
[901] ibid.
[902] Simon Situma Barasa, 'True Story About HIV: Theory of Viral Sequestration and Reserve Infection' (2011) 3 *HIV/AIDS* (*Auckland, N.Z.*) 125-133.
[903] Thomson (n 900).
[904] Wiida Fourie-Basson, 'New Research Warns Against Use of Sutherlandia Frutescens by HIV-positive Individuals' (*Stellenbosch University*, 1 December 2015) <http://www.sun.ac.za/english/Lists/news/DispForm.aspx?ID=3239> accessed 10 June 2017.
[905] ibid.
[906] ibid.
[907] Fourie-Basson (n 904).

out one another. Prescribing herbal medicines whose uses, effects and modes of action are not understood could be harmful to the health of patients or consumers. For this reason, it is acutely important to generate sound knowledge regarding the pharmacological uses of traditional medicine. To this extent, there is a need to promote collaboration and knowledge exchange between traditional and conventional medicine practitioners in utilising traditional medicine and investigating their safety and efficacy.[908]

It would be wrong to generalise based on this situation with *sutherlandia* that traditional remedies are not safe and effective against HIV/AIDS symptoms. There have been various movements in Uganda (located in East Africa) to promote the role of traditional medicine in fighting HIV/AIDS. The Ugandan Commission and the Joint Clinical Research Centre (JCRC) (a care and research institution established in 1990 to develop a scientific approach to the national HIV/AIDS challenge)[909] in Kampala have worked with traditional healers in assessing various traditional treatments used locally.[910] The research concluded that traditional medicine was more suitable for treating some AIDS symptoms such as weight loss, chronic diarrhoea, shingles and herpes zoster.[911] This is similar to the outcome of the clinical trials conducted by the Ugandan NGO, Traditional and Modern Health Practitioners Together Against AIDS (THETA), on Ugandan herbal treatments for herpes zoster.

THETA was established in 1992 to conduct research on potentially useful traditional medicine for HIV-related illnesses and to promote a mutually respectful collaboration between traditional and conventional health workers in the fight against AIDS.[912] The trials compared the experiences of patients receiving herbal treatment with those on acyclovir – the conventional treatment for herpes zoster.[913] Although the trials found that

[908] More on this in Chapters four and five.
[909] 'Joint Clinical Research Centre (JCRC)' <http://www.jcrc.org.ug> accessed 8 June 2017.
[910] See <http://www.aidsuganda.org/response/govt_sectors/cso_programs/theta.htm> accessed 1 June 2016.
[911] ibid.
[912] G Bodeker, M Dvorak-Little, G Carter and G Burford, 'HIV/AIDS: Traditional Systems of Health Care in the Management of a Global Epidemic' (2006) 12 *Journal of Alternative and Complementary Medicine* 563-576.
[913] Bodeker et al., 'HIV/AIDS: Traditional Systems of Health Care in the Management of a Global Epidemic' (n 912).

both groups experienced the same rate of resolution of herpes zoster attacks, the traditional medicine group had less super-infection and showed less keloid than did the patients on acyclovir.[914] Also, pains from herpes zoster resolved significantly faster in the traditional medicine group.[915] Thus, the researchers found that traditional medicine is an important local and affordable alternative in managing herpes zoster in HIV infected patients in Uganda.[916] Such traditional treatments for managing herpes zoster and other HIV opportunistic illnesses such as diarrhoea and tuberculosis also exist in Namibia. There, traditional healers use *Kigelia Africana* (Lam.) Benth (Sausage tree), *Garcinia livingstonei* (African Mangosteen) and *Garcinia buchananii* Bak. (Granite Mangosteen) for treating these diseases.[917]

Admittedly, the traditional medicine system is far from perfect. The research conducted to determine the safety and efficacy of its remedies are inadequate due to the utilisation of poor methodologies. It is within the bounds of possibility that in addition to the complexity of researching herbal medicines, the adoption of poor methodologies has culminated in the lack of good understanding regarding the safety and efficacy of some traditional treatments. While this situation necessitates further research to expand the knowledge base, it cannot be gainsaid that traditional medicine can make a valuable contribution to achieving sustainable development. Despite the challenges confronting its use, the traditional medicine system embodies curative and palliative remedies for malaria, tuberculosis and HIV/AIDS. These remedies have provided some of the world's poorest people with access to medicines for centuries.[918] The use of traditional medicines has continued to proliferate not only in developing and least-developed countries but also in the developed world, owing to its immense value in the healthcare system.[919] Because it improves health by providing medicines for malaria, tuberculosis and HIV/AIDS,

[914] ibid.
[915] ibid.
[916] ibid.
[917] Alfred Maroyi, 'Alternative Medicines for HIV in Resource-Poor Settings: Insight from Traditional Medicines Use in Sub-Saharan Africa' (2014) 13(9) *Tropical Journal of Pharmaceutical Research* 1527-1536, 1529-1530; see also K C Chinsembu and M Hedimbi, 'An Ethnobotanical Survey of Plants Used to Manage HIV/AIDS Opportunistic Infections in Katima Mulilo, Caprivi Region, Namibia' (2010) 6 *Journal of Ethnobiology and Ethnomedicine* 25-33; and A Cheikhyoussef, I Mapaure and I Shapi, 'The Use of Some Indigenous Plants for Medicinal and Other Purposes by Local Communities in Namibia with Emphasis on Oshikoto Region: A Review' (2011) 5 *Research Journal of Medicinal Plants* 406-419 for other medicinal plants used in treating herpes zoster and diarrhoea in Namibia.
[918] Strong (n 790) 17.
[919] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).

traditional medicine can facilitate the eradication of these pandemics by 2030, thereby contributing to sustainable development. The next section considers some of the reasons for the increased global use of traditional medicine.

3.3. Why People Resort to Traditional Medicine

That traditional medicine can provide treatment for malaria, tuberculosis and HIV/AIDS appears not to be the only reason why it is recognised widely as a vital source of primary health care. Besides this, there are other factors responsible for its appeal to some of the world's populations over conventional medicine. This section considers these factors and their implication for sustainable development.

To begin with, the conventional medicine approach to treatment is 'reductionist'. This means that it commences treatment based on the theory that illnesses stem from biological causes, thereby de-emphasising psychosomatic factors as capable of causing diseases.[920] Yet it must be pointed out that the cause of the illnesses of an estimated 70 to 80 per cent of patients is said to have no biological origin.[921] In contrast to this reductionist approach, the traditional medicine system understands diseases to be psychosomatic and psychosocial conditions.[922] A person's well-being is closely associated with his/her harmonious interaction with the community and other supernatural forces, and the balance between such interactions.[923] Thus, the healing practices of traditional systems of medicine emphasise the psychosomatic aspects of illness.[924] This difference in approach originates from the different understanding of the body.[925] From its inception, conventional medicine conceptualised humankind as comprised of separate parts (body, mind, and spirit), as opposed to an integrated whole.[926] The Cartesian scientific materialism, in which conventional medicine is rooted, emphasises the separateness of

[920] Oguamanam, International Law and Indigenous Knowledge (n 69) 112-113.
[921] ibid; see also Charles M Good, Ethnomedical Systems in Africa: Patterns of Traditional Medicines in Rural and Urban Kenya (New York and London: Guilford Press 1987).
[922] Oguamanam, *International Law and Indigenous Knowledge* (n 69) 112-113; see also Mamadou Koumare, 'Traditional Medicine and Psychiatry in Africa' in Robert H Bannerman, John Burton and Ch'en Wen-Chieh (eds), *Traditional Medicine and Health Care Coverage: A Reader for Health Administrators and Practitioners* (Geneva: World Health Organization 1983) 25.
[923] Oguamanam, International Law and Indigenous Knowledge (n 69).
[924] ibid.
[925] ibid 112-113.
[926] ibid; see also Cecil G Helman, *Culture, Health and Illness* (Oxford: Butterworth 2000) 81-82.

the mind and body.[927] Even the Judeo-Christian tradition subscribes to this view.[928] This largely accounts for the organismic approach to sickness, while disregarding the psychological dimension. In contrast, the traditional system of medicine views the individual as an integrated whole, comprising the indivisible unity of the mind, body and soul.[929] Extending this body-mind unity to the relationship between the individual and the community is the goal of the traditional system of medicine.[930]

Traditional medicine, therefore, proceeds on this assumption of body-mind unity, so that any disruption to its harmony and balance is the cause of sickness.[931] In treating such sickness, a holistic approach is taken without differentiation between the individual and his/her body parts.[932] 'Therapeutic intervention is a total package comprising complex diagnostic and curative rituals rooted in cultural, religious and psychosocial appeals'.[933] For instance in Asia, the traditional Ayurvedic healers in India regard life as holistic, comprised of body, sense, mind and soul.[934] It then means, in light of this, that good health is seen as a combination of physical, mental, social, moral and spiritual welfare.[935] The inclusion of moral and spiritual aspects adds a new dimension to man and the system of medicine by which he maintains health.[936] This difference in approach is one of the reasons some people find traditional medicine more appealing than conventional medicine; more so, because there is a revived interest in the 'whole-person-care' and disease prevention, which are offered by the traditional system of medicine.[937] According to the former Director-General of WHO, Dr Margaret Chan, there has been a public outcry against the 'over-medicalised' and 'over-specialised' health care offered by the conventional medicine system, where 'the patient is treated like a collection of specialised

[927] Oguamanam, International Law and Indigenous Knowledge (n 69).
[928] ibid.
[929] ibid.
[930] ibid.
[931] Bonnie B O'Connor and David J Hufford, 'Understanding Folk Medicine' in Eric Brady (ed), *Healing Logics: Culture and Medicine in Modern Belief Systems* (Logan: Utah State University Press 2001) 13, 19; see also Oguamanam, *International Law and Indigenous Knowledge* (n 69) 113.
[932] Oguamanam, International Law and Indigenous Knowledge (n 69).
[933] ibid.
[934] World Health Organization, The Promotion and Development of Traditional Medicine (787).
[935] ibid.
[936] ibid.
[937] Robert di Sarsina P, 'The Social Demand for a Medicine Focused on the Person: The Contribution of CAM to Healthcare and Healthgenesis' (2007) 4(1) *Evidence-Based Complementary and Alternative Medicine* 45-51.

body-parts, and not as a whole person'.[938] She further noted that '[patients] want more control over what is done to their bodies; they want to self-regulate their own health'.[939] However, some people mistrust that conventional medicine can offer such flexibility: because it strictly adheres to the dictates of science, in which objectivity is a virtue, both the therapeutic environment and the physician-patient relationship are purely formal and highly focused on treatment, leaving no room for any other form of interaction.[940]

Conversely, the traditional therapeutic environment is informal to the extent that patients interact with most, if not all, members of the therapeutic community who are involved in the healing process. This relationship focuses on spiritual and sociocultural processes with no place for objectivity.[941] Thus, while conventional medicine offers symptomatic treatment and ignores the underlying causes, traditional medicine considers the person's constitution, the surrounding environment, diet – conditions that gave rise to the illness in the first place.[942] The type of treatment prescribed by traditional medicine is tailored according to the needs of the individual. The course of treatment is a function of a belief that each has his or her peculiar constitution and social circumstances that disrupt the balance and harmony of the body and mind.[943] Different treatments may thus be given to different people even though conventional medicine finds that they suffer from the same sickness.[944] In essence, healing takes a holistic approach, treating the patient's spiritual, mental and physical well-being[945] – an approach which not only accords with WHO's definition of health, as 'a state of complete physical, mental and social well-being',[946] but also contemplates the spiritual aspect which, although it may not be important to some people, matters to others (as noted in Chapter one).

[938] Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (n 10).
[939] ibid.
[940] Oguamanam, International Law and Indigenous Knowledge (n 69).
[941] ibid.
[942] Carlin Carr, 'Traditional Healing: Modern Medicine's Friend or Foe?' *Guardian* (17 September 2014).
[943] World Health Organization, 'Technical Briefing on Traditional Medicine' (Manila, Philippines: Forty-Ninth Regional Committee Meeting 1998).
[944] ibid.
[945] Matthew Steinglass, 'It Takes a Village Healer – Anthropologists Believe Traditional Medicine Can Remedy Africa's AIDS Crisis. Are they Right?' (2001) 11(3) *Lingua Franca*.
[946] Constitution of the World Health Organization 1946; see also Oguamanam, *International Law and Indigenous Knowledge* (n 69) 94-95.

In Africa, the desirability of the traditional medicine system can equally be seen in the most fundamental psychological dilemma that reveals itself in the form of a 'why thought' in the minds of most sick people. When convinced that their health has deteriorated, most people in Africa usually struggle with thoughts such as: 'why me', i.e. why has this disease chosen to strike me in particular; 'why at this place, day and date?'[947] These questions are of a nature that cannot be resolved scientifically[948] or by simply attributing the disease to the activities of pathogens. In fact, they call attention to an understanding of causes of sickness very distinct from that of the conventional medicine system, thereby unearthing the point that beliefs that stem from their cultures influence the way some people react to diseases.[949] This underscores the appeal of the approach to treatment provided by witchdoctors, shamans, *Babalawos*, soothsayers and other traditional healers, as it is based on traditional medical knowledge rooted in communities' cultures and religious values, and reaches beyond organismic considerations to restore harmony between the individual and his/her environment. For this reason, some people opt for traditional therapies based on cultural preference or tend to be culturally motivated to use them, and subsequently feel more comfortable adhering to traditional health practices.[950] Moreover, it is 'the people's own health system' and thus, accepted by them.[951] Being an integral part of their culture, it is effective in solving their cultural health problems.[952] (Causation in the traditional medicine system will be discussed further in section 3.4 below.)

The extensive use of traditional medicine is also attributed to its accessibility, particularly in developing and least-developed countries. In this case, accessibility relates to the availability and affordability of medical services. In Africa, it would appear that there are more traditional practitioners than there are conventional physicians.[953] In South Africa

[947] Charles Takoyoh Eyong, 'Indigenous Knowledge and Sustainable Development in Africa: Case Study on Central Africa' in E K Boon and L Hens (eds), *Indigenous Knowledge Systems and Sustainable Development: Relevance for Africa* (Kamla-Raj Enterprises 2007) 121, 125.
[948] ibid.
[949] ibid.
[950] Stacey Links, 'HIV/AIDS and Traditional Medicine' (*Culture and Human Rights* 19 November 2013); see also F M C Sharples, R van Haselen and P Fisher, 'NHS Patients' Perspective on Complementary Medicine: A Survey' (2003) 11(4) *Complementary Therapies in Medicine* 243-248.
[951] World Health Organization, The Promotion and Development of Traditional Medicine (787).
[952] ibid.
[953] Nicolas Gorjestani, 'Indigenous Knowledge for Development: Opportunities and Challenges' (2000) Washington, DC: World Bank <http://www.worldbank.org/afr/ik/ikpaper_0102.pdf> accessed 20 May 2016; see also Christian (n 784).

where an estimated 80 per cent of the population depends on traditional medicine, statistics show that the ratio of traditional healers to conventional medicine practitioners is 8:1.[954] In Uganda also, the ratio of conventional physicians to patients is estimated to be about 1:20,000, whereas the ratio of traditional healers to patients is 1:200.[955] The brunt of this shortage in conventional medicine personnel is borne mostly by people living in rural areas, as there is a lopsided distribution of the available personnel, with the majority of them found in cities or urban areas, thereby making access difficult for rural dwellers.[956] Further aggravating this situation is the fact that hospitals and pharmacies are also unevenly distributed, with most of them located in cities. Access to these facilities is usually not easy, especially for rural dwellers, owing to the poor state of infrastructures in most African countries.

In Cameroon, people living in rural areas travel for days before finding the nearest dispensary and pharmacy or health clinic to seek health care.[957] The inconveniences resulting from this are multifold, ranging from loss of workdays to high transport fares, in addition to the high cost of medication.[958] Similarly, the majority of the rural Ethiopian population is said to rely mostly on traditional medicine for healthcare, mainly due to the absence of vehicular roads to access conventional health services, which are located in urban areas.[959] Efforts such as the construction of new hospitals and renovation of existing ones, including importing drugs and the training of doctors and nurses, do little to change the situation of the estimated 40 million rural Ethiopians, due to lack of infrastructure to access such services.[960] Likewise in South Africa, difficulty in physically

[954] Links (950).
[955] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[956] ibid.
[957] C N Fokunang, V Ndikum, OY Tabi, RB Jiofack, B Ngameni, NM Guedje, EA Tembe-Fokunang, P Tomkins, S Barkwan, F Kechia, E Asongalem, J Ngoupayou, NJ Torimiro, KH Gonsu, V Sielinou, BT Ngadjui, F Angwafor, A Nkongmeneck, J Ngogang, V Colizzi, J Lohoue and Kamsu-Kom, 'Traditional Medicine: Past, Present and Future Research and Development Prospects and Integration in the National Health System of Cameroon' (2011) 8(3) *African Journal of Traditional, Complementary and Alternative Medicines* 284-295.
[958] ibid.
[959] World Bank, 'Ethiopia: Traditional Medicine and the Bridge to Better Health' (2001) 35 *IK Notes* Washington, DC: World Bank <http://documents.worldbank.org/curated/en/2001/08/1561439/ethiopia-traditional-medicine-bridge-better-health> accessed 26 May 2016.
[960] ibid.

accessing conventional medical services has been cited as one of the reasons why there is a heavy reliance on traditional medicine by a significant number of the population.[961]

Regarding affordability, the high cost of some conventional medicines has made them inaccessible to people living on low wages in developing and least-developed countries.[962] As a result, traditional medicine has served as the primary source of health care, as it is affordable, accessible and acceptable in most local communities.[963] There is evidence that seems to substantiate this fact. Bob Stanley reported that studies conducted between 2004 and 2010 confirm that traditional medicine remains the most affordable and accessible form of health care for most Africans, mainly rural dwellers.[964] The WHO has also noted that research conducted in Ghana, Mali and Kenya showed that a course of pyrimethamine/sulfadoxine antimalarials cost more than the per capita out-of-pocket health expenditure which is about US$6 per year.[965] Meanwhile, traditional medicines for treating malaria are considerably cheaper and in some cases are paid for in kind or according to the wealth of the patient.[966] Peter Kooreman and Eric Baars have equally reported a study, which found that patients whose general practitioners also offered CAM pay less for health care, and live longer than those who do not.[967] The reduced cost was put down to fewer hospital stays and fewer prescription drugs.[968] Further, the low price of traditional medicine is attributed to its being derived from biological resources and in some cases costs little or nothing to produce.[969] Besides, traditional healers perceive their services as a humanitarian call, as opposed to an avenue for making profit.[970]

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[961] Links (950).
[962] Alex Okumo, 'The Making of a New Paradox' 9 *Pax Herbal Magazine* (28 November 2008) <http://magazine.paxherbals.net/paxmag/issue-09/the-making-of-a-new-paradox.html> accessed 15 June 2016.
[963] ibid.
[964] Bob Stanley, 'Recognition and Respect for African Traditional Medicine' (2004) International Development Research Centre <https://www.idrc.ca/en/article/recognition-and-respect-african-traditional-medicine> accessed 23 June 2017.
[965] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[966] ibid.
[967] P Kooreman and E W Baars, 'Patients Whose GP Knows Complementary Medicine Tend to Have Lower Costs and Live Longer' (2012) 13(6) *European Journal of Health Economics* 769-776.
[968] ibid.
[969] Okumo (n 962).
[970] ibid.

While there is some truth to the fact that traditional medicine is more affordable than conventional health services, this may not always be the case. As will be discussed in Chapters four and five, the standardisation of traditional medicine in order to ensure that it is of good quality, safe and effective could potentially inflate its cost, as such exercise requires a substantial amount of investment by manufacturers of herbal medicines who would seek to recoup sunk cost, as well as garner profit from their investment. Furthermore, some specialist-traditional healers charge very high prices for their services.[971] A study of traditional healers in Tanzania by Patterson Bakari concluded that they often charged higher than the government hospitals.[972] Yet high levels of spending were recorded on traditional medicine in Tanzania. [973] Hence in this instance, unaffordability of conventional medicines did not account for why people resorted to traditional medicine. It was found that one of the reasons was the flexibility offered by traditional healers in terms of *how* and *when* fees are to be paid.[974] This was tailored according to the economic circumstances of the population so that a person could pay for traditional treatments by alternative means, such as compensation in kind or in work, or payment on a credit basis.[975] Another reason according to Patterson Bakari was that people considered traditional medicine convenient, accessible and more effective than conventional medicines.[976]

The perception of traditional medicine as more effective is as a result of some inadequacies of conventional medicine. There is growing awareness regarding the resistance of bacteria to antibiotics and the existence of diseases that have proven incurable by conventional medicine, such as certain forms of HIV.[977] Likewise, there are trepidations about the adverse effects caused by the ingestion of chemical drugs.[978] These

[971] Katrina Brown, 'Medicinal Plants, Indigenous Medicine and Conservation of Biodiversity in Ghana' (1992) CSERGE Working Paper 9; see also J Falconer, 'Non-timber Forest Products in Southern Ghana' (Draft Report to ODA 1992).
[972] Patterson J Bakari, 'Co-operation and Collaboration Between Traditional Healers of the Biomedical Health Sector in Dar-es-salaam: Some Preliminary Observations' (2007) Paper Presented at the Eight International Congress of the World Federation of Public Health Association, Arusha, Tanzania 5; see also Muela et al. (n 129) 296.
[973] Muela et al. (n 129).
[974] ibid 301.
[975] ibid.
[976] Bakari (n 972) 5; see also Muela et al. (n 129) 296.
[977] Petra Ebermann, Patents as Protection of Traditional Medical Knowledge? A Law and Economics Analysis (Intersentia Publishing Limited 2012) 1.
[978] Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (n 10).

explain away the increase in the utilisation of traditional medicine for health care. For instance, a survey of the Royal London Hospital for Integrated Medicine pointed to the failure of other treatments and experience of adverse effects from conventional medicine as the reasons for patients' visit to the hospital.[979] Also, interviews with traditional medicine users in Australia disclosed that failure of conventional medical treatments and a desire for good health were the principal motives for resorting to traditional therapy.[980] In addition to these reasons, there is a strong belief that 'natural means safe'.[981] This means that patients hold the belief that traditional therapies are safe since they incorporate plants, animals and minerals.

However, this reasoning is misguided. The *Ephedra sinica* case (discussed above) supports this assertion. Although the therapeutic use of the herb under traditional Chinese medicine dates as far back as 2,000 years ago, its use in manufacturing weight-loss and athletic enhancement supplements in the US resulted in many people having heart attacks, strokes and death.[982] Recall that this adverse effect of *Ephedra* occurred from non-compliance by the manufacturers of the supplement with its traditional use, dosage and contraindications.[983] Therefore, herbal drugs could be harmful if they are prepared without recourse to the guidance of the traditional medical knowledge of their uses.[984] Using herbs, as well as their active ingredients, without proper diagnosis and independently of traditional guidelines should not be considered traditional medicine.[985] This can be rationalised on the grounds that a herbal preparation can only qualify as traditional medicine when it has been developed following traditional knowledge and practices used in diagnosis, prevention and elimination of physical, mental or social imbalance.[986] What this presupposes is that herbal medicines are more likely to be safe and effective when prepared and used according to the traditional knowledge of the indigenous peoples.

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[979] Sharples et al. (n 950) 243-248.
[980] M Williamson, J Tudball, M Toms, F Garden and A Grunseit, 'Information Use and Needs of Complementary Medicine Users' (2008) Sydney: National Prescribing Service.
[981] World Health Organization, Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (Geneva: World Health Organization 2004).
[982] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9; see also 'FDA Notice Prohibiting Sales of Supplements Containing Ephedrine Alkaloids (Ephedra)' (n 849).
[983] Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848) 3.
[984] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9.
[985] ibid; see also Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848) 1.
[986] See the definition of Traditional Medicine – AFRO Technical Report Series no 1 (n 733).

Thus, it is not only evident that traditional medicine has the potential to provide medicine for malaria, tuberculosis and HIV/AIDS, but these facts that account for its wide acceptance also establish that it can contribute to sustainable development by promoting universal health coverage. The idea behind universal health coverage is to ensure that all people (without leaving anyone behind) have access to promotive, preventive, curative and rehabilitative healthcare services of good quality to participate in, contribute to and enjoy development, as well as to ensure that people do not suffer financial hardship when paying for these services.[987] In light of this, when compared with conventional medicine, which is formalistic, over-medicalised, reductionist, expensive, unavailable and potentially harmful due to the possibility of adverse effects from ingesting chemical drugs, traditional medicine 'is care that is close to homes, accessible and affordable'.[988] In addition to mental, physical and social well-being, healing under the traditional medicine system also considers a patient's spiritual and cultural welfare, thereby adopting a more holistic approach to treatment ('whole-person-care'). These advantages over conventional medicine make it more appealing to some patients, and capable of functioning as a complementary tool to conventional medicine in providing healthcare services for all – thereby contributing to realising sustainable development by 2030.

3.4. Causation of Sickness in the Traditional Medicine System

The role of cultural beliefs in determining the choice of medical care was noted above. These beliefs at times influence the manner in which a person responds to sickness. They embody an understanding of the causes of sickness which cannot be discerned through science. This makes the deficiency of conventional medicine apparent because it focuses on organismic causes of sickness and pays less attention to the operation of psychosomatic and psychosocial elements in causing sickness, and as a result, fails to offer holistic care. A consideration of these psychosomatic and psychosocial elements would mean understanding the causes of sickness as not limited to pathogenic activities, but also other factors that are rooted in cultural belief systems. For instance, the traditional medicine system perceives well-being as dependent on a person's harmony with the

[987] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[988] Chan, 'Opening Remarks at The International Forum on Traditional Medicine' (n 10).

community and other supernatural forces, so that the disruption of this harmonious interaction is one of the causes of sickness. This understanding is one amongst other factors that makes traditional medicine the choice of treatment for some patients as it is steeped in cultural ideologies, and thus, best suited to deal with health problems considered to be cultural. The cultural beliefs surrounding the causes of sickness are as varied as there are different sicknesses and different traditional systems that try to comprehend and explain infirmities that plague humanity.[989] Therefore for different cultures, there are different causes of sickness. This section considers the various theories in traditional medicine regarding causation of sickness – 'causation' meaning the causes of sickness. While many traditional systems, in reality, have multiple theories of causation,[990] here the theories will be broadly categorised into mystical, animistic and magical causations.[991]

Causes of sickness, which cannot be traced to a human or supernatural entity are said to be *mystical*.[992] In other words, the affliction of the victim is brought about by neither the acts of human, nor supernatural forces. Such causes could be fateful occurrences that are associated with forces of astrology, destiny, and ill luck.[993] Or could be as a result of contact with defiling and polluting substances or persons – an idea similar to the conventional medicine theory of biological causation.[994] Things capable of polluting a person include contact with a corpse, swine, menstrual blood, menstruating women and social outcasts.[995] Also, a feeling that a dreadful occurrence is about to take place, resulting from dreams, visions, or some mystical experience is also categorised as mystical causation.[996] A person could fall ill due to mystical retribution, if he/she has committed an act considered a taboo or violated specific moral injunctions.[997] Such

[989] Oguamanam, International Law and Indigenous Knowledge (n 69) 114.
[990] Oguamanam, International Law and Indigenous Knowledge (n 69) 114.
[991] ibid 115.
[992] ibid; see also George P Murdock, *Theories of Illness: A World Survey* (Pittsburgh: University of Pittsburgh Press 1980) 17.
[993] Oguamanam, International Law and Indigenous Knowledge (n 69).
[994] ibid.
[995] ibid.
[996] ibid.
[997] ibid 115-116; see also E Evans-Anfom, *Traditional Medicine in Ghana: Practice, Problems and Prospects (J B Danquah Memorial Lectures)* (Academy of Arts and Sciences 1986) in which Evans-Anfom, a former Council Chairman of the Centre for Scientific Research into Plant Medicine, listed violation of taboos as one of the causes of illness as conceived by traditional healers; and Marian Ewurama Addy, 'Traditional Medicine'

taboos and moral injunctions could relate to rituals; sex, which would include incest, bestiality, or intergenerational intercourse; blasphemy and unacceptable drinking behaviour.[998]

In the case of *animistic* causations, the victim's sickness is attributed to a 'personalised supernatural being'.[999] The supernatural being is 'personalised' in the sense that every human being is believed to have his/her supernatural being, such as ghost, soul, spirit or god.[1000] An example of this is found in Africa among the *Ibos* in Nigeria. Every individual is believed to have a personal god known as *chi*, which is adulated or blamed for whatever circumstance the individual finds him/herself.[1001] *Chi*, as a concept in *Ibo* land, is akin to personal luck or ill luck, good fate or ill fate.[1002] Similarly, in Oceania among the Manus peoples of Papua New Guinea, 'the spirits of dead males of the family become its guardians, protectors, censors, dictators after death'.[1003] In return for their protection and preservation, these spirits demand from their wards the exercise of certain restraints and virtues, failing which 'the sinner' or 'some/one of his relatives' is met with the 'spirits' righteous wrath.[1004] Malaria is typically regarded as one of the spirits' wrath among this people.[1005] Such affliction is almost always followed by 'confessions and propitiatory payments' by the sinner, who usually recovers afterwards evincing that the spirits have been appeased.[1006]

The third categorisation of the theories of causation is the *magical* causation, which traces sickness to the surreptitious acts of malignant persons, whom either by themselves or through hired sorcerers or witches afflict their victims through the use of magic.[1007] This category is considered very controversial because it involves witchcraft – a topic that has

<http://www.s158663955.websitehome.co.uk/ghanaculture/privatecontent/File/traditional%20medicine%20practice.pdf> accessed 30 May 2016.
[998] ibid.
[999] Oguamanam, International Law and Indigenous Knowledge (n 69) 116.
[1000] ibid; see also Helman (n 926) 94.
[1001] Oguamanam, *International Law and Indigenous Knowledge* (n 69); see also Chinua Achebe, *Things Fall Apart* (New York: Anchor Books 1994).
[1002] Oguamanam, International Law and Indigenous Knowledge (n 69).
[1003] Margaret Mead, *Growing Up in New Guinea* (Penguin Books Ltd 1963) 79.
[1004] ibid 80.
[1005] ibid 241.
[1006] ibid.
[1007] Oguamanam, International Law and Indigenous Knowledge (n 69).

been highly debated across cultures.[1008] Witchcraft and sorcery are the two aspects of magical causation.[1009] Sorcerers or witches adopt various means to afflict their victims with sickness, including the casting of spells, curses, prayers, magically placing incapacitating objects in the victim's body, or performing rituals or exuvial rites over the victim's personal apparels or biological materials such as hair or nail cuttings, as well as excrement or semen.[1010] Magical causation also explains sickness which can be linked to acts of a member of a cult who has the capacity to perpetrate evil.[1011] An instance could be seen in a patient's colleague at work, employing *juju* to inflict sickness on him so that he might be invalidated out of service, thereby putting this colleague in an advantageous position when promotion came up.[1012] What is striking about this illustration is the level of superstition among educated and enlightened patients which the traditional healer exploits to diagnose and heal with traditional therapies.[1013] This resonates the point that the attitude and understanding of many patients, literate and illiterate alike, concerning sickness and its causes, stem from their cultural beliefs.

To be more comprehensible, therefore, these theories of causation should be considered from the perspective of sociocultural and religious belief systems in which sickness and healing unite as a way of life, as opposed to when they are perceived as an organismic or scientific inquiry.[1014] Healing, being a way of life, 'is a cultural and performative art and science that is administered within a people's cosmological milieu'.[1015] (Section 3.5 below elaborates on this.) These theories, however, should not be interpreted to mean that causation in traditional medicine system is limited only to supernatural explanations. Empirical medicine such as different forms of surgery such as cataract surgery, extraction of bullets and shrapnel and the cauterisation of wounds were all aspects of African medical experience dating back to ancient times.[1016] Therefore, traditional systems are

[1008] ibid.
[1009] ibid.
[1010] ibid; see also Murdock (n 992) 21; and Chidi Oguamanam, 'Between Reality and Rhetoric: The Epistemic Schism in the Recognition of Traditional Medicine in International Law' (2003) 16 *St Thomas Law Review* 59-108.
[1011] Oguamanam, International Law and Indigenous Knowledge (n 69).
[1012] Evans-Anfom (n 997).
[1013] ibid.
[1014] Oguamanam, International Law and Indigenous Knowledge (n 69).
[1015] ibid.
[1016] ibid; see also Cheikh Anta Diop, Precolonial Black Africa: A Comparative Study of the Political and Social System of Europe and Black Africa, from Antiquity to Formation of Modern States (Brooklyn, NY: Lawrence Hill Books 1987) 205-6.

malleable, and thus, open to comprehending and exploring other causation theories.[1017] Viewed from this understanding, the appropriate integration of traditional medicine into the national health systems of developing and least-developed countries could prove to be highly instrumental in providing more holistic healthcare services, thereby contributing to sustainable development.

3.5. Traditional Healers and How They Perform Healing in the Traditional Medicine Cosmology

Just as there are medical professionals in conventional medicine, there are also traditional healers who provide health care in indigenous and local communities using traditional medicine. The WHO describes these practitioners as:

> a group of persons recognised by the community in which they live as being competent to provide health care by using vegetable, animal and mineral substances and other methods based on the social, cultural and religious backgrounds as well as the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well-being and the causation of disease and disability.[1018]

Two categories of traditional healers are derivable from this definition: one group of healers is known as 'herbalists', whereas the other is the 'diviner-diagnosticians'. While the 'diviner-diagnosticians' are so called because they provide diagnosis usually through spiritual means, the herbalist chooses and applies remedies through the use of plants, animals and mineral substances.[1019] This holds true in Africa, for example, under the Ghanaian belief system where there are the herbalists who emphasise the physical aspect of illness and use mainly plants for treatment and another group that stresses the spiritual aspect.[1020] This classification is based on the perception of the world as divided into the natural or physical, and the supernatural or spiritual under this belief system. While the natural world is that which is seen, the supernatural is unseen, yet wields powerful

[1017] Oguamanam, International Law and Indigenous Knowledge (n 69).
[1018] World Health Organization, The Promotion and Development of Traditional Medicine (n 787).
[1019] F Jolles and S Jolles, 'Zulu Ritual Immunisation in Perspective' (2000) 70(2) *Africa* 230; see also Ritcher (n 852) 8.
[1020] Addy (n 997).

influences over the natural world.[1021] Due to this influence, the supernatural world is considered more important and dealt with more than the physical world.[1022] This explains traditional healers' propensity to emphasise the supernatural over the physical as the cause of an illness.[1023]

There is also a 'hybrid group' existing in Ghana delineated as herbalist-spiritualist because, in addition to treating the organismic causes of illness, they also treat the spiritual causes.[1024] They engage in occultic practices and are commonly known as *bokonowo* and *Okomfo* by the Ewe and Akan ethnic groups (respectively) in Ghana.[1025] Other traditional healers that belong to this category are identified by names such as soothsayers or diviners and shrine devotees.[1026] The main functions of soothsayers and diviners are to explain the '*why*' of certain illnesses and may predict the consequences of intended actions.[1027] This set of traditional healers, as well as *Mallams* – Islamic teachers who either use Qur'anic verses or prayers for healing and those who combine divination and prayers with herbal treatments – are mostly found in the Northern region of Ghana [1028] These functional distinctions seem to have been distorted by colonial rule, particularly in Africa, through the introduction of legislation such as the Witchcraft Suppression Acts of 1957 and 1970, which prohibited diviners from practising their trade in South Africa.[1029] Besides, the introduction of conventional medicine by colonialists and missionaries obscured these categorisations even further,[1030] so that now, it is possible that 'traditional medical practitioners' would include traditional healers and conventional medical professionals, such as doctors, dentists, and nurses who provide traditional medicine therapies to their patients.[1031] For instance, many doctors use acupuncture to treat their patients.[1032]

[1021] ibid.
[1022] ibid.
[1023] ibid.
[1024] ibid.
[1025] ibid.
[1026] Addy (n 997).
[1027] ibid.
[1028] ibid.
[1029] Jolles and Jolles (n 1019) 230; see also Ritcher (n 852).
[1030] ibid.
[1031] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1032] ibid.

In the traditional medicine system, there are various techniques employed by traditional healers to treat their patients. As will be seen in Chapters four and five, concerns regarding the safety and efficacy of traditional treatments are one of the challenges to the utilisation of traditional medicine to further the Agenda for Sustainable Development. Calls have been made mostly by members of the conventional medical community to subject traditional medical therapies and practices to rigorous clinical evaluations to ensure patients' health and safety. Mindful of this, some of the techniques engaged by traditional healers warrant a brief explanation, as this would enhance a proper determination (in the chapters to come) of whether or not traditional medicine is subject matter suited for clinical assessment. What must be understood at the outset is that based on the emphasis on the supernatural over physical causes, all the techniques engaged by traditional healers are geared towards restoring the patient's harmony with ecological, spiritual or supernatural and social forces believed to be responsible for the sickness.[1033] To achieve this reconciliation, sensory and emotive supplications are the basic communicative tools deployed.[1034]

Mystical philosophers and people immersed in the spiritual believe that 'the way to the soul is through the senses'.[1035] If this is so, then to successfully achieve healing, 'the sense must be engaged'.[1036] Therefore traditional healers perform healing through prayers, incantations, oratorical invocations, ventriloquism, recitations, exorcisms, hymns, songs and dances, mixing of colours, sacred paintings, ideographic signs, trances, séances or transcendental experiences, spells and oratorical performances.[1037] Whereas this list is not exhaustive, these techniques represent some of the ways traditional healers engage the sick, while trying to communicate with the supernatural to effect healing.

There is great power in the use of words under the traditional system of medicine, particularly when it is combined and dramatised with songs, poems, chants, verses, ecstatic outbursts and philosophical and oratory deliveries.[1038] Under the *Ngankari*

[1033] Oguamanam, International Law and Indigenous Knowledge (n 69) 133.
[1034] Oguamanam, International Law and Indigenous Knowledge (n 69) 133.
[1035] ibid.
[1036] Carol Laderman and Marina Roseman, *Performance of Healing* (New York and London: Routledge 1996) 4.
[1037] Oguamanam, International Law and Indigenous Knowledge (n 69) 133.
[1038] ibid.

Tjukurpa, an aboriginal traditional medical knowledge in Australia, treatments usually come from the hands when the traditional healer bellows 'Power! Power!'.[1039] It is believed that the *Ngankari* power enters the sick person and extracts the sickness in physical form so that the sufferer can see the cause with his/her eyes.[1040] In Africa, under the Yorubic traditional medicine in Nigeria, *Babalawos* (the chief diviners in *Yoruba* land) believe that some traditional medicines become effective only when 'potent words' (incantations) and *oriki* (praise names) are chanted during their preparation and administration.[1041] This means that treatment is not solely based on the therapeutic qualities of medicinal plants, but also includes the ability of the traditional healer to invoke the latent powers of the plant through incantations to treat diseases.[1042] The pertinent question becomes how these traditional claims can be scientifically investigated through clinical trials in order to ensure the safety and efficacy of traditional medicine practices for purposes of integration into the national health systems of developing and least-developed countries.[1043]

Besides words, there is another art of healing performance that involves occultic or ritual methods through which traditional healers diagnose patients and ascertain appropriate methods of treatment. This technique is known as 'divination'.[1044] Inclusive in this process are trance, séance, clairvoyance, and ecstasy, with the accompanying display of musicotherapy, incantations, poetic expressions and drama.[1045] For instance, traditional healers use medicinal plants that have hallucinogenic effects to induce ecstatic states while reciting some incantations in order to communicate with the spirit world from where the appropriate diagnosis is learnt through visions or revelations.[1046] This could be seen in South America from the practices of the early native Mexican priests who used drinks or ointments from the seed of olloliuhqui (*Rivea Corymbosa*) to induce visions and

[1039] Francesca Panzironi, Hand in Hand: Report on Aboriginal Traditional Medicine (ANTAC 2013).
[1040] ibid.
[1041] Borokini and Lawal (n 779) 26; see also Oguamanam, *International Law and Indigenous Knowledge* (n 69) 134; Una Maclean, 'Choices of Treatment Among the Yoruba' in Peter Morley and Roy Wallis (eds), *Culture and Curing: Anthropological Perspectives on Traditional Beliefs and Practices* (London: Peter Owen 1978) 152, 164; and Piero Coppo, 'Traditional Medicine and Psychiatry' in Bannerman et al. (n 922) 25.
[1042] Borokini and Lawal (n 779) 26.
[1043] See Chapters four and five for further discussions.
[1044] P M Peek, African Divination Systems: Ways of Knowing (Indiana University Press 1991); see also Oguamanam, International Law and Indigenous Knowledge (n 69) 138.
[1045] Oguamanam, International Law and Indigenous Knowledge (n 69) 138.
[1046] ibid.

delirium, as well as the use of peyote (*Lophophora williamsii*) and *Rauwolfia* by the indigenous peoples of Mexico.[1047] The inhalation of these hallucinogenic substances could also be for therapeutic purposes, as being in an ecstatic state provides the patient with an outlet for releasing inappropriate emotions or sentiments.[1048]

Other methods of divination include: observing a small metal ring hung on a thread and dangled before the patient in order to interpret what its movement means; deciphering the significance of the position in which cowries thrown randomly on the ground fall; reading the marks made on sand by animals; interpreting gesticulations or expressions made by possessed patients in a trance; and gazing consistently into the water in which the diviner interacts with spirits whose images are reflected in a pot of water made of calabash.[1049] As many traditional systems attribute sickness to acts of agency spirits, ancestors, gods, or other supernatural concepts, traditional healers may be required, depending on their diagnosis, to embark on a 'spiritual warfare' against evil forces, or intercede on behalf of the patient through prayer, mediation and appeasement.[1050]

Irrespective of the fact that traditional healers provide health care using these unconventional techniques, there are negative sentiments about their practices and the treatments they administer. Indeed, some traditional healers have merited these ill feelings. In Africa, the South African media has told horrendous stories of traditional healers and mysterious treatments that they prescribe for patients, claiming that such therapies cure AIDS.[1051] It needs to be pointed out that there is a marked difference between curing AIDS and improving the quality of life of persons living with AIDS by providing remedies for AIDS-related diseases such as tuberculosis, herpes zoster, and diarrhoea, and prescribing medicines that amplify the immune system. Likewise, in Togo, there have been cases where treatments alleged to be 'cures' for HIV/AIDS provided by traditional healers have worsened the conditions of HIV-positive patients.[1052] These have

[1047] Krippner and Colodzin (n 793) 16; see also Oguamanam, *International Law and Indigenous Knowledge* (n 69).
[1048] Carol Laderman, 'The Poetics of Healing in Malay Shamanistic Performances' in Laderman and Roseman (n 1036).
[1049] Addy (n 997); see also Evans-Anfom (n 997).
[1050] Oguamanam, International Law and Indigenous Knowledge (n 69) 138.
[1051] Ritcher (n 852) 9-10; see also H Malaudzi, 'Traditional 'AIDS Healer' Silenced' *City Press* (31 January 2001).
[1052] Steinglass (n 945).

provoked more concerns regarding the safety and efficacy of traditional medicine. They have further had the effect of tarnishing the reputations of those traditional healers whose practices are safe, effective and meet ethical standards.[1053] In light of these, utilising traditional medicine to achieve sustainable development would require the regulation of its practitioners, practices and therapies to ensure their proper use, safety and efficacy, and that they are of good quality (as will be assessed in Chapters four and five). Ensuring that traditional medicine is of good quality necessitates a brief insight into how it is prepared and administered.

3.6. Preparation and Administration of Traditional Medicine

Traditionally, the preparation and administration of traditional medicine can take various forms. While some medicines could be prepared using a combination of plants, others could be derived from a single source.[1054] Sometimes, instructions on conditions that must be observed during preparation of traditional medicine are revealed to traditional healers by supernatural forces.[1055] A traditional healer might be instructed to send an errand boy or girl who is 'clean', i.e. free of any manipulations by evil spirits, to the forest to collect certain plants to be used to prepare medicines.[1056] Also, the appointed errand boy or girl might be instructed to 'keep mute' after collection until the plants have been handed over to the healer.[1057] It is believed that failure to heed these instructions would render the medicine ineffective.[1058] Based on the proposition that RCTs are best suited to validate the safety and efficacy of traditional medicine, Chapter five queries how such conventional method would measure the impact these instructions have on the effectiveness of traditional medicine.

Having collected the medicinal plants as instructed, the traditional healer using bare hands would pick and separate unwanted parts from the useful parts of the plants usually the leaves, bark, roots, buds or seeds,[1059] and would mash, pound, stew, grind the plant part

[1053] Ritcher (n 852) 9-10.
[1054] Joeli Veitayaki, 'Building Bridges: The Contribution of Traditional Knowledge to Ecosystem Management and Practices in Fiji' (2005) The University of South Pacific 7-8.
[1055] Borokini and Lawal (n 779) 24.
[1056] ibid.
[1057] ibid.
[1058] ibid.
[1059] ibid; see also Brown (n 971) 9.

into a powdery substance or merely extract oil from the seeds.[1060] Depending on the nature of the sickness, the medicine could be ingested as decoction, infusion and tisane, or directly applied as poultices or rubs and lotions, enemas, eye drops, snuff or nasal drops.[1061] In Africa during the four-week period following childbirth commonly called '*Omugwo*' among the *Ibo* indigenous peoples of Nigeria, the new mother is usually given a herb called '*Udah*' which is usually prepared and administered by stewing in a hot soup consisting of dried fish, meat and yams with a lot of pepper.[1062] The function of the herb is to contract the uterus, thereby expelling blood clots.[1063] This diet serves the purpose of restoring blood and energy lost during childbirth, and aiding the healing of wounds, enhancing lactation, and restoring normal bodily functions.[1064] Thus, it improves maternal health, which is one of the targets of the health-related sustainable development goal, although beyond the scope of this research, as stated in the introductory chapter.

It must be noted that to ensure quality, safety and efficacy, most methods of preparing traditional medicine are directed towards cleansing and purification of the plant ingredients; reducing herbal toxicity and side effects; activating their medicinal properties for application; changing their therapeutic efficacy, as well as improving their flavour; and facilitating preparation and storage.[1065] In Asia, the *Paozhi* process is used for these purposes in the traditional Chinese medicine system.[1066] The process involves methods such as cutting, crushing, calcining and frying, with or without the inclusion of liquid adjuvants.[1067] For example, the process is used to reduce the toxicity of *Fuzi*, derived from the processed lateral root of *Aconitum carmichaelii*, before it is incorporated into other traditional Chinese medicine formulae and used for treatment.[1068]

[1060] Brown (n 971) 9.
[1061] ibid.
[1062] IK Program, 'Traditional Knowledge Case Studies' World Bank <http://www.worldbank.org/afr/ik/guidelines/casestudies.pdf> accessed 2 April 2016.
[1063] ibid.
[1064] ibid.
[1065] Helen Sheridan, Brigitte Kopp, Liselotte Krenn, Dean Guo and Jandirk Sendker, 'Traditional Chinese Herbal Medicine Preparation: Invoking the Butterfly Effect' (2015) The *Science*/AAAS Custom Publishing Office S64; see also Wu Boping, 'Processing Chinese Herbs' (*Mercurius Institut Für Chinesische Medizin*) <http://www.tcm-germany.de/fachbeiträge/arzneimittel/kräuteraufbereitung-pao-zhi/> accessed 18 June 2016.
[1066] Sheridan et al. (n 1065).
[1067] ibid.
[1068] ibid; see also Eric Brand, '*Pao Zhi*: A Collection of Short Articles' Legendary Herbs <http://www.legendaryherbs.com/goopages/pages_downloadgallery/downloadget.php?filename=27568.pdf&orig_name=paozhi.pdf> accessed 18 June 2016.

Furthermore, as mentioned under section 3.1, nowadays the preparation of traditional medicine incorporates contemporary science and technology to research and develop quality, safe and effective herbal products. Through the use of contemporary science and technology, manufacturers of traditional medicine standardise the entire stages of production, including planting, harvesting, processing and marketing in compliance with mandatory management regulations such as Good Agricultural Practice (GAP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Supplying Practice (GSP).[1069] The finished products are usually soluble granules and tablets that are neatly packaged and labelled with information regarding the therapeutic claims, dosification, 'best before' dates and methods of preservation.[1070] The modernisation of traditional medicine in this manner is highly essential because it scientifically explains the material basis for the efficacy of herbal products, as it is important to provide consumers with such information to enable them to make informed health choices.[1071] Nonetheless, there have been widespread concerns over heavy metal contamination of herbal medicines and intentional adulteration using synthetic pharmaceutical drugs,[1072] as will be seen in Chapter four. What is more, standardisation could adversely affect the cost of herbal medicines since it would require substantial investment. These are legitimate trepidations (reflected upon in Chapters four and five) that bode ill for the utilisation of traditional medicine in the national health systems of developing and least-developed countries for sustainable development.

Nevertheless, there is a global recognition of the invaluable contribution that traditional medicine can make in providing access to health care. Significant international bodies have at one time or another, through statements, resolutions and declarations, encouraged the utilisation of the potential of traditional medicine to further sustainable development goals. The following section sets out this international validation as evidence in support of the hypothesis that traditional medicine could be deployed as a complementary tool to

[1069] Xiuwen Wu, Yannan An, Ming Yuan and Rufeng Wang, 'On the Modernization of Traditional Chinese Medicine' (2012) 1(1) *Medicinal and Aromatic Plants*.
[1070] Borokini and Lawal (n 779) 29.
[1071] Wu et al. (n 1069).
[1072] Bhushan Patwardhan, Dnyaneshwar Warude, P. Pushpangadan and Narendra Bhatt, 'Ayurveda and Traditional Chinese Medicine: A Comparative Overview' (2005) 2 *Evidence-Based Complementary and Alternative Medicine* 465-473.

the use of TRIPS flexibilities and (probably) a convention on drug R&D to promote universal health coverage and access to medicines in developing and least-developed countries.

3.7. Global Recognition of the Role of Traditional Medicine in Achieving Sustainable Development

As already established in Chapter one, the right to health has a mutually dependent relationship with environmental, economic and social factors (the sustainable development triad). While individuals and populations require the enjoyment of some degree of health to achieve development goals, health depreciates if development and improvement in living standards are undermined. The UN, an international organisation founded in 1945 currently with a membership of 193 states,[1073] aims to 'achieve international cooperation in solving problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respects for human rights and for fundamental freedoms of all…' [1074] This means that it is charged with the responsibility of contriving solutions to not only economic and sociocultural issues but also global public health problems in order to realise sustainable development. Consequently, Goal 3 of its Agenda for Sustainable Development adopted in 2015 by the UN General Assembly is to 'ensure healthy lives and promote well-being for all at all ages' by among other things, eradicating malaria, tuberculosis and HIV/AIDS by 2030.[1075]

In the past, notable bodies of the UN have endorsed the value of traditional medicine in promoting development goals. Mindful that malaria, tuberculosis and HIV/AIDS pose significant challenges to global health, the UN Commission on Population and Development – established in 1946 by the UN Economic and Social Council (mentioned in Chapter one) to advise the Council on issues regarding population and development[1076]

[1073] 'About the UN' (*United Nations*) <http://www.un.org/en/about-un/index.html> accessed 18 June 2016.
[1074] Charter of the United Nations 1945, art 1(3).
[1075] 'Sustainable Development Goals 3: Ensure Healthy Lives and Promote Wellbeing for All at All Ages' (*World Health Organization*) <http://www.who.int/sdg/targets/en/> accessed 9 July 2017.
[1076] United Nations General Assembly, 'Report of the International Conference on Population and Development' (Res 49/128, 92nd Plenary Session, A/RES/49/128 1994).

– identified traditional medicine as a source of primary health care that could contribute to improved health outcomes targeted by the Millennium Development Goals.[1077] One might argue that the 2030 Agenda for Sustainable Development nurses a higher ambition than the Millennium Development Goals, for while the latter only sought to 'combat', i.e. 'reduce or prevent' [1078] malaria, tuberculosis and HIV/AIDS, the former seeks to 'eradicate', i.e. 'destroy completely or put an end to'[1079] these diseases. Nevertheless, traditional medicine could still provide the much needed treatment for malaria and tuberculosis and improve the quality of life of persons living with HIV/AIDS. Thus, as noted by Ms Sylvie Lucas, the former President of the UN Economic and Social Council, traditional medicine has the potential to advance the realisation of international development objectives related to global health, and to improve the world's health care especially for developing and least-developed countries lacking access to it.[1080]

It is noteworthy that the UN 2030 Agenda for Sustainable Development does not expressly consider traditional medicine useful for promoting universal health coverage and access to medicines under Goal 3. However, it recognises traditional medicine's potential to contribute to sustainable development under Goal 15 which seeks to 'sustainably manage forests, combat desertification, halt and reverse land degradation, and halt biodiversity loss'.[1081] Goal 15 targets to achieve this through *inter alia*, the conservation of biodiversity in order to enhance its capacity to provide benefits that are essential for sustainable development, and to promote the fair and equitable sharing of benefits arising from the utilisation of genetic resources, and promote appropriate access

[1077] United Nations' Commission on Population and Development, 'Resolution 2010/1 Health, Morbidity, Mortality, and Development' (E/2010/25 E/CN.9/2010/9) <http://www.un.org/en/development/desa/population/commission/pdf/43/CPD43_Res2010-1.pdf> accessed 5 May 2016.
[1078] 'Combat' <https://www.google.co.uk/search?noj=1&q=combat+definition&oq=combat+de&gs_l=serp.1.0.0i67k1j0j0i67k1j0l7.58163.58823.0.60289.3.3.0.0.0.0.73.213.3.3.0....0...1.1.64.serp..0.3.212.4eDtOhzjOww> accessed 9 July 2017.
[1079] 'Eradicate' <https://www.google.co.uk/search?client=safari&rls=en&q=combat+definition&ie=UTF-8&oe=UTF-8&gfe_rd=cr&ei=2iNiWanhKOzv8AfYqL2AAg#q=eradicate+definition> accessed 9 July 2017.
[1080] United Nations, 'Potential of Traditional Medicine Should Be Fostered, Economic and Social Council President Tells Panel on Attaining Millennium Development Goals in Public Health' (*United Nations' Meetings Coverage and Press Releases*, 12 February 2009) ECOSOC/6385 <http://www.un.org/press/en/2009/ecosoc6385.doc.htm> accessed 5 May 2016.
[1081] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development' (n 3) Goal 15.

to such resources, as internationally agreed.[1082] It notes, as one of such benefits, that 80 per cent of people living in rural areas of developing and least-developed countries rely on traditional medicine for primary health care and only less than 1 per cent of over 80,000 tree species have been studied for potential use.[1083] Thus, while encouraging conservation and sustainable use of biodiversity in order to ensure access to traditional medicine for rural dwellers (discussed in Chapter six), the Agenda impliedly recognises its potential to contribute to sustainable development by promoting universal health coverage and access to medicines in developing and least-developed countries, as envisaged under Goal 3.

More, the WHO equally endorses the potential of traditional medicine for sustainable development. Founded as an organ of the UN in 1948 with a membership totalling 194 states, the WHO is the most authoritative body charged with global public health policy and governance.[1084] It is vested with broad powers to enable the performance of its global health duties, one of such powers being to make recommendations on the subject of international health.[1085] The WHO has at various times, beginning from the 1970s, recommended traditional medicine as a source of accessible and affordable medicine for improving global health. Through various statements and resolutions, it has encouraged the formulation and implementation of policies and regulations for the integration and utilisation of traditional medicine in the health systems of its member states.[1086] For example, the World Health Assembly (WHA), which is the governing body of the WHO, in Resolutions WHA29.72 and WHA30.49 passed in 1972 and 1977 respectively, recognised the role of traditional practitioners in delivering health care and therefore, urged its member states to consider the use of traditional medicine in their healthcare systems.[1087]

[1082] ibid.
[1083] ibid.
[1084] Constitution of the World Health Organization 1946.
[1085] ibid.
[1086] Jan Stephan, 'Legal Aspects: Patterns of Legislation Concerning Traditional Medicine' in Bannerman et al. (n 922).
[1087] ibid.

Similarly, in 1978, the WHO together with UNICEF – another agency of the UN created in 1946 for child health purposes[1088] – convened an International Conference on Primary Health Care held in Alma-Ata, USSR. In this conference, member states adopted a Declaration focused on achieving health for all by the year 2000 through promoting and strengthening healthcare systems.[1089] To accomplish this, the Alma-Ata Declaration encouraged WHO member states to recognise the role of traditional medicine and its practitioners in primary health care.[1090] Even though under international law a declaration does not create a legally binding obligation on its signatories (as earlier mentioned),[1091] there have been notable efforts to implement the intention of the Alma-Ata Declaration. In Africa, the West African Health Organization (WAHO), a specialised institution of the Economic Community of West African States (ECOWAS) established in 1987 with the primary aim of attaining the highest possible health for the peoples belonging to the sub-region,[1092] established its traditional medicine programme in 2007.[1093] The purpose of this programme is to assist the ECOWAS member states to institutionalise traditional medicine in their national health systems.[1094] This step was viewed as historical, as ECOWAS became the first regional economic community to take steps towards attaining the objectives of the Alma-Ata Declaration.[1095]

In the same manner, the Health Ministers of the South-East Asian countries, namely: Bangladesh, Bhutan, India, Nepal, Sri Lanka, Timor-Leste, DPR Korea, Indonesia, Myanmar, Maldives and Thailand, adopted the Delhi Declaration on behalf of their Governments at an International Conference on Traditional Medicine for South-East Asian countries held in New Delhi on 12-14 February 2013.[1096] Reiterating the

[1088] 'UNICEF' <https://www.unicef.org/about-us/timeline-1946-1979> accessed 9 July 2017.
[1089] Declaration of Alma-Ata 1978.
[1090] ibid.
[1091] 'Declaration' (*UNESCO*) <http://www.unesco.org/new/en/social-and-human-sciences/themes/international-migration/glossary/declaration/> accessed 7 July 2017.
[1092] 'About WAHO' (*Organisation Ouest Africaine de la Santé*) <http://www.wahooas.org/spip.php?page=rubriqueS&id_rubrique=24&lang=en> accessed 19 June 2016.
[1093] Kofi Busia and Ossy M J Kasilo, 'Overview of Traditional Medicine in ECOWAS Member States' *African Health Monitor* (World Health Organization Regional Office for Africa 2010) 17.
[1094] ibid.
[1095] ibid.
[1096] Delhi Declaration on Traditional Medicine for South-East Asian Countries 2013 <http://ayush.gov.in/sites/default/files/0198493426-Delhi%20Declaration%20on%20Traditional%20Medicine%20%20%20%20%202.pdf> accessed 6 May 2016.

importance given to the inclusion of traditional medicine and its practitioners in the planning and implementation of health care by the Alma-Ata Declaration, the Health Ministers agreed to promote policies, develop institutionalised mechanisms for the exchange of information, and pursue a harmonised approach for the education, research and regulation of traditional medicine in order to promote its appropriate use in the healthcare delivery system.[1097]

Forty years after the adoption of the Alma-Ata Declaration, there has been an accelerated growth in the use of traditional medicine for health care. Traditional medicine has served as the primary source of health care in most developing and least-developed countries, particularly in Africa and Asia. For example, in Ethiopia and India, 70-80 per cent of the population depends on the treatment offered by traditional medicine and practitioners.[1098] Many developed countries have equally found traditional medical care appealing, for instance in Germany and Canada, where it is referred to as complementary or alternative medicine (CAM)[1099] (as noted in section 3.1). As observed by the former WHO Director-General, Dr Margaret Chan in 2013:

> Traditional medicines, of proven quality, safety and efficacy, contribute to the goal of ensuring that all people have access to care. For many millions of people, herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible and affordable. It is also culturally acceptable and trusted by large numbers of people. The affordability of traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity. Traditional medicine also stands out as a way of coping with the relentless rise of chronic non-communicable diseases.[1100]

[1097] ibid.
[1098] 'Background of WHO Congress on Traditional Medicine' (*World Health Organization*) <http://www.who.int/medicines/areas/traditional/congress/congress_background_info/en/> accessed 8 July 2017.
[1099] ibid.
[1100] Margaret Chan, 'Address at the International Conference for Traditional Medicine for South-East Asian Countries, New Delhi, India' (World Health Organization 2013).

Nonetheless, there are concerns about lack of adequate national policies; quality, safety and efficacy; and the rational use of traditional medicine. These have proven to be significant challenges to its proper integration into national healthcare systems. While emphasising the importance of traditional medicine and encouraging member states to integrate it into their national health systems, the Beijing Declaration (adopted by government officials representing WHO member states in 2008) urged its members to formulate national policies on traditional medicine and promote education and research into traditional medicine, as well as foster communication between healthcare providers,[1101] i.e. both traditional and conventional practitioners. Before 2008, the WHO developed a traditional medicine strategy which was to be implemented for four years: 2002-2005. This strategy's objectives were: to assist member states in formulating national policies for the integration of traditional medicine into national health care; to develop international standards, technical guidelines and methodologies for the proper use of traditional medicine; and to provide a clearing-house to facilitate information exchange in the field of traditional medicine.[1102]

As will be seen in Chapter four, while significant progress was made after the four years, for there was steady growth in regulating and managing traditional medicine in some regions of the world, notably Africa and Asia,[1103] concerns regarding the quality, safety and efficacy of traditional medicine and practices equally grew. This necessitated the development of the traditional medicine strategy 2014-2023 in response to the Beijing Declaration and to build on the work done by the 2002-2005 strategy by addressing the new challenges, responding to the needs identified by member states, and focusing on prioritising health services and systems, including traditional and complementary medicine products, practices and practitioners.[1104] It is these challenges and strategic responses to ensure the *appropriate* use of traditional medicine for sustainable development that subsequent chapters address.

In conclusion, traditional medicine can play an all-important role in achieving sustainable development. There is a global recognition that it has the potential to enhance access to

[1101] Beijing Declaration adopted by the WHO Congress on Traditional Medicine 2008.
[1102] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1103] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1104] ibid.

essential and affordable medicines. Several instances have been cited in this chapter to prove that the traditional medicine system embodies curative and palliative remedies for malaria, tuberculosis and HIV/ADS. In actuality, these remedies have been a source of primary health care for the populations of developing and least-developed countries, particularly in Africa and Asia for many centuries. The traditional medical approach to treatment in terms of causation of sickness and healing practices makes it more appealing to some patients than conventional treatments, as traditional healing methodologies are directed towards achieving the whole-person-care. Based on these findings, it should be integrated into the healthcare system of developing and least-developed countries as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D to promote universal health coverage and access to medicines for progress towards sustainable development by 2030, as proposed in Chapter two.

However, the traditional medicine system is far from perfect; as already mentioned, concerns abound regarding the inadequacy of existing regulations of its practices, practitioners and products, which has obvious implications for its quality, safety and efficacy. Moreover, attempts to ascertain the pharmacological effects of herbal medicines are unconvincing due to the adoption of inadequate research methodologies. These have heightened anxieties over the use of traditional medicine for treatment. Because of this, there is the need for more effective policy and regulatory actions by developing and least-developed countries to address these challenges confronting the proper use of traditional medicine in order to achieve appropriate integration into the healthcare system for sustainable development. Chapter four discusses these challenges in detail.

CHAPTER FOUR

CHALLENGES AFFECTING THE PROPER USE AND INTEGRATION OF TRADITIONAL MEDICINE INTO THE NATIONAL HEALTHCARE SYSTEMS OF DEVELOPING AND LEAST-DEVELOPED COUNTRIES

Chapter three investigated whether traditional medicine can contribute to achieving sustainable development by 2030 through providing treatment for malaria, tuberculosis and HIV/AIDS. It concluded that traditional medicine has an immense potential to contribute to progress towards sustainable development through promoting universal health coverage and access to essential medicines for these diseases, and thus, should be integrated into the healthcare systems of developing and least-developed countries. Nonetheless, it noted that there are challenges to the proper use and integration of traditional medicine into the healthcare systems of developing and least-developed countries. This chapter evaluates these challenges in more depth. It considers that these challenges to the proper use and integration of traditional medicine stem from inadequate policies and regulatory frameworks regarding the practice of traditional medicine at the national level.

Regulating traditional medicine would entail the introduction of appropriate and adequate measures relating to the training and licencing of traditional practitioners, and the safety, efficacy and quality of traditional medicine practices and therapies. Given the inadequacy of regulation, what has been obtainable are negative reports of unscrupulous and unsafe practices by some traditional medicine practitioners and manufacturers, which have had immediate and harmful effects on the health of patients. Such reports have resulted in the delineation of some traditional remedies as ‘fake’ and its practitioners as ‘quacks’. Another consequence of inadequate regulation is the increasing global demand for the generation of more knowledge regarding the safety and efficacy of traditional medicine, in spite of the recognition of its potential as a source of primary health care. This chapter assesses these challenges, beginning with the general concern for lack of national policies and regulatory frameworks.

4.1. Lack of Adequate National Policies and Regulatory Frameworks

The lack of adequate national policies and regulatory frameworks poses a significant challenge because they are the foundation for the proper use and integration of traditional medicine into the national health system. In the past 20 years, there has been a progression in the number of countries that has developed policies or regulations on traditional medicine. For instance, national regulations in Africa have increased from one in 2000 to 28 in 2010.[1105] In South-East Asia, five countries developed national traditional medicine policies between 2002 and 2012.[1106] An encouraging development has also been observed in North America.[1107] However, there are emerging accounts of harmful traditional practices and remedies which make the adequacy of existing national policies and regulations questionable. For example, a Lutheran priest in Tanzania sold a 'cure-all' herb claiming that it cured various diseases, including tuberculosis and HIV.[1108] Each day, he consulted about 2,000 patients with over 15,000 waiting their turn in a queue.[1109] It was reported that more than 50 patients died en route or shortly after receiving the herbal treatment.[1110] More problematic was the absence of either scientific evidence of the safety and efficacy of the herb or confirmation from any hospital that anyone tested negative after receiving the treatment.[1111] Yet, Tanzania is one of the African countries that has developed a national policy that regulates the practice of traditional medicine.[1112] Likewise, China has developed regulations on traditional Chinese medicine (TCM);[1113] still, there was a case in its North-western region of Xinjiang Uygur, where a fake anti-diabetic drug that claimed to reduce blood sugar killed two people and hospitalised nine.[1114]

[1105] 'WHO Traditional Medicine Strategy 2014-2023' (n 11) 63.
[1106] ibid.
[1107] ibid.
[1108] IRIN 'Authorities Urge Caution on Popular "Cure-All" Herb' (n 205).
[1109] ibid.
[1110] ibid.
[1111] ibid.
[1112] Andrew F Cooper, John J Kirton, Franklyn Lisk and Hany Besada, Africa's Health Challenges: Sovereignty, Mobility of People and Healthcare Governance (Routledge 2016).
[1113] Regulation of the People's Republic of China on Traditional Chinese Medicine (Adopted at the Third Executive Meeting of the State Council on 2 April 2003, promulgated by Decree No 374 of the State Council of the People's Republic of China on 7 April 2003, and effective as of 1 October 2003).
[1114] Zhang Xiang, 'Deadly Counterfeit Diabetes Drug Found Outside China's Xinjiang Xinhua' *News* (5 February 2009).

It is evident from these incidents that such policy failures leave patients vulnerable to unsafe practices which are detrimental to their lives. This underscores the need for adequate governmental supervision, which could be accomplished through appropriate policies and regulations.[1115] It is recognised that national regulation is most suitable for traditional medicine considering that its practices differ between traditional systems;[1116] in essence, national policy would best capture its nuances and address country-specific challenges. In doing so, policies and regulatory frameworks should clearly define the role of traditional medicine and traditional practitioners in healthcare delivery.[1117] They should also form the legal basis for promoting and enforcing good practices, and ensuring that traditional therapies are safe, effective and have a high standard of quality. This would involve addressing issues such as the training, education, qualification and licencing of traditional practitioners; regulation and registration of herbal products; developing consumer information on proper use of traditional medicine products; expanding the evidence base of safety and efficacy of traditional medicine and maintaining quality control standards.[1118]

Similarly, funding for traditional medicine is an important subject matter which should be covered by national policies and regulatory frameworks. Funding for research, traditional medicine clinics, training and education of traditional practitioners is essential for assuring that traditional medicine is appropriately harnessed in the national health systems of developing and least-developed countries.[1119] However, Health Ministries, for instance in Nicaragua (a developing country in Central America), have noted the difficulty in allotting budgets for the operation of traditional medicine because of its approach of tailoring treatment according to the individual needs of patients, which usually involves varying remedies and costs.[1120] Low funding may result in lack of access to traditional medicine, as it may negatively impact on the utilisation of traditional

[1115] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 3.
[1116] ibid.
[1117] ibid 3, 20-21.
[1118] ibid 20-27.
[1119] ibid 20.
[1120] Johan Wedel, 'Bridging the Gap between Western and Indigenous Medicine in Eastern Nicaragua' (2009) 15(1) *Anthropological Notebooks,* 49-69.

medicine in areas of a country where it is needed.[1121] Thus, it is crucial for the government to work out in detail, particulars for funding traditional medicine in national policies and regulations.

Fundamentally, an effective policy and regulation should consist of ways in which traditional medicine would be properly utilised in healthcare delivery and should equally determine what traditional medicine practices and remedies are acceptable in the national health system. Without this, the odds are that the traditional medicine system would be unsafe and expensive, thus failing to provide affordable medicines for treatment.[1122]

4.2. Accessibility of Traditional Medicine

As explained in Chapter one, malaria, tuberculosis and HIV/AIDS predominantly affect the populations of developing and least-developed countries, particularly the regions of sub-Saharan Africa, Southeast Asia, and Central and Southern America. Aggravating this situation, the majority of people located in these areas lack access to essential medicines to treat these diseases and alleviate suffering. This background together with the sustainable development goal of eradicating these diseases by 2030, draws attention to the appeal of integrating traditional medicine into the national health systems of developing and least-developed countries, as a complementary measure to the use of TRIPS flexibilities and (probably) a convention on drug research and development (R&D) in promoting universal health coverage and access to medicines. Already, the majority of the populations of developing and least-developed countries depend on traditional medicine for health care. And when compared with conventional medicines, traditional medicine is less expensive, as established in Chapter three. However, there is a lack of quantitative research to ascertain the levels of existing access to traditional medicine – regarding both cost and geographic accessibility.[1123] Also, there is lack of qualitative research to determine factors constraining such access.[1124]

[1121] Heather Carrie, Tim K Mackey and Sloane A Laird, 'Integrating Traditional Indigenous Medicine and Western Biomedicine into Health Systems: A Review of Nicaraguan Health Policies and Miskitu Health Services' (2015) 14(129) *International Journal for Equity in Health*.
[1122] Wayne B Jonas, 'Alternative Medicine – Learning from the Past, Examining the Present, Advancing the Future' (1998) 280(18) *Journal of the American Medical Association*, 1616-1618.
[1123] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.
[1124] ibid.

As noted (in 4.1) above, the issue of providing for adequate funding for the operations of traditional medicine in national policies and regulations is one example of such factors. Again, as will be seen in Chapter five, regulation could potentially increase the cost of traditional medicine as a result of the quality control measures it requires of traditional medicine manufacturers. In order to ensure the quality, safety and efficacy of traditional medicine, manufacturers of herbal products are required to standardise the entire stages of production, including planting, harvesting, processing and marketing in accordance with mandatory management regulations, such as Good Agricultural Practice (GAP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Supplying Practice (GSP).[1125] This could potentially increase the cost of herbal medicines, as manufacturers would seek to recoup and profit from their investment. Consequently, the high cost of herbal medicines could constrain access.

Another factor that could impede access to traditional medicine is the unsustainable use of biological diversity. This is explained by the fact that traditional medicine is derived from the use of plants and animals. In recent times, there have been observations regarding the loss of biological resources resulting from human activities.[1126] This means that how humans use land and resources, as well as production, consumption and waste are responsible for the causes of the loss of biological resources.[1127] Such causes include climate change, pollution, unsustainable trade, habitat loss, and invasive species, among others.[1128] For instance, the rainforest, which is a major source of biodiversity, has been reduced by two thirds.[1129] Petra Ebermann remarked that a study reported that 19 out of 20 unknown species are destroyed as a result of eliminating the rainforests.[1130] Over-exploitation by humans, therefore, needs to be addressed to guarantee access to traditional medicine. (More on this point later.) Paradoxically, even the exploitation of local resources for traditional medicine could threaten biodiversity. In Eastern and Southern

[1125] Wu et al. (n 1069).
[1126] Ebermann (n 977) 26.
[1127] 'Human Activities Cause Loss of Biodiversity' (*WWF*) <http://www.wwf.org.au/our_work/saving_the_natural_world/wildlife_and_habitats/threats_to_species/loss_of_habitat/human_activities_cause_loss_of_habitat/> accessed 21 June 2016.
[1128] ibid.
[1129] Ebermann (n 977) 26.
[1130] ibid.

Africa for example, the sustainability of the wild stocks of African Potato (*Hypoxis hemerocallidea*) faces the threat of extinction because the knowledge that it could be used to treat HIV/AIDS has increased demand for it.[1131]

Also, certain intellectual property issues could affect access to traditional medicine. As will be seen later on in this chapter and Chapter five, research and documentation of traditional medicine are fundamental to ensuring its quality, safety and efficacy. The objective is to provide evidence to support the quality, safety and efficacy of traditional medicine through research and documentation. While this may be a good measure to ensure that traditional medicine is used appropriately, the concern is that the subject of research and what is to be documented is the knowledge of the indigenous peoples. For instance, documentation would involve the identification of the plant and the plant part that is pharmacologically active; the diseases it cures; methods of preparation and administration – all based on the traditional knowledge of the medicinal uses of plants. The danger is that documentation of traditional medical knowledge would make it easily accessible and exploitable by anyone, and research would be beneficial particularly to scientists.[1132]

Before now, there has been an increased interest on the part of western researchers and the biotechnology and pharmaceutical industries in exploiting genetic resources and the implicated traditional knowledge regarding their medicinal uses. Three factors are responsible for this: first, it has become common knowledge that bacteria are growing resistant to antibiotics and some diseases have become untreatable by conventional medicines, for example, some forms of HIV.[1133] Secondly, the number of new molecular entities entering the market in recent decades is now minimal, in spite of considerable investments in R&D of drugs.[1134] Thirdly, the development in biotechnology created the possibility of producing pharmaceuticals derived from plants.[1135] As a result of these,

[1131] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.
[1132] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.
[1133] Ebermann (n 977) 1.
[1134] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-based Biopiracy' (n 192) 238.
[1135] Greg K Venbrux, 'When Two Worlds Collide: Ownership of Genetic Resources Under the Convention of Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights' (2005) 6 *Pittsburgh Journal of Technology Law & Policy* 1, 3; see also David Downes, 'New

there has been an intensified search by scientists in nature for pharmacologically active plants. It is almost impossible to ignore the vital role of traditional knowledge in this process, as the search usually revolves around gathering information on plants that have been used traditionally with great success, including details of the plant parts used and the indication and method of treatment.[1136] Subsequently, scientists or their companies obtain monopoly rights and commercialise the products derived from this search.

This form of exploitation has been described by developing and least-developed countries housing the majority of the world's genetic resources, and the knowledge-holding communities as equivalent to piracy and dubbed 'biopiracy'. [1137] This means the uncompensated commercial use of genetic resources and associated traditional knowledge by corporations, as well as obtaining an exclusive monopoly over inventions derived from such use.[1138] Examples include: the US patent on the anti-malarial drug, quinine, which was developed based on observations that chewing the bark of Cinchona prevented the Peruvian Indians from taken ill with malaria;[1139] the European patent on Tadenan, a drug for benign prostate hyperplasia (BPH), was developed based on the revelation by the indigenous Bakwerians in Cameroon that the bark of pygeum had treated 'old man's disease' for centuries;[1140] and the US patent claiming the anti-diabetic effects by an American company of kerala, which had been used in India to treat diabetes since ancient times.[1141]

Because of this, research and documentation could potentially expose traditional medical knowledge to further exploitation through biopiracy patents. It then becomes crucial that to promote access to safe and effective traditional medicine through research and documentation, the rights of the indigenous peoples to give prior informed consent and

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Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology and Intellectual Property in the Convention on Biological Diversity' (1993) 4 *Touro Journal of Transnational Law* 1, 8-14.
[1136] Ebermann (n 977) 20.
[1137] Graham Dutfield, 'TRIPS-Related Aspects of Traditional Knowledge' (2001) 33 *Case Western Reserve Journal of International Law* 233, 235; see also Graham Dutfield, 'What is Biopiracy?' (2004) International Expert Workshop on Access to Genetic Resources and Benefit Sharing.
[1138] Graham Dutfield, 'Bioprospecting: Legitimate Research or Biopiracy?' (2003) Science and Development Network.
[1139] Victoria Sutton, *Law and Biotechnology: Cases and Materials* (Carolina Academic Press 2007) 237.
[1140] A J Simons, I K Dawson, B Dugumba and Z Tchoundjeu, 'Passing problems: Prostate and Prunus (1998) 43 *Herba Gram*, 49-53; see also Eyong, 'Indigenous Knowledge and Sustainable Development' (n 947) 121, 133.
[1141] U.S. Patent No. 5,900,240 (4 May 1999).

share in the benefits derived from the utilisation of traditional knowledge in accordance with the Convention on Biological Diversity 1992 and its Nagoya Protocol 2010, should be safeguarded as will be seen in Chapter six. Also, there will be a need for developing and least-developed countries to develop national legislation for the protection of traditional medical knowledge. Here, 'protection' is used in the intellectual property sense of legally ensuring that traditional medical knowledge is not misappropriated, copied and used without authorisation of the indigenous peoples.[1142] In this regard, Chapter six explores the ongoing process within the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) to develop an international instrument (or instruments) for the protection of traditional knowledge (including traditional medical knowledge), genetic resources and traditional cultural expressions.[1143]

Along similar lines, the loss of biodiversity, as previously mentioned, can be addressed through conservation and sustainable use of its components, as prescribed by the Convention on Biological Diversity.[1144] In this respect, it is noteworthy that in very exceptional cases, biopiracy could also lead to depletion, as it involves the exploitation of biodiversity. Indeed, genetic resources can be reproduced scientifically away from their area of domestication,[1145] and all that is needed to commence the biotechnological process is a small sample of the plant. Of course, this cannot lead to depletion of resources.[1146] However, it is possible that different corporations could be exploiting a particular plant for various purposes, as plants are known to consist of hundreds of natural properties. This could potentially reduce resources, resulting in the threat of extinction. For instance, Peru's 'cat's claw' (*Uncaria tomentosa*) was on the verge of extinction owing to massive exploitation by the biotechnology and pharmaceutical industries for its

[1142] Wend Wendland, 'Intangible Heritage and Intellectual Property: Challenges and Future Prospects' (2004) 56(1-2) *Museum International* 97-107; see also Lucas Lixinski, *Intangible Cultural Heritage in International Law* (OUP Oxford 2013).
[1143] WIPO, 'Traditional Knowledge and Intellectual Property: Background Brief - No 1' (2016).
[1144] Convention on Biological Diversity 1992, art 1.
[1145] Burton Ong, 'Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political and Environmental Issues' in Burton Ong (ed), *Intellectual Property and Biological Resources* (Singapore: Marshall Cavendish Academics 2004) 7.
[1146] Ebermann (n 977) 19.

medicinal properties.[1147] Cases such as this make conservation of biodiversity and the sustainable use of its components all the more critical.

Therefore, to ensure access to traditional medicine, there should be a comprehensive understanding of the extent of existing access and how to best deal with these factors that could impede access.

4.3. Rational Use

There are various aspects of the challenge to ensure the appropriate and effective use of traditional medicine. To begin with, there is the need to ensure the adequate training and qualification of traditional practitioners.[1148] This would entail establishing regulations, examinations and licencing systems so that only those who are qualified can deliver traditional health services.[1149] To this extent, unethical practices such as administering fake remedies and selling counterfeit products such as the anti-diabetic drug that was sold in China and the 'cure-all' herb in Tanzania, would be reduced to the barest minimum. Additionally, it is important to use these training and qualification programmes as mediums for ensuring that traditional and conventional medicine practitioners understand the need for complementarity between the types of healthcare services they provide.[1150] The importance of this cannot be overemphasised due to an ongoing 'cold war' between traditional and conventional medicine practitioners, particularly where there is a clear separation between both systems. As noted in Chapter three, it is possible to find a dentist, nurse or doctor who also provides traditional care in some health systems.

At the centre of the cold war are ideological differences:[1151] for traditionalists, there is a link between the spiritual world and diseases.[1152] This is a phenomenon viewed with considerable scepticism by conventional practitioners.[1153] Thus, they condemn traditional

[1147] Timmermans, 'Trips, CBD and Traditional Medicines' (n 869).
[1148] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1149] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1150] ibid.
[1151] Joan Liverpool, Randall Alexander, Melba Johnson, Ebba K Ebba, Shelly Francis and Charles Liverpool, 'Western Medicine and Traditional Healers: Partners in the Fight Against HIV/AIDS' (2004) 96(6) *Journal of National Medical Association*, 822-825.
[1152] Wedel (n 1120) 49-69.
[1153] ibid.

healing practices as 'superstitious' and 'quackery'.[1154] On the other hand, traditional practitioners who have no training in conventional medicine dismiss its value in delivering safe and effective health care.[1155] These have inhibited collaboration between both systems and instead, fostered suspicion, disdain[1156] and marginalisation of the traditional medicine system. For instance, following the outbreak of HIV/AIDS in developing countries such as South Africa, many infected people turned to traditional healers for a cure, even though they were advised by their doctors to distance themselves from traditional quack practices.[1157] While this sparked a feeling of resentment from traditional healers who felt that conventional medicine practitioners sought to 'monopolise the market of HIV positive patients',[1158] many patients who truly believed that traditional practitioners could heal them stopped using prescribed antiretroviral drugs.[1159] Having expended large sums of money in making these drugs available, governments and donor agencies suffered a significant loss.[1160]

These drugs were administered as a combination drug therapy, and any patient who had commenced treatment was expected to continue until there was a good medical reason to discontinue treatment.[1161] A patient who defaulted for a long time required a different type of antiretroviral drug which was more expensive and toxic to the body.[1162] Besides, defaulting patients were more likely to die sooner than had they continued with the original treatment, since the use of herbs might have counteracted and reduced the efficacy of the antiretroviral (and possibly caused damage to the liver).[1163] Given situations such as this, it is crucial for conventional and traditional practitioners to understand that both systems are not in competition, but rather share the same objective – providing health care. This is of utmost importance if both systems are to collaborate

[1154] Malefetsane Soai, 'Medicinal Practitioners Versus Traditional Healers: Implications for HIV/AIDS Patients' (*Polity Org.Za,* 23 February 2012).
[1155] Wedel (n 1120).
[1156] Carrie et al. (n 1121).
[1157] Liverpool et al. (n 1151) 822-825.
[1158] James Watson, 'Traditional Healers Fight for Recognition in South Africa's AIDS Crisis' (2005) 11(1) *Nature Medicine* 6; see also Soai (n 1154).
[1159] Soai (n 1154).
[1160] ibid.
[1161] Cynthia Dzilla, 'The Cost of Defaulting on Medication' (*Media for Environment, Science, Health & Agriculture,* 24 May 2011) <https://meshakenya.wordpress.com/2011/05/24/the-cost-of-defaulting-on-medication/> accessed 13 March 2016.
[1162] ibid.
[1163] ibid; see also Soai (n 1154).

in achieving the sustainable development goal of eradicating malaria, tuberculosis and HIV/AIDS by 2030. Including the need for collaboration as a learning outcome in training and qualification programmes of medical practitioners could achieve complementarity, and in the same vein sustainable development.

Such training and qualification programmes must aim to ensure that conventional and traditional practitioners understand the value of both systems in delivering health care. Traditional practitioners play a vital role in enhancing the availability of healthcare personnel, as well as for scaling-up HIV/AIDS care and prevention strategies in developing and least-developed countries.[1164] In spite of this, conventional medical providers appear to consult traditional practitioners as a last-resort remedy, particularly in cases characterised as 'spiritual' or 'cultural'.[1165] This was observed in Central America in the collaborative efforts between conventional and traditional healthcare providers among the RAAN Miskitu population of Nicaragua. Here, the utilisation of traditional medicine was subject to the inclination of the conventional medicine providers.[1166] As opposed to working together, they controlled the use of traditional medicine and referred to it only when they thought the medical case to be outside the purview of conventional medicine.[1167]

This display of marginalisation is also observed in the exclusion of traditional practitioners during crucial health programmes in the health sector. After the outbreak of HIV/AIDS, there was an increased dependence on traditional medicine because it bore the burden of clinical care for the AIDS epidemic, especially in Africa.[1168] Considering this, one would have expected the conventional medicine system to have offered support, education and cooperation to traditional practitioners while expanding the coverage of its HIV prevention and treatment programmes, by soliciting their help.[1169] However, what happened was that traditional practitioners were sidelined during important health

[1164] G Bodeker, D Kabatesi, R King and J Homsy, 'Regional Task Force on Traditional Medicine and AIDS' (2000) 355(9211) *The Lancet* 1284; see also J Homsy, R King, D Balaba and D Kabatesi, 'Traditional Health Practitioners are Key in Scaling up Comprehensive Care for HIV/AIDS in Sub-Saharan Africa' (2004) 18(12) *AIDS* 1723-1725.
[1165] Wedel (n 1120).
[1166] Carrie et al. (n 1121); see also Wedel (n 1120).
[1167] Wedel (n 1120).
[1168] Bodeker et al., 'Regional Task Force on Traditional Medicine and AIDS' (n 1164) 1284.
[1169] Ritcher (n 852) 11.

programmes in the health sector, thus deprived of opportunities to learn about new diseases and to develop their practices accordingly.[1170] For instance, despite the fact that Zimbabweans rely heavily on traditional medicine, traditional practitioners have alleged that they were not consulted in the initial stages of the HIV self-testing pilot programme.[1171] They contended that such programmes were an opportunity to learn and keep up-to-date with recent developments in the health sector.[1172] Likewise, after the International Conference on AIDS and Sexually Transmitted Infections in Africa held in Harare in 2015, traditional practitioners voiced discontent because they felt shunned at the conference.[1173] Not a single practitioner made a presentation at the conference. Instead, they were consigned to group discussions and did not have the opportunity to interact with others.[1174]

It must be pointed out that aside from the ideological dissimilitude, it is recognised that these actions towards traditional healers could be inspired by the negative reports of malignant traditional healing practices, causing the system to be shunned.[1175] Nevertheless, it must be understood that traditional healers cannot be treated as a stereotype. As with any other vocation, there are the charlatans, as well as those who adhere to practices that meet ethical standards. Even among conventional medicine practitioners, there are the so-called 'Doctor-Charlatans'.[1176] With this in mind, the discontentment of traditional practitioners seems reasonable, given the fact that they play an all-important role in providing health care, and for this reason, need to be educated on new diseases afflicting people.[1177] More, there is a need to incorporate traditional practitioners into activities of the health sector, as well as create an enabling environment for them to work together with conventional medicine providers for health. Thus, to achieve proper collaboration it would be essential to include in the curriculum of the training and qualification programmes for traditional practitioners, basic elements of primary health care and public health, and also ensuring that degrees in pharmacy,

[1170] Chara (n 870).
[1171] ibid.
[1172] ibid.
[1173] ibid.
[1174] ibid.
[1175] Liverpool et al. (n 1151) 822-825; see also Soai (n 1154).
[1176] Henry W Paul, Henri de Rothschild, 1872-1947: Medicine and Theatre (Routledge 2016).
[1177] Liverpool et al. (n 1151) 822-825; see also Soai (n 1154).

medical and public health include a curriculum on traditional medicine;[1178] these would ensure the rational use of traditional medicine in the national health systems.

Another aspect of rational use is ensuring that traditional medicine products are of assured quality. Risks associated with traditional medicine products such as herbal medicines can be reduced by this means.[1179] However, adequate policies regarding the regulation and registration of these products are lacking in many countries.[1180] It is possible that products may be contaminated, or vary in terms of content, quality and safety. For instance, the cholesterol-lowering effect of garlic may not be activated if it is not processed in the right way.[1181] It is equally important to know these risks associated with using traditional medicine and how they could be avoided. Yet, this information is lacking.[1182] For this reason, consumers are unaware of how important it is, for example, to consult only trained and qualified traditional healers, and why they should exercise caution in using specific herbal products.[1183] Also, standards for regulating publicity and labelling of herbal medicines, which could be employed to keep consumers well-informed, are few.[1184] This is a cause for concern because traditional medicine products are classified differently between countries. Based on the medicine regulation of a given country, traditional medicine products may be categorised as a dietary supplement, a food, functional food or herbal medicine.[1185] Various problems arise from this classification because drug regulatory authorities in countries that define these products as food or dietary supplements do not call for evidence of quality, safety and efficacy before marketing.[1186] More, standardisation measures are usually not rigorous[1187] (although as already mentioned, rigorous requirements could inflate cost, thereby impacting on access to traditional medicine).

[1178] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1179] ibid 26.
[1180] ibid.
[1181] H K Berthold, M D Sudhop and K Bergmann, 'Effect of a Garlic Oil Preparation on Serum Lipoproteins and Cholesterol Metabolism' (1998) 279 *Journal of American Medical Association* 1900-1902.
[1182] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1183] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1184] ibid.
[1185] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1186] ibid.
[1187] ibid.

The likely consequence of inadequate regulation, quality assurance standards and absence of consumer education would be events similar to the *Ephedra sinica* case discussed in Chapter three. Recall that it was used to manufacture a weight loss and athletic enhancement supplement between the 1980s and 1990s, which caused heart attacks, strokes and death to many in the US.[1188] It should be noted that in the US, herbal products are marketed as dietary supplements under the provisions of the Dietary Supplement Health and Education Act (DSHEA) of 1994.[1189] Not until 2007 did the law mandate the production of dietary supplements according to Good Manufacturing Practices (GMPs).[1190] Nonetheless, the quality control requirements do not meet the standard of those mandated for prescription or over-the-counter drugs.[1191] In the *Ephedra* case, there was little or no compliance with quality control requirements, safety and efficacy standards in producing the dietary supplement. According to a report, the manufacturing process did not draw upon the traditional use, posology or contraindications of *Ephedra sinica*.[1192] Consumers' lives were further endangered by the fact that even though the manufacturers knew that the product could have the effect of raising blood pressure and acting as a stimulant to cardiovascular and central nervous systems, consumers were neither warned nor the information publicised.[1193]

Making it all the more important that consumers should be informed on the proper use of traditional medicine is the fact that it is not common knowledge that side effects could occur as a result of reactions between herbal medicines and chemical drugs.[1194] This information is worth having because some patients with chronic diseases combine

[1188] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 9; see also Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848) 3; and 'FDA Issues Regulation Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids and Reiterates Its Advice That Consumers Stop Using These Products' (*U.S. Food and Drug Administration*, 6 February 2004) <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108242.htm> accessed 15 June 2016.
[1189] M M Pandey, Subha Rastogi and A K S Rawat, 'Indian Traditional Ayurvedic System of Medicine and Nutritional Supplementation' (2013) *Evidence-Based Complementary and Alternative Medicine*.
[1190] Current Good Manufacturing Practices in Manufacturing, Packaging, or Holding Dietary Ingredients and Dietary Supplements, 72 Fed. Reg. 34752-39958 (June 25, 2007) (to be codified at 21 C. F. R. pt. 111).
[1191] Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1192] Hui, 'Ephedra Sinica in the Practice of Traditional Chinese Medicine' (n 848) 3.
[1193] Christina A Haller and Neal L Benowitz, 'Adverse Cardiovascular and Central Nervous System Events Associated Dietary Supplements Containing Ephedra Alkaloids' (2000) 343 *New England Journal of Medicine* 1833-1838, 1836.
[1194] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.

conventional drugs with herbal ones. Herbs might alter the pharmacokinetics of conventional drugs, resulting in either an increase or decrease in plasma concentrations thereby altering the therapeutic outcomes.[1195] It is also possible that combining both drugs could also lead to many other short- or long-term consequences.[1196] Ginseng, for example, has few side effects. However, if combined with warfarin, its antiplatelet activity risks causing overanticoagulation.[1197] Also, St John's wort is an effective antidepressant, comparable with the standard antidepressant, imipramine.[1198] Nevertheless, if used by patients who are also using indinavir – an HIV protease inhibitor, it reduces the levels of indinavir in the blood lower than the level required to prevent HIV multiplication.[1199] Where this knowledge is lacking, patients would not see the need to communicate to doctors about the herbal products they are using.[1200]

In fact, it was discovered from a population study on 2,526 adults in Australia that about half of herbal medicine users took two forms of therapy on the same day, and only half had voluntarily informed their doctors about their herbal use.[1201] Doctors, on the other hand, might inadvertently fail to ask.[1202] It is also possible that doctors, nurses and pharmacists might have little or no knowledge about traditional medicine, and thus would be unable to answer questions from patients regarding traditional medicine treatment options.[1203] By the same token, patients should be made aware of the possibility of herb-herb interactions, occasionally referred to as 'contraindications'.[1204] This type of

[1195] Gabriel Kigen, Hillary K Ronoh, Wilson K Kipkore and Joseph K Rotich, 'Current Trends of Traditional Herbal Medicine Practice in Kenya: A Review' (2013) 2(1) *African Journal of Pharmacology and Therapeutics* 32-37.
[1196] ibid.
[1197] J Kleijnen, P Knipschild and G ter Riet, 'A Review of the Evidence from Human Experiments with Emphasis on Commercially Available Preparations' (1989) 28 *British Journal of Clinical Pharmacology* 535-544; see also 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1198] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1199] J L Nortier, 'Urothelial Carcinoma Associated with the use of a Chinese Herb (*Aristolochia Fangchi*)' (2000) 342(23) *New England Journal of Medicine* 1686-1692; see also S C Piscitelli, A H Burstein, D Chaitt, R M Alfaro and J Fallon, 'Indinavir Concentrations and St John's Wort' (2000) 355(9203) *The Lancet* 547-548; and 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 26.
[1200] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 27.
[1201] A L Zhang, D F Story, V Lin, F Vitetta and C C Xue, 'A Population Survey on the use of 24 Common Medicinal Herbs in Australia' (2008) 17(10) *Pharmacoepedimiology and Drug Safety* 1006-1013; see also Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1202] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1203] ibid.
[1204] Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).

interaction is properly recorded in ancient textbooks on TCM formulae.[1205] The adverse reactions and toxicity of the herbs detailed in these books were unearthed through clinical evaluations carried out centuries ago.[1206] For example, *Aconitum rhizome* (Wu Tou) should not be used alongside *Pinellia ternata rhizome* (Ban Xia); and *Radix aconiti* (Fu Zi) clashes with *Bulbus fritillariae* (Bei Mu).[1207]

Against the backdrop of these issues outlined above, for traditional medicine to be used rationally in national health care in developing and least-developed countries, it is imperative to overcome the challenges of quality, safety and efficacy (more on this in the next section), traditional medicine education for conventional medicine practitioners, communication between patients and healthcare providers (i.e. both conventional and traditional practitioners), and information on the proper use of traditional medicine for consumers' safety. With regard to the latter, developing and least-developed countries can internalise the technical Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine formulated by the WHO in 2004. Details of strategies to deal with these challenges are discussed in Chapter five, as this chapter merely seeks to highlight these issues.

4.4. Quality, Safety and Efficacy of Traditional Medicine

The first step to ensuring that traditional medicine therapies are safe and effective is to guarantee that the source raw materials are of good quality.[1208] This is often referred to as 'quality assurance'.[1209] The quality of raw materials for preparing traditional medicine, in turn, depends on intrinsic factors (e.g. genetics) and extrinsic factors (such as the environment, cultivation and harvesting, collection, transportation and storage).[1210] Owing to these, performing quality controls of raw materials is a complex and convoluted exercise, and has proved to be a grave challenge.[1211] There have been observations regarding failings in carrying out quality controls during manufacturing activities. For

[1205] ibid.
[1206] ibid; see also G J Zhang and G L Li, 'Treatment of Angina with Combination of Wutou, Gualou and Banxia' (2009) 24(1) *Journal of Hebei Traditional Chinese Medicine and Pharmacology*.
[1207] Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1208] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1209] ibid.
[1210] ibid.
[1211] ibid.

example, studies have shown nanoparticles to be present in some Ayurvedic preparations.[1212] Traditional preparations such as *mahasudarshan churna* (an Ayurvedic medicine used for treating all kinds of fevers)[1213] and *bala guti* (an Ayurvedic medicine used for child fever and viral fevers),[1214] which are not prepared with metals, have been observed to contain large quantities of toxic metals.[1215] Sometimes the adulteration with heavy metals, and microbial and chemical agents during the manufacturing of herbal medicines could be unintentional.[1216] Importantly, the cultivation and collection of source materials, especially where more than a single species is grown in a particular farm, could result in the inadvertent introduction of non-targeted species.[1217] This sort of substitution or adulteration is well-documented in the case of *Periploca sepium* for *Eleutherococcus senticosus* (eleuthoro or colloquially referred to as 'Siberian ginseng'). [1218] Also, investigations by the US Food and Drug Administration (FDA) have revealed that the adverse reactions ascribed to plantain (*Plantago ovata*) were in fact caused by *Digitalis lanata* (woolly foxglove) – a contaminant introduced when plantains are harvested.[1219]

However, the most atrocious is intentional adulteration using synthetic pharmaceutical drugs. This is well-documented regarding some Chinese and Ayurvedic preparations comprised of multiple herbs, which have shown the presence of synthetic anti-inflammatory drugs such as phenylbutazone, indomethacin, and corticoid steroids in remedies for arthritis.[1220] In other cases, manufacturers truncate the long and laborious processes involved in the production of herbomineral complexes in order to meet large commercial productions. [1221] This invariably undermines quality and results in contamination. [1222] Given this, it is of acute importance that developing, and least-

[1212] Patwardhan et al., 'Ayurveda and Traditional Chinese Medicine' (n 1072) 465-473.
[1213] 'Maha Surdasharn Churna' (*Ayurpages.com*, 13 April 2015) <http://www.ayurpages.com/maha-sudarshan-churna/> accessed 22 May 2017.
[1214] Divya Vohora and Shashi B Vohora, *Safety Concerns for Herbal Drugs* (*CRC Press* 2015) 95-96.
[1215] Patwardhan et al., 'Ayurveda and Traditional Chinese Medicine' (n 1072).
[1216] Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1217] ibid.
[1218] ibid; see also D V Awang, 'Quality Control and Good Manufacturing Practices: Safety and Efficacy of Commercial Herbs' (1997) 53 *Food Drug Law Journal* 341-344.
[1219] Nancy M Slifman, William R Obermeyer, Brenda K Aloi, Steven M Musser, William A Correll, Stanley M Cichowicz, Joseph M Betz and Lori A Love, 'Contamination of Botanical Dietary Supplements by *Digitalis Ianata*' (1998) 339(12) *The New England Journal of Medicine* 806-811; see also Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1220] Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1221] ibid.
[1222] Patwardhan et al., 'Ayurveda and Traditional Chinese Medicine' (n 1072) 465-473.

developed countries should develop appropriate regulatory systems to ensure quality assurance of herbal medicines. Such regulatory systems could be formulated in line with the Good Guidelines on GMP for herbal medicines formulated by the WHO in 2007. This technical guideline itemises various 'requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and special sanitation and cleaning methods for various materials'.[1223]

Closely related to the issue of quality assurance is that of conducting clinical evaluations of traditional medical therapies to ensure their safety and efficacy. As noted in Chapter three, some studies have validated traditional therapeutic claims. However, such studies are usually of poor quality due to lack of understanding of research ethics, lack of sound research methodology, short supply of resources and infrastructure, and the unwillingness of researchers to evaluate evidence.[1224] Further complicating this situation, research has proven difficult as a result of the complex nature of herbal medicines. It is essential to the process of evaluating safety and efficacy of herbal medicines to identify plants used in preparation accurately, as well as isolating the active ingredients.[1225] While a herbal medicine prepared by a single medicinal plant may contain hundreds of natural constituents, a multi-component herbal product may probably be comprised of triple that number.[1226] In view of this, it can be prohibitively expensive to investigate what plant component is responsible for what effect.[1227] It would be even more prohibitive for traditional practitioners and local manufacturers who do not possess the means to carry out such investigation. This gives prominence to the need for collaboration between traditional and conventional medicine systems, where traditional medicinal knowledge of plants could serve as a starting point for further clinical research. A good example is the collaboration (known as the Kirumba Crisis-Management Group), which involved the indigenous people of Kirumba Sub-County in the Rakai District in Uganda, a non-governmental organisation and a government research institute, which was targeted to

[1223] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1224] 'WHO Traditional Medicine Strategy 2002-2005' (n 12); see also World Health Organization, *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine* (Geneva: World Health Organization 2000).
[1225] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1226] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887); see also 'WHO Traditional Medicine Strategy 2002-2005' (n 12); and Fong et al. (n 887) 11.
[1227] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).

provide essential medicines to a community that was devastated by the impact of HIV/AIDS, using local resources and traditional knowledge of their medicinal uses[1228] (as will be seen in Chapter five).

Furthermore, it has been suggested mainly by conventional medicine practitioners that the best means to generate evidence to support the safety and efficacy of traditional medicine is through the only source of valid knowledge regarding the effect of treatment intervention: randomised controlled trials (RCTs).[1229] However, as will be seen in Chapter five, it is questionable whether clinical trials are suitable for evaluating the safety and efficacy of traditional medicine based on magico-religious practices and beliefs. Taking the mystical nature of the collection of plants to be used for healing as an example, some traditional healers instruct their underlings not to look back or talk to anybody on their way home from picking plants to be used for healing.[1230] Many herbalists also claim that their knowledge of herbs was passed down to them from their parents, grandparents or ancestors. Others claim to have received such knowledge through dreams or visions.[1231] The issue then becomes how the effect of looking back[1232] and the significance or impact of the source of the knowledge on the efficacy of the herbs can be incorporated into a trial design.

Another concern that warrants mention here is the safety monitoring of herbal medicines otherwise known as pre- and post-marketing surveillance or pharmacovigilance systems. It is already known that adverse events arising from the use of herbal medicines can result from factors caused by the failure of quality assurance and rational use, such as adulteration, contamination with toxic or hazardous substances, simultaneous use of herbal medicines with other medicines, overdosage and wrong labelling.[1233] Regarding the latter, there have been reports of the content of traditional medicine products not meeting their label claims. For instance, a post-market surveillance of a collection of commercial ginseng products prepared from *Panax ginseng*, *Panax quinquefolius* L.

[1228] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 848).
[1229] Tilburt and Kaptchuk (n 785); see also Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1230] Addy (n 997).
[1231] ibid.
[1232] ibid.
[1233] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).

(American ginseng) and *Eleutherococcus senticosus* sold in North America between 1995 and 1998 discovered that 26 per cent of these products failed to meet the label claims regarding the claimed ginsenoside content of the *Panax ginseng* and *Panax quinquefolius* L. products.[1234] This can have deleterious effects on consumers' health, and underscores the importance of market surveillance systems, which enable the 'detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug-related problems'.[1235]

However, due to the inadequacy of national policies and regulatory frameworks on traditional medicine, there has been slow development of national surveillance systems to monitor and assess adverse events in order to ensure the safety of consumers when using traditional medicine products.[1236] To improve this situation, developing and least-developed countries could internalise the Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems developed by the WHO in 2004 to assist its member states in strengthening national capacity in monitoring the safety of herbal medicines and in analysing the causes of adverse events, and share safety information at national, regional and global levels. (More on this in Chapter five.)

In conclusion, although there is a global recognition of traditional medicine as a potential contributor to realising sustainable development, these challenges could undermine such prospects. The way forward would be to formulate adequate national policies and regulatory frameworks on traditional medicine; provide for the training, qualification and licencing of traditional practitioners; promote collaboration between traditional practitioners and their conventional medicine counterparts; ensure access to traditional medicine both in terms of accessibility and affordability; and guarantee the quality, safety and efficacy of traditional medicine therapies. Overcoming these challenges (as seen in Chapter five) is key to integrating traditional medicine into the national health systems of developing and least-developed countries because policies and regulations on traditional

[1234] J Fitzloff, P Yat and Z Z Lu, 'Perspectives on the Quality Assurance of Ginseng Products in North America' in H Huh, K J Choi and Y C Kim (eds), *Advances in Ginseng Research – Proceedings of the 7th International Symposium on Ginseng* (Seoul, Korea: The Korean Society of Ginseng 1998) 138-145; see also Zhang et al., 'Integration of Herbal Medicine into Evidence-based Clinical Practice' (n 204).
[1235] World Health Organization, Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems (Geneva: World Health Organization 2004).
[1236] 'WHO Traditional Medicine Strategy 2002-2005' (n 12).

medicine would delineate its role in the health system and ensure its proper use in delivering health care to patients/consumers. Chapter five addresses the way forward.

CHAPTER FIVE

SOLVING THE CHALLENGES TO TRADITIONAL MEDICINE'S UTILISATION AND INTEGRATION INTO THE NATIONAL HEALTH SYSTEMS OF DEVELOPING AND LEAST-DEVELOPED COUNTRIES: THE WAY FORWARD

Chapter four addressed the challenges of using traditional medicine for health care, particularly highlighting the unscrupulous practices of some traditional practitioners, lack of adequate policies and regulatory frameworks on traditional medicine, and various issues regarding access, quality, safety and efficacy of traditional medicine. That said, the aim of this chapter is first, to advance strategic actions targeted at addressing these challenges through appropriate and effective regulation. Regulations and policies on traditional medicine should recognise its role in healthcare delivery and provide the necessary basis for its use as an affordable health care option. Such regulations should cover issues such as education and training; collaboration between conventional and traditional medicine practitioners; consumer information on proper use; quality, safety and efficacy of traditional medicine therapies; and regulation and registration of traditional medicine products.

Secondly, while regulating traditional medicine has its advantages, there are concomitant drawbacks, which this chapter points out, that deserve special consideration during the process of formulating national frameworks on traditional medicine. It underscores the necessity for these issues to be further discussed, particularly by the World Health Organization (WHO), non-governmental organisations (NGOs), and other stakeholders who strongly advocate the integration of traditional medicine as a source of primary health care in national health systems, as they have the potential to render any policy or regulation on traditional medicine defective. Thirdly, this chapter demonstrates how adequate national policies and regulations can facilitate the integration of traditional medicine into national healthcare systems. Overall, the objective is to ensure the appropriate use of traditional medicine in national health systems of developing and least-developed countries as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug research and development (R&D) to promote universal health coverage and access to medicines for realising sustainable development by 2030.

It is important to reiterate a few points noted in the introductory chapter: locating apt examples of countries that have developed regulations, policies or practices, touching upon some of the solutions discussed in this chapter, proved a challenge. Notwithstanding that the WHO has developed a number of technical guidelines to assist its member states in developing national regulations to ensure the proper use of traditional medicine, notably: Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine 2004; Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004; Guidelines on the Assessment of Herbal Medicines 1991; and Traditional Medicine Strategy 2014-2023, only China and India have fully integrated traditional medicine into their national health systems. Even so, while there is literature on these two jurisdictions, the handicap was that they provided little or no instances on some best practices covered in this chapter for utilising traditional medicine in healthcare systems. Besides, some literature is not in the English language (as noted later on) as with the majority of existing evidence on the use of traditional medicine. In view of these and coupled with the fact that other jurisdictions have partially integrated or merely tolerated traditional medicine in their health systems, this chapter collects evidence of practices of traditional medicine from various jurisdictions, with the aim of demonstrating how traditional medicine can be appropriately utilised to provide essential care in the national health systems of developing and least-developed countries.

Also, this chapter relies on the technical guidelines established by the WHO, and on the works of and insight from Dr Tara Kelly, who has conducted extensive research on traditional medicine, ethnobotany, female infertility, children's ailments (particularly malaria) and chronic illnesses, especially in Oku, Cameroon since 1999[1237], to proffer solutions on how best to integrate traditional medicine into the national healthcare system in order to achieve sustainable development by 2030. Although many instances are

[1237] Essentially, this research involved desk-based research to gain an introductory understanding and outline salient issues regarding the use of traditional medicine for treating chronic conditions, infertility and children ailments; interviews with government officials and elected representatives responsible for regulating the herbal medicine sector; and importantly, patients/consumers. Observation was also a crucial part of the research: Dr Kelly spent time in Oku, Cameroon with traditional medicine practitioners and watched while they administered traditional therapies to patients and collaborated with conventional medical practitioners, including conducting semi-structured interviews to extract key information about treatment interventions – Tara B. Kelly, 'Contemplating Collaboration: Traditional Medicine, Biomedicine, and Coordination of Health Care in Cameroon' (*African Research Institute,* 8 September 2015).

borrowed from China and India, this research does not suggest that other developing and least-developed countries should model their policies and regulatory frameworks on traditional medicine after those of these jurisdictions. Because realities differ from country to country, the examples of how China and India have integrated traditional medicine into their health systems should primarily serve as lessons from which other developing and least-developed countries can formulate policies and regulatory frameworks on traditional medicine that best suit their circumstances. Furthermore, while laws and regulations on traditional medicine have been closely aligned with that of conventional medicine, this is not the ultimate vision.[1238] Ensuring, through adequate policies and regulatory frameworks which are amenable to the intricacies of the traditional medicine system, the appropriate use of traditional medicine in providing primary health care in developing and least-developed countries is the most important consideration.

5.1. Formulation of National Policies and Regulatory Frameworks

As mentioned in previous chapters, traditional medicine can make valuable contributions to healthcare delivery. However, it has not been fully integrated into the national health systems of most developing and least-developed countries as a viable health care option, notably due to the challenges (discussed in Chapter four) surrounding their proper use. To maximise its full potential in national health systems, there is the need to develop adequate national policies and regulatory frameworks on traditional medicine directed towards enhancing and maintaining good practices, assurance of quality, safety and efficacy of traditional therapies, and equitable access to traditional medicine. Such national policies should clearly state government's perspective on the role of traditional medicine in delivering health care, and provide a basis for promoting the proper use of traditional medicine as an affordable and cost-effective form of health care.[1239] They should also contain appropriate provisions that support the quality, safety and efficacy of traditional medicine products and practices.[1240] In China, for instance, government's

[1238] Azusa Sato, 'Rationales for Traditional Medicines Utilisation and its Equity Implications: The Case of Ghana' A Thesis Submitted to the Department of Social Policy of the London School of Economics for the Degree of Doctor of Philosophy, London, May 2012 21.
[1239] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (World Health Organization, 2012) 14.
[1240] ibid.

regulation on traditional medicine (officially known as 'Traditional Chinese Medicine') requires an institution of traditional medicine that engages in providing medical services to fully exploit the characteristics and advantages of traditional Chinese medicine (TCM), combine traditional theories and practices with modern scientific and technological means, incorporate the knowledge of traditional Chinese medicine in disease prevention, health care and rehabilitation; and provide quality traditional Chinese medicine services to people at *reasonable prices.*[1241]

National policies on traditional medicine should equally establish a government department that would be responsible for the administration of traditional medicine. This body would provide governmental oversight on the practice of traditional medicine, in the absence of which, there would be no consumer protection. For example, the Indian Medicine Act of 1970 created the Central Council.[1242] This body is responsible for prescribing the minimum standards of education in traditional medicine; advising the government on matters concerning issuing and withdrawing of medical qualifications to practise traditional medicine in India; and maintaining a central register of Indian medicine which it revises periodically, prescribing standards of professional conduct and etiquette, and formulating a code of ethics to be observed by practitioners of traditional medicine in India.[1243] A similar body exists in China. China's Regulation on Traditional Chinese Medicine 2003 established the administrative department of traditional Chinese medicine of the State Council.[1244] The department oversees the administration of traditional Chinese medicine in China.[1245]

Before engaging in the practice of traditional Chinese medicine, an institution of traditional medicine must meet the standard for the establishment of such institution formulated by the administrative department of the State Council, including the regional health plan of its locality, and must pass the examination and approval formalities in accordance with the provisions of the Regulations on Administration of Medical

[1241] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 9.
[1242] Department of Health and Family Welfare, Ministry of Health and Family Welfare, 'Annual Report 1998-1999' (Government of India).
[1243] ibid; see also World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A World Wide View' (Geneva: World Health Organization 2001).
[1244] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 6.
[1245] ibid.

Institutions, before it obtains a licence to practice.[1246] Where an institution of traditional medicine violates the requirements of the regulation, either by failing to meet the standards for the establishment of institutions of traditional medicine or failing to provide basic medical services having obtained a licence to render such services, the administrative department of traditional medicine would order the institution to take corrective steps within a specified period.[1247] Should such institution further default, the body could order it to suspend its business for rectification, revoke its licence or disqualify it as a recognised medical institution; and such persons in charge or responsible for the default would be liable to disciplinary sanctions.[1248] Thus, the main purpose for the inclusion of an equivalent of these sorts of government departments in a national policy and regulatory framework on traditional medicine to serve as administrators and watchdogs of traditional medicine practices, is to repress the practices of charlatans, and instead promote the rational use of traditional medicine by qualified practitioners for the patients' good.

Another key element that should be included in a national policy on traditional medicine is a provision for the qualification of traditional medicine practitioners. As explained in Chapter three, these are persons 'recognised by the communities in which [they live] as competent to carry out diagnoses with local sociocultural methods, and contribute to the physical, mental, social, and spiritual well-being of the members of their communities'.[1249] Provisions on the qualification of these persons are crucial because they help to eliminate quackery,[1250] thereby having a direct bearing on patient safety.[1251] In some countries, regulations require traditional medicine practitioners to complete formal education or a training programme. For instance, a practitioner of traditional Chinese medicine would not engage in delivering medical services unless he had passed the qualification examination in accordance with the laws, administrative regulations and department rules on health administration, and obtained a licence through registration in China.[1252] Likewise in Hong Kong, any person wishing to practise as a traditional

[1246] ibid art 8.
[1247] ibid art 32.
[1248] ibid.
[1249] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1250] ibid.
[1251] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1252] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 11.

medicine practitioner must possess an undergraduate degree of training in Chinese medicine, and pass the licencing examination conducted by the Chinese Medicine Practitioners Board (PB) maintained by the Chinese Medicine Council of Hong Kong (CMCHK).[1253]

Given the nature of the knowledge and skills related to traditional medicine, i.e., that they are deeply rooted in the culture and belief systems of the indigenous peoples, and are orally transmitted from generation to generation, Chinese regulation requires persons who have studied traditional Chinese medicine by way of *apprenticeship* or who have proven to have special expertise in this field to pass an appraisal and examination to practise as licenced traditional medicine practitioners.[1254] Equally, the Hong Kong Chinese Medicine Ordinance 1999 provided a transitional arrangement for the registration of traditional medicine practitioners, so that if a person had been practising Chinese medicine in Hong Kong as at 3 January 2000, such person might apply to the Practitioners Board to be listed as a traditional medicine practitioner.[1255] A registered practitioner must then apply for a certificate of practice, usually valid for three years, and must fulfil continuing education requirements in Chinese medicine before being able to renew their certificate after its expiration.[1256]

The situation in which a traditional medicine practitioner is qualified and registered in one country but practises his trade in another raises a critical dilemma. This is because such a situation might make it difficult to identify qualified practitioners and new unregulated practices in the latter country.[1257] This is more so as traditional medicine has become global, in the sense that there is now widespread use and a remarkable expansion of international markets for herbal products.[1258] As a result, national policies and frameworks on traditional medicine should contemplate new forms of traditional medicine and practices introduced from other countries.[1259] In view of this, it is useful to

[1253] Chinese Medicine Ordinance 1999 <http://www.legislation.gov.hk/eng/home.htm> accessed 13 February 2017; see also 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1254] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 11.
[1255] Chinese Medicine Ordinance 1999; see also 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1256] ibid.
[1257] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1258] World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine' (n 1243).
[1259] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).

consider the experiences and information originating from other countries when developing national policies and regulations, including recognising qualifications from other jurisdictions. [1260] For example, licencing bodies of traditional medicine in Singapore [1261] recognise certification and qualifications acquired from accredited institutions of higher learning abroad.[1262] In Thailand also, licences to practise traditional medicine are granted to persons with a bachelor's degree in traditional medicine from Universities in Thailand or overseas.[1263]

In addition, policies and regulations on the practice of traditional medicine should be directed at ensuring that it is utilised in a manner that advances the sustainable development goal of promoting universal health coverage and affordable medicines by 2030. For example, China's regulation on traditional Chinese medicine mandates the establishment of urban and rural health service institutions, such as community health service centres and township hospitals, which will provide medical services with traditional Chinese medicine.[1264] According to the regulation, these institutions must provide high quality traditional Chinese medicine services at reasonable prices.[1265] Through these provisions, traditional medicine regulations can ensure that it is safe and affordable, and made accessible even to the poorest people at the grass roots level for treatment and disease prevention. However, the inefficiency of government and lack of proper implementation of policies and regulations could hinder the realisation of these objectives.

For instance, under the National Policy on Indian Systems of Medicine and Homeopathy (ISM and H Policy) formulated in 2002, 10 per cent of the central health budget should be allocated to AYUSH (Ayurveda, Unani, Siddha, Naturopathy, and Homeopathy, which make up the Indian traditional medicine system).[1266] Nonetheless, AYUSH

[1260] ibid.
[1261] Peter Wilson, *Economic Growth and Development in Singapore* (Edward Elgar Publishing 2002), noted that there are legal ambiguities as to whether or not Singapore is a developed or developing country given that its economy is in the advanced stages. Nonetheless, the official position in Singapore is that it is still a developing country.
[1262] 'WHO Traditional Medicine Strategy 2014-2023' (n 11).
[1263] ibid.
[1264] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 10.
[1265] ibid art 9.
[1266] Balpreet Singh, Manoj Kumar and Amarjeet Singh, 'Evaluation of Implementation Status of National Policy on Indian Systems of Medicine and Homeopathy 2002: Stakeholders Perspective'(2013) 33(2)

receives only 2-4 per cent of the total health budget.[1267] This low funding consequently affects research, availability and upgradation of infrastructure, replacement of used resources and enforcement of measures regarding quality control of traditional medicine.[1268] In fact, AYUSH facilities are in deplorable conditions in most Indian states.[1269] Therefore, government's effort in ensuring the proper use of traditional medicine is not limited to framing national policies or regulations. There is a need for continuous support and political commitment regarding effective implementation, which is critical to realising the objectives of policies and regulations on traditional medicine.

Furthermore, bureaucracy in administrative departments of traditional medicine can equally pose a challenge to realising the objectives of policies and regulations on traditional medicine. Poor administrative set-ups and red-tapism account for the poor execution of prescribed strategies to revive and utilise AYUSH in India, as complex bureaucratic processes stymie plans and efforts to implement these strategies.[1270] This instance calls attention to the importance of simplifying the structure and procedures of administrative departments of traditional medicine to enable efficiency in the administration and regulation of traditional medicine. Otherwise, failures of this administrative mechanism can lead to corruption and improper use of traditional medicine. For example, as a result of weak vigilance system, AYUSH doctors and staff falsify outpatient departmental records and are negligent in maintaining their stations.[1271] Also, inadequate vigilance and evaluation of various AYUSH schemes prescribed by regulation have led to lack of information on how to further improve AYUSH systems.[1272] This has resulted in the reduced performance of AYUSH health systems.[1273]

Moreover, it is possible that the administrative departments of traditional medicine could become corrupt and collect bribes to register unqualified traditional medicine practitioners or health service institutions. This situation is very plausible, particularly in

Ancient Science of Life 103-108 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4171850/> accessed 20 September 2016.

[1267] ibid.

[1268] ibid.

[1269] Singh et al. (n 1266).

[1270] ibid.

[1271] ibid.

[1272] ibid.

[1273] ibid.

Africa, where corruption is prevalent in most governmental departments.[1274] Therefore, it is vital to not only streamline the structure and procedures of the administrative department, but also to insert provisions in national policies or regulations prohibiting any form of corruption in the department, hospitals and by traditional medicine practitioners. For instance, China's regulation on traditional Chinese medicine forbids any organisation or individual from misappropriating for other purposes funds designated for traditional Chinese medicine undertaking.[1275] This provision is a step in the right direction, but it is not comprehensive. Such provisions should go further to prohibit any forms of bribe and criminalise these acts of corruption with penalties. These measures would ensure efficiency and transparency in the regulation of traditional medicine practice.

Nevertheless, a group of advocates for non-regulation of traditional medicine have voiced the concern that regulating traditional medical practices would devalue cultural values.[1276] This stems from the fact that cultural beliefs and customs permeate traditional medical practices, and traditional medicine practitioners are viewed as cultural symbols, given the services they render to their communities.[1277] Some of these traditional practices involve human sacrifice and pouring of libations to the spirits of the dead.[1278] Thus, it is feared that regulations would inhibit this cultural aspect. Notwithstanding that there may be a point in this argument (but from a different perspective to be reflected upon later), the respect for culture and the enjoyment of cultural rights must not be contrary to other human rights.[1279] Traditional beliefs that involve human sacrifice, rape and bodily mutilation, which are opposed to the rights to life and the dignity of the human person, have been prohibited and criminalised in most national constitutions and criminal

[1274] Milena Veselinovic, 'Why Corruption is Holding Africa Back' *CNN* (8 January 2016) <https://edition.cnn.com/2015/12/24/africa/africa-corruption-transparency-international/index.html> accessed 8 January 2016; see also Robyn Dixon, 'In South Africa, Even the Schoolchildren Pay Bribes' *Los Angeles Times* (Johannesburg, South Africa, 30 September 2015) <http://www.latimes.com/world/africa/la-fg-south-africa-corruption-20150930-story.html> accessed 8 January 2016.
[1275] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 25.
[1276] Hope Kyomugisha, 'Traditional Medicine: Oversight of Practitioners and Practices in Uganda' (2008) *SSRN Electronic Journal* 37 <https://www.researchgate.net/publication/228226637_Traditional_Medicine_Oversight_of_Practitioners_and_Practices_in_Uganda> accessed 19 October 2016.
[1277] ibid.
[1278] ibid.
[1279] ibid 38.

laws.[1280] Therefore, cultural values should be respected and protected insofar as they do not violate other human rights. Accordingly, charlatan traditional practitioners should be prohibited from practising traditional medicine if it is discovered that their practices are inhumane.[1281] To this extent, regulating the practice of traditional medicine would ensure ethical practices and patients' safety.

Furthermore, there is the likelihood that regulating traditional medicine practices would encourage traditional medicine practitioners to collaborate with government research institutions to develop treatments for various diseases and enhance traditional medicine.[1282] More so, when regulated, traditional medicine practitioners might be inclined to disclose their trade secrets, thereby enabling scientists to carry out research to support the safety and efficacy of traditional medicine.[1283] For example, there is strong research in the field of traditional medicine in China, particularly pharmacology research and drug development because traditional Chinese medicine is regulated.[1284] However, research on the safety and efficacy of traditional medicine therapies adopting conventional methodologies raises crucial issues assessed later in this chapter.

On the whole, developing national policies and regulatory frameworks on traditional medicine is vital to ensuring that it is of high quality, safe, effective and is appropriately integrated into the national health systems of developing and least-developed countries. National policies and regulatory frameworks should aim to permit only qualified traditional medicine practitioners, who adopt ethical practices, to engage in practising traditional medicine. However, aside from developing national policies and regulations, other issues such as the sound and appropriate use (otherwise 'rational use') of traditional medicine exist, which must be dealt with to properly and effectively utilise it in national health systems. These issues will be addressed in the following sections.

5.2. Rational Use of Traditional Medicine

[1280] ibid.
[1281] ibid 35.
[1282] Kyomugisha (n 1276) 33.
[1283] ibid.
[1284] ibid.

This section addresses the need to ensure the sound and appropriate use of traditional medicine by both providers and consumers. Achieving this would require the development of appropriate standards to enhance the skills and competencies of traditional medicine practitioners, and to ensure that they and their conventional medicine counterparts understand the need for complementarity between both systems. Closely related to this is the importance of adopting strategies to foster collaboration and good communication between traditional and conventional medicine providers on the one hand; and between providers (i.e. both traditional and conventional) and patients/consumers on the other hand. It is equally essential to develop consumer information for purposes of keeping consumers well informed and preventing instances of improper use.

5.2.1. Education and training of traditional medicine practitioners

Educating and training of traditional medicine practitioners are essential for ensuring the quality, safety and efficacy of traditional medicine. Developing appropriate standards to enhance the knowledge, skills and competencies of traditional medicine practitioners will arouse confidence from patients and consumers in traditional medicine practitioners and their practices, boost the status of traditional medicine practitioners, and eventually lead to better quality health care.[1285] The objectives of such standards are twofold. The first is to ensure that the training is adequate:[1286] that is, that traditional medicine practitioners possess sufficient knowledge to evaluate advantages and limitations, and have conviction in the quality, safety and effectiveness of traditional medicine before administering treatment.[1287] The second objective entails using training to ensure that traditional medicine practitioners and conventional medicine practitioners understand and appreciate the need for complementarity between the types of health care they offer.[1288] This is extremely important if traditional medicine is to be successfully used in complementarity to conventional medicine to promote universal health coverage and access to affordable medicines for sustainable development (as proposed by this research).

[1285] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (n 1239).
[1286] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.
[1287] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (n 1239).
[1288] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.

As regards the first objective, its accomplishment would require (as discussed under 5.1. above) establishing traditional medicine institutions of learning, examinations and licencing systems, and regulations, so that only those who are qualified can practise traditional medicine and market traditional medicine products.[1289] For example, South Africa regulates the practice of traditional medicine practitioners under the Associated Health Service Professionals Amendment Act of 1993.[1290] Registration under this law permits these practitioners to practise for gain and call themselves members of that profession.[1291] It is punishable under this law by a fine or imprisonment for up to one year if a person practises traditional medicine for gain without registration.[1292] To qualify for registration as a traditional practitioner under the 1993 Act, one must undergo an apprenticeship of between one and five years and must be recognised by other traditional practitioners in the community in which s/he serves.[1293] Those who are qualified to practise traditional medicine are required to register with the Traditional Healers' Organisation and are given a form of certification to show that they are eligible traditional medicine practitioners.[1294]

In respect of establishing traditional medicine institutions of learning, there are instances in China and India. For example, there are an estimated 57 secondary schools that offer courses on traditional Chinese medicine existing in China.[1295] There are also 28 universities and colleges of Chinese traditional medicine and pharmacology.[1296] These universities and colleges provide 14 professional undergraduate programmes, including Master's and Doctorate degrees programmes.[1297] To qualify as a traditional Chinese

[1289] ibid.
[1290] Sharma Sharad, Patel Manish, Bhuch Mayank, Chatterjee Mitul, Shrivastava Sanjay, 'Regulatory Status of Traditional medicine in African Region (2011) 2(1) *International Journal of Research in Ayurveda & Pharmacy* 103-110.
[1291] Sharad et al. (n 1290).
[1292] ibid.
[1293] ibid.
[1294] ibid.
[1295] World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine' (n 1243).
[1296] ibid 151.
[1297] ibid; see also B Liu, 'The National Government Policy and Efforts on Promoting Traditional Medicine in China' in WHO Centre for Development (*ed*), *Traditional Medicine, Its Contribution to Human Health Development in the New Century: Report of an International Symposium, Kobe, Japan, 6 November 1999* (Kobe, Japan: World Health Organization 2000).

medicine practitioner from any of these universities or colleges, a candidate must complete five years of study.[1298] Similarly, the Indian government has established national institutes for the training of traditional medicine practitioners and homoeopaths. Notable among them are: the National Institute of Postgraduate Teaching and Research in Ayurveda (New Delhi), which offers PhD and MD degrees in Ayurveda; National Institute of Unani Medicine (Bangalore), which offers postgraduate research opportunities in Unani; and National Institute of Homoeopathy (Calcutta), which provides Bachelor's and MD degrees in homoeopathy.[1299] Colleges of traditional medicine in India are only established with the authorisation of the central government and the prior approval of their infrastructure and curriculum.[1300] There are also annual and impromptu visits to ensure that the colleges comply with educational and infrastructural standards, and government reserves the right to rescind authorisation issued to any college that fails to meet such standards.[1301]

Concerning the second objective, there will be a need for structuring the training programmes for traditional medicine practitioners to include fundamental principles of primary and public health care, as well as ensuring that degrees in pharmacy, medical and public health include a module on traditional medicine.[1302] A good example of this educational structure exists in China, where medical education is integrated. Although conventional medical schools outnumber traditional medical schools in China, every conventional medical school comprises a department of traditional medicine.[1303] Likewise, every traditional medical school consists of a department of conventional medicine.[1304] An estimate of 10 to 20 per cent of the syllabi in conventional medical schools is allocated to traditional medicine.[1305] While there is no evidence of any shortcoming of this hybrid curriculum in China, the same cannot be said for India, which

[1298] Milton Irwin Roemer, *National Health Systems of the World* (Vol 1, Oxford University Press 1991).
[1299] Department of Health and Family Welfare, Ministry of Health and Family Welfare, 'Annual Report 1998-1999' (n 1242).
[1300] Ministry of Health and Family Welfare, 'Communication with WHO from Government of India' (Government of India 2013); see also World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine' (n 1243).
[1301] ibid.
[1302] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 25.
[1303] Marilynn M Rosenthal, 'Modernization and Health Care in the People's Republic of China: The Period of Transition' in Marilynn M Rosenthal (*ed*), *Health Care Systems and their Patients: An International Perspective* (Boulder: Westview Press 1992).
[1304] ibid.
[1305] ibid.

has a similar structure for training traditional medicine practitioners. This system of integrated education has been criticised for producing inadequately trained graduates in conventional and traditional systems in India.[1306] Candidates who from the outset intended to qualify at the end of their studies as AYUSH doctors tend to deviate towards the practice of conventional medicine.[1307] This is because elements of conventional medicine dominate the course curricula in Indian institutions of learning.[1308]

This points to the need to ensure that when establishing such a system, the course content of integrated education is designed to promote complementarity, as opposed to engendering superiority of one system of health care over the other. In this regard, traditional medicine courses must consist of relevant topics, such as traditional medicine policies or regulations, methods of evaluating the toxicity of herbal products, healthcare management, and procedures for standardisation, cultivation and marketing of medicinal plants.[1309] Thus, as a means of ensuring the quality, safe and effective use of traditional treatments, it is essential to develop a broader education base for traditional medicine practitioners. The establishment of training institutions will ensure that persons who practise traditional medicine are qualified and possess sufficient knowledge and skills to administer traditional treatments. Also, the integration of courses on conventional and traditional medicines in training institutions will enhance a better understanding of the differing practices of both systems.[1310] While conventional medicine practitioners will become aware of the context of traditional medicine and its approaches to health care, traditional medicine practitioners will learn the basic practices and principles of conventional medicine.[1311] This knowledge integration will not only promote the best care for patients but will also foster collaboration and respectful co-existence between the two systems of medicine[1312] in the national health systems of developing and least-developed countries.

[1306] Patwardhan et al., 'Ayurveda and Traditional Chinese Medicine' (n 1072) 465-473.
[1307] Singh et al. (n 1266).
[1308] ibid.
[1309] Kishor Patwardhan, Sangeeta Gehlot, Girish Singh and H C S Rathore, 'Global Challenges of Graduate Level Ayurvedic Education: A Survey' (2010) 1(1) *International Journal of Ayurveda Research* 49-59.
[1310] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (World Health Organization 2000).
[1311] ibid.
[1312] ibid.

5.2.2. Collaboration and Communication between Traditional Medicine Practitioners and Conventional Medicine Practitioners

Practitioners of conventional and traditional medicines have reacted in differing ways to the concepts and practices of the two systems, as noted in Chapter four. These reactions range from complete rejection by conventional medicine practitioners of traditional medicine, and vice versa, to the parallel existence of the two systems with little communication over patient care, and to forced acceptance, subsuming and integration of one system (usually traditional medicine) by the other.[1313] None of these reactions is ideal because none confers adequate respect on the practices of the other.[1314] From patients' perspective, lack of collaboration and communication between conventional and traditional medicine practitioners may translate into inadequate health care because these may lead to a weak utilisation and exploration of the benefits presented by each system.[1315]

What is more, some patients lean towards not disclosing the use of traditional medicine to their conventional medicine physician. This is usually in anticipation of a negative response or an impression of disinterest from the physician.[1316] Other patients believe that some physicians are unwilling to contribute useful information or have a perception that traditional medicine is not relevant to the conventional treatment they are receiving at the time.[1317] This is detrimental to the health of the patient as it has been understood that adverse effects resulting from taking herbal drugs and chemical drugs together can occur. For instance, recall from Chapter four that if patients who are placed on Indinavir – an HIV protease inhibitor – take St John's wort (a herbal anti-depressant), levels of Indinavir in the blood are reduced below the level required to fight HIV multiplication.[1318] Further, the indifference of conventional medicine practitioners is of concern because patients value their physician's attitude and judgement regarding treatment choices, sometimes

[1313] ibid.
[1314] ibid.
[1315] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (n 1239).
[1316] Moshe A. Frankel and Jeffery M. Borkan, 'An Approach for Integrating Complementary and Alternative Medicine into Primary Health Care' (2003) 20(3) *Family Care* 324-332.
[1317] ibid.
[1318] 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 27.

even when both parties disagree.[1319] Thus, it is important to adopt strategies to foster not only good communication between traditional medicine practitioners and their conventional counterparts but also to create an open relationship between patients and their respective healthcare providers.

To create these webs of relationships, these strategies should be directed at providing education to conventional medical practitioners to increase awareness on the health-related cultural backgrounds, beliefs and benefits of traditional medicine.[1320] According to the WHO, such strategies should also gear towards promoting mutual understanding and respect, and facilitate referrals between practitioners of traditional and conventional medicines.[1321] The WHO also observes that another target should be to encourage people-centred health care through enhancing the communication between health providers and their patients.[1322] This relationship will create a suitable environment in which patients can see their physicians as partners in choosing treatment and feel comfortable about disclosing traditional medicine use.[1323] Ultimately, the purpose of working towards collaboration and good communication is to achieve the best care for the patient by pursuing the best route to health and wellness. A Ugandan case study provides a good illustration of how collaboration between traditional and conventional medicine can provide improved care for patients. This case study is also relevant because it demonstrates critical issues regarding the proper use of traditional medicine. The collaboration, reported in 2010, known as 'the Kirumba Crisis-Management Group' involved the indigenous people of Kirumba Sub-County in the Rakai District of Uganda, an NGO, and a government research institute.[1324] This partnership aimed to provide affordable primary health care to the community which was overwhelmed by the outbreak of AIDS and other diseases.[1325] The group developed herbal medicines to treat common disease symptoms by identifying some plant species that could be used to treat these diseases; isolating plants with toxic effects and associated side effects by screening 184

[1319] Frankel and Borkan (n 1316).
[1320] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (n 1239).
[1321] ibid.
[1322] World Health Organization, 'The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2012' (n 1239).
[1323] Frankel and Borkan (n 1316).
[1324] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1325] ibid.

samples of medicinal plants and distributing the improved herbal medicines to over 600 patients.[1326]

While the obvious inference from this case study is that collaboration between traditional medicine and conventional medicine can deliver improved and affordable care, it is arguable that such collaboration can also enhance the quality, safety and efficacy of traditional medicine. This argument is supported by the fact that the involvement of, notably, the government research institute could have facilitated the screening of the plants to ascertain those with toxic and adverse effects. The result of screenings such as this could be documented, with clear categorisation of safe and unsafe plants, and such document could constitute evidence of safety and efficacy of the herbal medicines contained in it. Besides, it is also arguable that when genetic resources are utilised based upon prior informed consent, with the involvement, and for the benefit of the indigenous peoples, as provided by the United Nations Declarations on the Rights of the Indigenous Peoples (UNDRIP) 2007, the Convention on Biological Diversity 1992 and its Nagoya Protocol 2010, the indigenous peoples would be inclined to share their traditional knowledge regarding the medicinal uses of plants.[1327] This is based on the theory that the Kirumba local community is likely to have been responsible for pointing out to the researchers plants with medicinal value based on traditional uses. In addition to the screening, members of the community could also have helped in identifying plants that were toxic and had adverse effects based on traditional medical knowledge.

Further highlighting the importance of communicative and synergistic treatment between traditional and conventional medicine is the referral system in Oku in Cameroon. Traditional healers in Oku refer their patients to conventional medicine institutions for diagnostic lab tests.[1328] This is usually done in conjunction with divination to determine the patient's sickness.[1329] Sometimes after treatment, traditional healers instruct their patients to repeat the lab tests to establish the effectiveness of the traditional treatment.[1330] In some other cases, they may also send their patients to conventional medicine

[1326] ibid.
[1327] The rights of the indigenous peoples are dealt with extensively in Chapter six.
[1328] Kelly, 'Contemplating Collaboration' (n 1237).
[1329] ibid.
[1330] ibid.

practitioners to receive other forms of treatment.[1331] On the other hand, some conventional medicine practitioners have collaborated with traditional healers (besides carrying out diagnostic tests on patients sent to them by traditional healers) mainly for two reasons. First, there is a situation in which partnership appears to be inevitable. This is where the patient has a firm belief that the sickness has a spiritual origin, and can only be cured spiritually by traditional medicine.[1332] Secondly, there is the situation of referring patients to traditional healers in cases of terminal illness when conventional medicine options have been exhausted.[1333] In this case, both conventional medicine practitioners and their patients tend to find traditional medicine appealing because diseases diagnosed as terminal and incurable by conventional medicine may have existing cures within the traditional medicine system.[1334]

This case study is significant for two reasons. First, the practice of referring patients to conventional medical practitioners by traditional healers for diagnostic lab tests and for testing the effectiveness of treatment, illustrates that the willingness to collaborate between these two systems could lead to traditional practitioners adopting safe practices by taking advantage of modern scientific technologies existing in conventional medicine, thereby ensuring that patients receive quality, safe and effective treatment. Secondly, this case demonstrates the need for conventional medical practitioners to be open-minded and accepting of the traditional context surrounding the use of traditional medicine. The consideration should be less of whether or not some of traditional medicine's practices are superstitious and unverifiable, and more of what is in the best interest of the patient, which includes making an allowance for the patient's belief system. More so, there is evidence supporting the relevance of traditional medicine in providing primary health care. They could capitalise on this system of medicine for promoting the highest level of patient care. Thus, the collaboration between traditional and conventional medicines is a major factor towards realising the proper use of traditional medicine to achieve the best care for patients and as a result, a crucial step towards integrating traditional medicine into the national health systems of developing and least-developed countries to achieve sustainable development by 2030.

[1331] ibid.
[1332] ibid.
[1333] ibid.
[1334] ibid.

Nonetheless, there is a significant factor militating against the successful collaboration between conventional and traditional practitioners, notwithstanding its enormous advantages. More often than not, there is an absence of transparency in the method of collaboration that results in a situation where the purported collaboration is dominated by one system, usually the conventional medicine system,[1335] as mentioned earlier. It is possible that in some circumstances, this domination could be fostered by a government policy that favours one system over the other. For instance, Dr Balpreet Singh of the Centre for Public Health, Panjab University, India, and his colleagues reported a study evaluating the implementation status of India's national policy on traditional medicine, which noted that one key problem responsible for the poor performance of the AYUSH system was the treatment meted out to AYUSH district officers.[1336] Whereas conventional district officers had official vehicles to monitor their health facilities, most AYUSH district officers were given none.[1337] This mirrored 'a step-motherly treatment to AYUSH by authorities'.[1338] Thus, for collaboration to be successful, it must be based on equal treatment and respect, mutual understanding through dialogue, and free exchange of technology and information concerning management of diseases.[1339] Such collaboration must emphasise complementarity between both systems by referral from one system to the other, particularly to traditional medicine practitioners that are recognised in the community as competent in managing diseases.[1340] As put succinctly by the former WHO Director-General, Dr Margaret Chan:

> [T]he two systems of traditional and [conventional] medicine need not clash. Within the context of [primary health care], they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made.[1341]

[1335] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1336] ibid.
[1337] ibid.
[1338] Singh et al. (n 1266).
[1339] Singh et al. (n 1266).
[1340] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1341] Chan, 'Address at the WHO Congress on Traditional Medicine' (n 207).

Also, religious and biomedical societies should be advised against stigmatisation of traditional medicine in their communications.[1342] Governments of developing and least-developed countries should hold a dialogue on this issue with religious leaders and medical educators as part of their efforts to promote access to health care for the poor.[1343] This step would be in the interest of prospective collaboration and the rational use of traditional medicine.[1344]

5.2.3. Developing Consumer Information on the Proper Use of Products of Assured Quality

There are various instances of improper use of traditional medicine by consumers not limited to cases of overdose, ingesting suspect or counterfeit herbal products, and injuries – in some cases death – caused by unqualified traditional medicine practitioners. These occurrences are borne out of the current trend in which patients are more proactive towards their health and resort to different forms of self-care. Based on these, it has become crucial to develop information regarding the proper use of traditional medicine to ensure that consumers are well informed in order to prevent similar instances of improper use of traditional medicine in the future. WHO, with the support of the Regional Government of Lombardy, Italy, developed a set of technical Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine in 2004. Under the guidelines, information relevant to proper use should include:

5.2.3.1. Information as to the quality of traditional medicine

Identifying traditional medicine therapies of assured quality is fundamental to preventing improper use by consumers. This makes it important to provide information regarding quality on packages, label or leaflets that are provided with the medication given by a traditional medicine provider or retailer.[1345] Such information would include information on compliance with Good Manufacturing Practices (GMP), the product registration

[1342] Kelly, 'Contemplating Collaboration' (n 1237).
[1343] ibid.
[1344] ibid.
[1345] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).

number, active ingredients and other relevant information about the product.[1346] This information is even more important if in a given jurisdiction, certain traditional medicine therapies are marketed as food supplements,[1347] for instance, as practised in the US, Japan, Canada and India, to mention a few.[1348] This could potentially make it difficult for consumers to assess quality, as such traditional medicine is not subjected to rigorous regulations compared with when it is marketed as a pharmaceutical;[1349] thus, highlighting the need to enable consumers to make informed decisions in relation to quality. In providing this information, consumers should be informed to pay attention to the quantitative composition and the local and *Latin* names when attempting to identify active ingredients in traditional medicine products.[1350] Identifying species in their local and *Latin* names, whether plant or animal species including minerals and vitamins, is imperative because local names are sometimes used for different species with different biological activities.[1351] Equally important, *Latin* binomial names consist of two parts: the first part identifies the genus, while the second part describes the particular species.[1352] For example, while neem (which is used to treat malaria) is locally known as 'Ogwuakon' in South-Eastern Nigeria, its binomial name is *Azadirachta indica*: *Azadirachta* being its genus, whereas *indica* is the species.[1353]

In addition, because different parts of species can also have different biological activities, it is crucial to inform consumers of the need to identify the parts of the species (e.g. plant leaves, roots or bark) used for the preparation of the traditional medicine therapy so as to ensure that the part was used correctly.[1354] It would be helpful to have such information regarding ingredients of a traditional medicine product stated clearly on its label or explained orally by the retailer at the point of purchase.[1355] This raises a critical issue, which inasmuch as can be seen from existing literature, has not been considered. For a

[1346] ibid.
[1347] ibid.
[1348] Pandey et al. (n 1189).
[1349] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1350] ibid.
[1351] ibid.
[1352] ibid.
[1353] Emeka Okonkwo, 'Traditional Healing Systems Among Nsukka Igbo' (2012) *Journal of Tourism and Heritage Studies* 78.
[1354] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1355] ibid.

retailer to explain the identity of the ingredients to a consumer, s/he ought to possess sufficient traditional medical knowledge. Consequently, there is a need for licencing retailers of traditional medicine in order to ensure that they are qualified persons capable of appropriately advising consumers on the proper use of traditional medicine. Furthermore, official product-quality-certifications should be available based on national quality standards and registration or licencing policies for traditional medicine therapies.[1356] For instance, marking the product with specific labels, such as the licence symbol used by Swissmedic[1357] (Swiss Agency for therapeutic products) or the 'L' sign together with a registration number used by the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC)[1358] to certify that a product is of quality and fit for public use. Moreover, the product's label should bear information concerning storage of the medicinal preparation and expiry date.[1359] This information is relevant for preventing early ageing or destruction of the product, and to deter consumers from purchasing or using traditional medicine therapies beyond their expiry date.[1360] In the main, providing this information will guide consumers to choose quality products.

5.2.3.2. Formulating treatment guidelines

It would be useful to develop a set of treatment guidelines regarding traditional medicine therapies that are commonly used. This could serve as a guide to traditional medicine practitioners, conventional medicine providers and users of traditional medicine. One should be able to identify the advantages and disadvantages of a traditional medicine therapy by consulting these guidelines. Thus, a traditional medicine treatment guideline should consist of information as to methods of diagnosis and treatments, benefits, risks, health promotion and strategies, as well as the philosophy underlying any traditional medicine therapy.[1361] For example in India, there are the National Essential Drug List, containing both conventional and AYUSH medicines; and the Clinical management Protocol or a Joint Behaviour Change Plan incorporating AYUSH-based lifestyle

[1356] ibid.
[1357] ibid.
[1358] Borokini and Lawal (n 779) 31.
[1359] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981); see also Carvalho et al. (n 757) 467-473.
[1360] ibid.
[1361] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).

guidelines for adolescent health, geriatric care, mental health, non-communicable diseases and nutrition.[1362] Competent national or local authorities should be able to determine what therapies are to be included in such guidelines based on for instance, the extent to which certain traditional medical therapies are utilised, taking into consideration proofs of their quality, safety and efficacy.[1363] Overall, a reliable treatment guideline is vital to forestall irrational use and essential in aiding users in making informed choices concerning traditional medicine use.[1364]

5.2.3.3. Information on risks, adverse events, interactions and contraindications

Consumers, particularly those with allergies, should be made aware of any risks, unintended or undesirable events associated with the use of traditional medicine, as well as their causality.[1365] This cannot be overemphasised, as awareness and vigilance are crucial to reducing risks.[1366] Likewise, consumers need to be provided with instructions on what to do in case of adverse events or an overdose, including whom to contact.[1367] It is equally important for them to be able to identify the holder of the market authorisation for the traditional medicine therapy. The development and dissemination of 'standard reporting forms' would be beneficial for reporting suspected adverse reactions to traditional medicine.[1368] These forms should be made available to traditional medicine practitioners, retailers or other persons involved in the provision of traditional medicine. However, it should also be possible to receive such reports by telephone, e-mail, or letter.[1369] Also, consumers need to understand the importance of informing their conventional and traditional medicine providers about any concurrent use of medicines. This is because the interaction between traditional and conventional medicines is not well known, as mentioned in Chapter four. While the parallel use of both therapies may yield

[1362] Kounteya Sinha, 'Traditional Medicine to Get Separate Drug Control Chief' *The Times of India* (5 May 2012) <http://timesofindia.indiatimes.com/india/Traditional-medicine-to-get-separate-drug-control-chief/articleshow/13002441.cms?> accessed 30 January 2017.
[1363] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1364] ibid.
[1365] ibid.
[1366] Edzard Ernst, The Desktop Guide to Complementary and Alternative Medicine: An Evidence Based Approach (Harcourt Ltd 2001).
[1367] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1368] ibid.
[1369] ibid.

good results, it may also 'magnify and oppose the effects of the treatments'.[1370] Thus, this interaction requires further study, making it all the more essential for healthcare providers, as well as consumers, to be alert in this regard and report cases of possible interactions.[1371]

5.2.3.4. Information on prescription, posology, and self-medication of traditional medicine

Traditional medicine consumers should be made aware of some therapies, which although potent, could be toxic as well. Such medicines are usually processed in ways that would lower their toxicity level.[1372] However, if wrongly processed or misused, they could be very harmful and result in poisoning. Thus, consumers need to be informed that such medicines should not be used without prescription and guidance from a registered traditional medicine provider.[1373] Besides, it is only traditional medicine practitioners that are usually legally empowered to prescribe potent and toxic therapies.[1374] Certainly, this should be brought to the attention of consumers. Moreover, developing treatment guidelines, as already mentioned, would be helpful in this case as it would enable consumers to identify medications that are potent and toxic and requiring a prescription by a traditional medicine practitioner. Also, common symptoms of poisoning and steps for reporting possible poisoning cases should be spelt out in the information material provided with the therapy.[1375]

Further, consumers should be provided with instructions on when to take the medication – whether in the morning, afternoon, night, before, with or after meals; how to take the medication – with or without certain foods, or hot or cold drinks; and the duration for which it should be taken.[1376] The traditional medicine practitioner should provide this information, and if possible it should be clearly written on the label or leaflet

[1370] ibid.
[1371] ibid.
[1372] ibid.
[1373] ibid.
[1374] ibid.
[1375] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1376] ibid.

accompanying the medication.[1377] Regarding consumers who choose to self-medicate, they should be made aware of the importance of following instructions and proper recommendations.[1378] In this connection, consumers should be encouraged to discuss their self-medication with their traditional medicine and conventional medical providers, particularly if there is no clearance of symptoms, no general improvement or if symptoms worsen or adverse effects are suspected after consuming any traditional medical therapy.[1379] More, a list of conditions and traditional medicine therapies suitable for self-medication (contained preferably in the treatment guidelines) would be useful in guiding the consumer who wishes to self-medicate.[1380] Suitability of self-medication should also depend on the extent of the consumer's knowledge of traditional medicine.[1381]

5.2.3.5. Information on methods of preparation and administration of traditional medicine

It is common for consumers to prepare their medicines from raw materials, especially those who elect to self-medicate. Recall from Chapter three the 1998 African survey by the WHO Roll Back Malaria Programme in Ghana, Mali, Nigeria and Zambia, which revealed that over 60 per cent of children with high fever received treatment at home with herbal medicines.[1382] As noted by the Department of Health in Hong Kong (SAR), China, it is essential that consumers possess some knowledge regarding the preparation of traditional medical therapies.[1383] In view of this, it is important to develop a recipe that would inform the consumer regarding, for instance, the amount of raw material to use for a certain amount of water; the order in which to add specific ingredients; how long to boil, simmer, or steep the ingredients; and the length of time to use the preparation.[1384] Traditional medicine practitioners could also provide this information. However, it would be expedient to make this information publicly available by means such as a brochure to

[1377] ibid.
[1378] ibid.
[1379] ibid.
[1380] ibid.
[1381] ibid.
[1382] Oguamanam, *International Law and Indigenous Knowledge* (n 69) 119; see also 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 13; and Aginam (807) 87-103.
[1383] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1384] ibid.

provide directions for preparing traditional medicine therapies.[1385] While this idea is desirable, making knowledge of traditional medicine publicly available and accessible raises intellectual property concerns, such as ownership and misappropriation of the knowledge regarding the formula for preparing a particular traditional medicine, whether the prior informed consent of the knowledge holders was sought prior to the dissemination of the knowledge; and if such person(s) have been compensated for the wider application of the knowledge. These issues have ramifications for access to traditional medicine as examined in Chapter six.

Additionally, it is fundamental that information concerning how to administer traditional medicine therapies is clearly detailed on the label. This would enlighten consumers on the appropriate method of administration of different dosage forms, such as tablets, capsules, salves, decoctions, tinctures and tisanes.[1386] For instance, it may be more suitable for children to take medicines that are in the form of syrups or tinctures rather than tablets. Traditional medicine practitioners or retailers are also available for consumers to discuss what method of administration is most appropriate, and this should be encouraged.[1387]

5.2.3.6. Information regarding children, pregnant or lactating women and the elderly

Children and the elderly usually require a dosage different from that normally prescribed for adults. Also, pregnant or lactating women may risk their health, as well as their baby's by using certain traditional medicine therapies due to possible adverse effects.[1388] In light of these, this group of people should be informed that the decision to use traditional medicine cannot be made without consulting a traditional medicine provider.[1389] It would be helpful if such information were clearly stated on the label of the medication, particularly emphasising that women who are pregnant or breastfeeding should consult a

[1385] ibid.
[1386] ibid.
[1387] ibid.
[1388] Ernst (n 1366).
[1389] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).

registered traditional medicine practitioner before using the medication.[1390] Even where the available health care is conventional, consultation of the healthcare provider in the case of this group before using traditional medicine should be heavily encouraged on the label.[1391]

5.2.3.7. Information on how to identify qualified traditional medicine practitioners and report incidents of malpractice

To ensure consumer safety, consumers should be provided with information on how to identify qualified traditional medicine practitioners. The provision of this information would enable consumers to avoid consulting charlatans.[1392] In this instance, policies and regulations on training and qualification are essential because traditional medicine practitioners have to fulfil their requirements to be considered qualified to practise traditional medicine. In like manner, systems for registration and reporting incidents of malpractice are crucial for ensuring that only qualified practitioners practise traditional medicine.[1393] Such qualified/registered traditional medicine practitioners are often issued certificates by national authorities or voluntary professional organisations by which they can be identified. It would be equally helpful to develop a directory of qualified/registered traditional medicine practitioners, which would be made publicly available in print, on the Internet, through a traditional medicine information centre, local authorities, consumer organisations, or professional organisations.[1394] Consumers should be made aware of all these, and also notified as to where reports of malpractice by traditional medicine practitioners can be lodged.[1395]

5.2.3.8. Information on treatment claims

Importantly, claims concerning what diseases a traditional medicine therapy treats should be unambiguously stated on the label. It must be ensured that products claimed to be

[1390] ibid.
[1391] ibid.
[1392] ibid.
[1393] World Health Organization, *Guidelines on Basic Training and Safety in Acupuncture* (Geneva: World Health Organization 1999).
[1394] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1395] Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).

marketed for their traditional use are used in the same manner.[1396] Regulatory or licencing authorities have a vital role to play in this regard, as they can provide or verify such treatment claims, as well as ensure that such claims are in accordance with their traditional methods of use.[1397]

While the information enumerated under this section is vital for ensuring proper use of traditional medicine by consumers, it is also of great consequence to consumer safety to consider measures necessary to ensure the quality, safety and efficacy of traditional medical therapies and practices.

5.3. Quality, Safety and Efficacy of Traditional Medicine

Promoting the quality, safety and efficacy of traditional medical therapies and practices to achieve universal health coverage and access to medicines for sustainable development can be realised through expanding the evidence-base of traditional medicine and providing guidance on regulatory and quality assurance standards.

5.3.1. Quality Assurance of Traditional Medicine

One basic fact about traditional medicine therapies, as noted in Chapter four, is that the quality of the raw materials ultimately impacts on the effectiveness of the medicines.[1398] As for the quality of the raw materials, endogenous factors (e.g. genetics) and exogenous factors (such as environmental conditions, cultivation and harvesting, field collection and post-harvest/collection, transport and storage) are major determinants of quality.[1399] With this in mind, implementing quality control standards is a complex and demanding exercise. As already mentioned in Chapter three, standardisation of traditional medicine has become very important due to the 'modernisation' of traditional medicine. While formerly healers and shamans in indigenous and local communities collected plants from

[1396] ibid.
[1397] ibid; see also World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine' (n 1243); and World Health Organization, 'Regulatory Situation of Herbal Medicines: A Worldwide Review' (Geneva: World Health Organization 1998).
[1398] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1399] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).

nearby forests and fields to prepare and administer treatment, there now exist herb sellers and manufacturers in urban markets and indeed around the world selling herbal preparations,[1400] sometimes in finished dosage forms.[1401] Recall from Chapter four that there have been reports that these preparations are occasionally contaminated, adulterated or spiked. For example, Harvard Medical School has recommended mandatory toxic heavy metal testing for some Ayurvedic herbal preparations after reporting that they had heavy metal contents.[1402]

Given this situation, establishing quality has become a mandatory process in the production of any herbal therapeutic agent. GMP[1403] and Good Laboratory Practices (GLP)[1404] stipulate many requirements to this end. For instance, the Good Guidelines on GMP for herbal medicines developed by WHO requires proper identification (through Ethnobotany and Pharmacognosy)[1405] to establish the authenticity of the source of the plant material.[1406] Also, fungal and bacterial contamination, including heavy metals, radionuclide, and adulteration with pharmaceutical drugs must be controlled throughout the production stages.[1407] In terms of certifying the bioactive properties of raw materials used in production, pharmacological and toxicological evaluations can be conducted in accordance with GLP.[1408] Fortunately, newer techniques that are useful for standardisation are evolving. For example, multi-component preparations can be standardised using DNA fingerprinting, High-Pressure Chromatography and Liquid Chromatography-Mass Spectroscopy to separate, identify and quantify samples.[1409] More often than not, these evaluations are predictors of the safety of the products

[1400] Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (2005) WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH).
[1401] 'Use of Chinese Proprietary Medicine' (*HSA*, 7 July 2016) <http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Consumer_Information/Consumer_Guides/Complementary_Health_Products/Use_of_Chinese_Propriatary_Medicine.html> accessed 21 November 2016.
[1402] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).
[1403] World Health Organization, Good Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines (Geneva: World Health Organization 2009).
[1404] World Health Organization, Handbook of Good Laboratory Practices (GLP): Quality Practices for Regulated Non-clinical Research and Development (2nd edn, Geneva: World Health Organization 2009).
[1405] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1406] Good Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines (n 1403).
[1407] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887); see also World Health Organization, 'The Regional Strategy for Traditional Medicine in Western Pacific 2011-2012' (n 1239).
[1408] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1409] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).

manufactured. [1410] Notwithstanding, these quality assurance procedures must be implemented by developing and least-developed countries through national regulations and guidelines. Such regulations and guidelines should touch on all aspects of production (growing, collection and storage); manufacturing (GMP and GLP); pre-market assessment of quality, safety and efficacy; product registration and post-market activities; as well as surveillance in the marketplace; effective and timely recall procedure; audit of GMP; and effective controls of advertising products.[1411] More on this issue further on.

5.3.2. Expanding the Evidence-base of Traditional Medicine

The history of the use of traditional medicine is extensive, spanning over thousands of years.[1412] In fact, the safety and efficacy of many traditional medicine therapies are reinforced by empirical evidence.[1413] Such evidence is located in sources such as traditional scriptures, pharmacopoeias and clinical experience recorded over centuries.[1414] Also, there has been a proliferation of scientific studies in very recent times that corroborate the use of traditional medicine to treat diseases. For example, researchers have conducted pilot studies on traditional medicine in some countries.[1415] Some of these studies on the use of traditional medicine to care for HIV/AIDS patients in Burkina Faso, Kenya, South Africa, Uganda, Zambia and Zimbabwe showed the effectiveness of traditional medicine.[1416] Nonetheless, it must be added that others showed the presence of toxicity when traditional medicine was used in certain doses or for a lengthy period – an adverse reaction which is not uncommon with conventional medicines.[1417]

That said, one of the reasons for statements such as 'there is no evidence supporting the safety and efficacy of traditional medicine' is that most existing evidence such as those

[1410] Kasilo and Trapsida, 'Regulation of Traditional Medicine in the WHO African Region' (n 887).
[1411] World Health Organization, 'The Regional Strategy for Traditional Medicine in Western Pacific 2011-2012' (n 1239).
[1412] Biljana Bauer Petrovska, 'Herbal Review of Medicinal Plants' Usage' (2012) 6(11) *Pharmacognosy Review* 1-5.
[1413] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1414] Petrovska (n 1412); see also ibid.
[1415] Cooper et al., *Africa's Health Challenges* (n 1112).
[1416] ibid.
[1417] Cooper et al., *Africa's Health Challenges* (n 1112).

alluded to are not published in the English language.[1418] A good counter would then be that the 'absence of evidence is not evidence of absence'.[1419] This highlights the need to translate, collate and disseminate such research findings.[1420] However, some other existing evidence of the safety and efficacy of traditional medicine are heavily criticised for methodological flaws.[1421] For example, during the reign of the Song Dynasty in China, comparative trials were conducted to verify the efficacy of traditional medicines such as ginseng.[1422] Such trials consisted of as little as two participants, one of whom was given ginseng to eat; after which, both were required to run in order to observe who developed shortness of breath sooner – the one who ate the ginseng or the one who ran without.[1423] The contention is that trials of this nature do not subject traditional medicine to a rigorous systematic evaluation to improve the state of knowledge regarding its safety and efficacy.[1424]

5.3.2.1. Evidence-based medicine (EBM)

Beginning from 1992, there has been a worldwide movement in medicine towards EBM. EBM understates 'intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research', and the 'conscientious, explicit, and judicious use' of the results of such clinical research in treating patients.[1425] In support of this movement, conventional medicine practitioners have argued that the only source of valid knowledge regarding clinical efficacy is the randomised controlled trial (RCT) which is often regarded as the gold standard for a clinical trial.[1426] The limited evidence of the efficacy of traditional medicine based on RCT presents another reason why traditional medicine

[1418] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1419] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).
[1420] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1421] ibid.
[1422] ibid.
[1423] Charles Vincent and Adrian Furnham, *Complementary Medicine: A Research Perspective* (John Wiley & Sons 1997) 147; see also Bencao Tujing, *Atlas of Materia Medica* (1061AD).
[1424] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1425] ibid.
[1426] Tilburt and Kaptchuk (n 785).

is accused of being devoid of evidence in support of its safety and efficacy.[1427] As a result, there are now calls for traditional medicine and treatment claims of traditional medicine practitioners to be subjected to such 'high standards'.[1428] Whether or not this suggestion is a cause for concern will be discussed later.

5.3.2.2. National strategic actions

For traditional medicine to be integrated into the national health systems of developing and least-developed countries in light of the above, it is important to promote clinical research with a view to establishing its safety and efficacy. One way of achieving this is to build and strengthen national research capacity and programmes.[1429] Also, the amount of research on the safety and efficacy of traditional medicine can be enhanced through selective investment.[1430] More, research programmes involving government, academic institutions and the private sector should be established.[1431] Training programmes on research methodology should be provided, including developing technical guidelines and establishing criteria for assessing quality, safety and efficacy of traditional medicine.[1432] Such guidelines and criteria could be developed in line with, for example, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA). The strategy promotes new thinking on innovation and access to medicines and aims to secure an enhanced and sustainable basis for needs-driven essential health R&D relevant to diseases that disproportionately affect developing and least-developed countries.[1433]

Some of the provisions of China's regulation on traditional Chinese medicine offer good examples of national strategic actions. Article 22 of the regulation provides that with regard to the scientific research of traditional Chinese medicine, traditional and modern technological methods should be employed in basic theoretical and clinical research,

[1427] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).
[1428] ibid.
[1429] World Health Organization, 'The Regional Strategy for Traditional Medicine in Western Pacific 2011-2012' (n 1239).
[1430] ibid.
[1431] ibid.
[1432] ibid.
[1433] World Health Organization, 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (Geneva: World Health Organization 2011) 1.

including research for the prevention and treatment of common diseases, frequently occurring diseases, and difficult and complicated cases.[1434] The regulation also urges research institutions, universities, colleges and medical institutions of traditional Chinese medicine to cooperate in tackling key problems in scientific research of traditional Chinese medicine, enhance the popularisation and application of the scientific and technological achievements of traditional Chinese medicine, and train technical personnel for traditional Chinese medicine.[1435] In addition to these strategies, it would be useful to collate and document traditional medical knowledge to serve as a knowledge base and a starting point for further research.[1436] Closely related to this is the importance of also documenting clinical research outcomes to provide future evidence of the safety and efficacy of traditional medicine. For example, Article 28 of China's traditional Chinese medicine regulation requires the government to take measures to strengthen collection, collation, study and protection of traditional Chinese medicine literature.[1437] It also requires relevant units and institutions of traditional Chinese medicine to strengthen management, protection and use of traditional Chinese medicine literature.[1438]

As contemplated by this provision, China has created a series of databases that contain information relating to traditional Chinese medicine, *inter alia:* the Traditional Chinese Medical Literature Analysis and Retrieval Database, which records over 600,000 references and abstracts of traditional Chinese medicine literature including Chinese herbal medicines, acupuncture, qigong, Chinese massage and others; and the Database of Chinese Medical Formula, which consists of about 85,000 medical formulas collected from over 700 ancient medical books.[1439] Some of these databases are protected in accordance with Article 28, as they are not available in the public domain, for example, the China Traditional Chinese Medicine Patent Database (CTCMPD), which contains 22,000 TCM-related patents and 40,000 traditional Chinese medicine formulas, recorded

[1434] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 22.
[1435] ibid, art 22.
[1436] World Health Organization, 'The Regional Strategy for Traditional Medicine in Western Pacific 2011-2012' (n 1239).
[1437] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 28
[1438] ibid.
[1439] R Lakshmi Poorna, M Mymoon and A Hariharan, 'Preservation and Protection of Traditional Knowledge – Diverse Documentation Initiatives Across the Globe' (2014) 107(8) *Current Science* 1240, 1242-1244.

from 1985 to the present.[1440] Nevertheless, others are widespread and accessible,[1441] and the public is free to exploit the information they contain on traditional medical knowledge. Such exploitation is problematic; one that forms part of the intersection between intellectual property rights and traditional medical knowledge as assessed in Chapter six.

5.3.3. Regulation and Registration of Traditional Medicine Products

As previously explained, quality assurance standards must be implemented through national policies and regulations. The same applies to regulations encouraging the generation of clinical evidence, as well as national standards, technical guidelines and methodology to ensure the safety and efficacy of traditional medicine; governments of developing and least-developed countries must be proactive in this regard. That said, regulations and guidelines on traditional medicine products should be detailed enough to include all aspects of production, laboratory testing for quality and contamination, audit of GMP, pre-market assessment, product registration and post-market activities, including monitoring adverse events, market-place surveillance, timely recall procedure and adequate check on advertisements for traditional medicine products.[1442] A fact that should be borne in mind is that regulations should be tailored to address a country's particular situation.[1443] While traditional medicine is well established in some countries, other countries (already mentioned earlier) consider traditional medicine to be food and so do not allow therapeutic claims.[1444] In those that allow the sale of traditional medicine as medicinal agents, regulations require marketing approval by regulatory authorities for traditional medicine therapies. For instance, China classifies new raw materials and traditional herbal formulas as drugs requiring approval.[1445] An applicant for marketing authorisation, which is usually a corporation, pharmaceutical manufacturer, government

[1440] Poorna et al. (n 1439) 1242-1244.
[1441] ibid.
[1442] World Health Organization, 'The Regional Strategy for Traditional Medicine in Western Pacific 2011-2012' (n 1239).
[1443] 'WHO Traditional Medicine Strategy 2002-2005' (n 12); see also Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (n 981).
[1444] World Health Organization, 'National Policy on Traditional Medicine and Regulation of Herbal Medicine: Report of a WHO Global Survey' (Geneva: World Health Organization 2005).
[1445] ibid.

agency or scientific institution,[1446] is required to provide documentation of identification, cultivation, physical and chemical characteristics, pharmacology, standards of clinical use, stability, and preparation methods, as well as three reference samples.[1447]

In Brazil, the drug regulatory authority, the National Sanitary Surveillance Agency (ANVISA), requires proof of safety and efficacy before approving and registering any herbal medicine for marketing. The GMP Guideline provides four requirements for proving the safety and efficacy of traditional medicine, out of which a pharmaceutical company must submit one.[1448] First, to register herbal medicines, pre-clinical and clinical trials must be conducted, as is the case with other medicines in Brazil.[1449] Brazil developed a guide that provides a minimum standard for conducting pre-clinical toxicological trials.[1450] Standardised herbal medicine product samples or the herbal derivatives from which they were produced should be used in carrying out such trials.[1451] Following pre-clinical tests, clinical studies are required to determine the pharmacokinetic and pharmacodynamics effects and probable adverse reactions of the drug.[1452] During all stages of these trials, the regulation requires the application of Good Clinical Practice guidelines to ensure that quality control standards are maintained.[1453] Secondly, these trials may be waived if the plant is listed in the 'list of simplified registration of herbal medicines'.[1454] This list comprises 36 plant species and was compiled by examining a number of scientific literature on these exotic species.[1455] The effect of using any plant on this list is that the pharmaceutical company would not be

[1446] Frank Xiaoqing Liu and Jack Warren Salmon, 'Herbal Medicine Regulation in China, Germany and the United States' (2010) 9(5) *Integrative Medicine* 54, 56.
[1447] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1448] Resolution ANVISA RDC No 17 of 16 April 2010 <https://translate.google.co.uk/translate?hl=en&sl=pt&u=http://189.28.128.100/dab/docs/legislacao/resolucao17_16_04_10.pdf&prev=search> accessed 1 February 2017; see also Carvalho et al. (n 718) 467-473.
[1449] Carvalho et al. (n 757) 467-473; see also Rian F M Araujo, Pedro J Rolim-Neto, Jose L Soares-Sobrinho, Flavia M M Amaral and Livio C C Nunes, 'Phytomedicines: Legislation and Market in Brazil' (2013) 94(3) *Revista Brasileira de Farmácia*.
[1450] Resolution – RE No 90/04, Guides for Studies of Pre-clinical Toxicity (2004); see also Araujo et al. (n 1449) 333; and Carvalho et al. (n 757).
[1451] Carvalho et al. (n 757).
[1452] ibid.
[1453] ibid.
[1454] ibid.
[1455] Araujo et al. (n 1449) 333; see also Carvalho et al. (n 757).

required to validate its safety and efficacy.[1456] However, this is subject to the rider that the company must use the plant in accordance with the specification contained in the list relating to the plant organ, chemical standard, plant derivative, therapeutic indications, posology, route of administration and restrictions of use.[1457]

Thirdly, a company can submit a literature containing data that validate the safety and efficacy of herbal medicines.[1458] There is a list of bibliographic references for assessment of safety and efficacy of herbal medicines, which consists of 35 reference books from which such data can be obtained.[1459] Each reference is informative as to the herbal derivative used, the plant from which it is derived, its method of extraction, posology and therapeutic indication.[1460] Also, data on safety and efficacy can be found in monographs and articles on plant species published in journals.[1461] The fourth requirement is attesting to the traditional use of the product[1462] (and this is material to a later discussion). Observation of traditional use or ethnopharmacological studies must verify that the herbal medicine has proven safe and effective for over a period of 20 or more years of use in order to meet this requirement.[1463]

While this aspect of regulation on registering traditional medicine products that require validation of quality, safety and efficacy covers the pre-marketing stage, there are the post-marketing activities which are equally important, as they relate to the monitoring of continuing quality, safety and efficacy of registered traditional medicine products once they have been placed on the market. Pharmaceutical companies and local manufacturers are required to have an effective pharmacovigilance system in place to be able to detect adverse effects or harm occasioned by the use of their products. Pharmacovigilance 'is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any possible drug-related problems'.[1464] WHO developed a guideline in 2004 on Safety and Monitoring of Herbal Medicines in

[1456] ibid.
[1457] Carvalho et al. (n 757).
[1458] RDC No 17/10; see also Araujo et al. (n 1449) 334.
[1459] Carvalho et al. (n 757) 467-473.
[1460] ibid.
[1461] ibid.
[1462] ibid.
[1463] RDC No 17/10; see also Araujo et al. (n 1449) 334; and Carvalho et al. (n 757).
[1464] Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems (n 1235).

Pharmacovigilance Systems to assist its member states in strengthening national capacity in monitoring the safety of herbal medicines and in analysing the causes of adverse events, and sharing safety information at national, regional and global levels.[1465]

Member states are advised to include herbal medicines in existing national pharmacovigilance systems (where such systems have been established in accordance with the WHO International Drug Monitoring Programme which has been in existence since the 1970s).[1466] In countries where such systems have not been established, WHO encourages its members to develop comprehensive national pharmacovigilance systems which cover herbal medicines. [1467] Brazil, for example, has internalised this recommendation by developing guidelines on pharmacovigilance to support the regulated sector.[1468] Also, Singapore has a post-market surveillance programme to monitor the safety of finished products which contain Chinese herbs, animal parts and/or minerals as active ingredients (CPM – Chinese Proprietary Medicines).[1469] This programme has two components: a risk-based market surveillance programme to sample and test products found in the market; and an adverse reaction monitoring programme, which exploits Singapore's Health Science Authority's (HSA; charged with protecting and advancing national health and safety[1470]) network of local healthcare professionals and international regulatory partners to obtain signals of any health products that may be causing adverse reactions.[1471] It is important to point out that this system of checks and controls has enabled the HSA to initiate timely recalls of products that are harmful and of inferior quality.[1472] It is also noteworthy that Brazil and Singapore are WHO member states as at 2017.[1473]

[1465] ibid.
[1466] Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems (n 1235).
[1467] ibid.
[1468] Regulatory Guide – ANVISA, 'Good Pharmacovigilance Practices and Inspection (GPPI) for MAH' RDC No 04/09, Brazil; see also Araujo et al. (n 1449) 338; and Carvalho et al. (n 757).
[1469] Health Science Authority, 'Corporate Profile' (*HSA* 15 October 2015) <http://www.hsa.gov.sg/content/hsa/en/About_HSA/Corporate_Profile.html> accessed 24 April 2017.
[1470] ibid.
[1471] 'Use of Chinese Proprietary Medicine' (n 1401).
[1472] ibid.
[1473] 'Alphabetical List of WHO Member States' (*World Health Organization*) <http://www.who.int/choice/demography/by_country/en/> accessed 23 April 2017.

Furthermore, some adverse events caused by the use of traditional medicine products have been attributed to inadequate regulation regarding issues such as advertisement and Internet sales. In the Australian jurisdiction, for example, 'complementary medicines' (as defined in Chapter three), which refer to medicinal products 'containing ingredients such as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations' are regulated by the Therapeutic Goods Act (TGA) 1989.[1474] The 'advertising of therapeutic goods is subject to the advertising requirements of the TGA, which adopts the Therapeutic Goods Advertising Code (TGAC) and the supporting regulation, the Trade Practices Act 1975'.[1475] The TGAC (which took effect on 14 November 2015) ensures that the marketing and advertising of therapeutic goods (including complementary medicines) are 'conducted in a manner that promotes the quality use of the product', are 'socially responsible', and do 'not mislead or deceive the consumer'.[1476] Again, 'advertisements appearing on television or radio, newspapers, consumer magazines, billboards and cinema films are required to be approved before publication'.[1477] Newspapers and consumer magazines' advertisements must include an approval number, and approvals are valid for two years.[1478]

Whereas the TGA does not regulate products available on international websites, the Therapeutic Goods Administration (the regulatory body for therapeutic goods in Australia) advises consumers not to order medicines, including dietary supplements and herbal preparations over the Internet unless they are aware of the ingredients of the preparation and have confirmed the legality of importing such medicine into Australia.[1479] Possessing this information is essential, as uninformed consumers could potentially risk their health, lose their money and break the law by purchasing complementary medicines via the Internet.[1480] Because of these, the Therapeutic Goods Administration suggested

[1474] Therapeutic Goods Administration, 'An Overview of the Regulation of Complementary Medicines in Australia' (*Department of Health, Government of Australia* 25 March 2013) <www.tga.gov.au/overview-regulation-complementary-medicines-Australia> accessed 1 March 2017.
[1475] ibid.
[1476] ibid.
[1477] See <www.tga.gov.au/making-complaint-about-advertising-therapeutic-product> accessed 1 March 2017.
[1478] ibid.
[1479] Therapeutic Goods Administration, 'Buying Medicines and Medical Devices Online' (*Department of Health, Government of Australia* 27 June 2016) <https://www.tga.gov.au/community-qa/buying-medicines-and-medical-devices-online> accessed 1 March 2017.
[1480] ibid.

four 'Stay Safe' steps [1481] to follow when deciding whether or not to purchase complementary medicines online. The first step is to talk to a doctor or pharmacist (either complementary or conventional that possesses knowledge of complementary medicines). The second step is to find who the seller is and what exactly is being bought. The third step is to consult the '*can I import it?*' page,[1482] which provides a list of prohibited substances in Australia. The fourth and last step is to be suspicious of 'wild claims' because if a website or product seems 'too good to be true, it probably is'.[1483]

While the importance of regulating and registering herbal medicines, formulating national policies and regulatory frameworks on traditional medicine, adopting strategies and policy measures for the quality, safety, efficacy and rational use of traditional medicine in providing primary health care in the national health systems of developing and least-developed countries cannot be overemphasised, there are key drawbacks to regulation which deserve special consideration when formulating national frameworks on traditional medicine. This is because these issues have the potential to make any policy or regulation on traditional medicine defective; and therefore, require further investigation and discussion by the WHO, NGOs and other stakeholders interested in or that encourage the utilisation of traditional medicine for promoting public health. Further, future regulations on traditional medicine will benefit from the outcomes of such discussions, or at least, take these issues into contemplation. The next section examines these problems.

5.4. Other Considerations When Regulating Traditional Medicine

5.4.1. Definition of 'Apprenticeship'

The parameters within which 'apprenticeship' should be understood in the context of qualification and licencing of traditional medicine practitioners is not clear. Even if 'apprenticeship' were to be understood as a period (e.g. 5-10 years) during which a person learns the therapeutic properties of plants and the art of healing, this does not represent the only means through which traditional medical knowledge can be transmitted. There

[1481] ibid.
[1482] See <www.tga.gov.au/can-I-import-it> accessed 1 March 2017.
[1483] Therapeutic Goods Administration, 'Buying Medicines and Medical Devices Online' (n 1479).

is also the 'divine selection' of traditional medicine practitioners.[1484] These practitioners are called to serve by some deity or their ancestors. For example, in the *Ibo* (of Nigeria) cosmology, there is the *Agwu* deity (which is recognised as the god-head of medicine – *chi ogwu*) that can bestow healing responsibilities on a person.[1485] The *Agwu* assists such a person in his work as a healer either by leading him into the bush during the day and revealing medicinal herbs to the person or doing so at night in his dreams.[1486] Refusal to heed the call to shoulder such responsibility will be met with severe afflictions or misfortunes (known as *ihe Agwu* – deific disturbance) by the *Agwu* until the person accepts.[1487] While this form of knowing is metaphysical and involves no practical training, it is also possible that a person could receive training partly with the spirit world and partly with a master healer.[1488]

Moreover, there is the 'family inheritance or transmission'.[1489] Two examples are apt: in North America, there is the practice of the inheritance and transfer of 'medicine bundles' within or between families, which is accompanied by the transmission of traditional medical knowledge and the attendant rights to practise, transmit and apply the knowledge.[1490] In Africa, traditional medical knowledge transmission from father to son, or mother to daughter begins from early childhood.[1491] Every opportunity is seized to educate the child in traditional medicine. Usually, on the way to the farm, the parent stops to obtain some plants and explains their medical values to the child.[1492] While on the farm, the parent does the same. As a result, the child becomes knowledgeable about some plants and their therapeutic qualities, and the environment in general.[1493] Should these qualify as 'apprenticeship' for the purposes of qualification and licencing to practise traditional medicine? China's regulation requires persons who have studied traditional Chinese medicine by way of apprenticeship or *who have proven to have special expertise*

[1484] Okonkwo (n 1353) 79.
[1485] Patrick Iroegbu, 'Igbo Medicine and Culture: The Concept of Dibia and Dibia Representations in Igbo Society of Nigeria' (*Health and Welfare,* 14 November 2011).
[1486] Okonkwo (n 1353) 71.
[1487] Iroegbu (n 1485).
[1488] ibid.
[1489] Okonkwo (n 1353) 79.
[1490] WIPO, 'Traditional Knowledge and Intellectual Property: Background Brief - Booklet No 2' (WIPO Publication No 920(E)) 25.
[1491] Borokini and Lawal (n 779) 22.
[1492] ibid.
[1493] ibid.

in this field (of traditional medicine) to *pass an appraisal and examination to practise as licenced traditional medicine practitioners*.[1494] Perhaps there is something to be learnt from the Chinese jurisdiction: that aside from persons who have undergone 'apprenticeship', there are also those with 'special expertise', both of whom should be subjected to appraisal and examination before being licenced as traditional medicine practitioners. Or a better construction may well be that: persons who have expertise in traditional medicine, *acquired through apprenticeship or other means*, should be subjected to appraisal before being licenced as practitioners. Whatever construction is adopted, the paramount issue is that regulation should recognise other forms of acquisition of traditional medical knowledge, as 'apprenticeship' is not all-embracing.

5.4.2. Suitability of Clinical Trials for Evaluating Traditional Medicine Steeped in Magico-Religious Practices and Beliefs

Another issue that requires mention is whether clinical trials are suitable for evaluating the safety and efficacy of traditional medicine based on magico-religious practices and beliefs. The rationale for utilising clinical trials in the first place is said to be the need to clarify the extent and limitations of traditional practices through methodologically sound research.[1495] The reason is that the process will assist in 'increasing credibility' of traditional medicine practices.[1496] It must be noted that it means one thing for clinical research to 'give credibility', and another for it to assist in 'increasing credibility'. While the former suggests the non-existence of credibility, the latter presupposes adding to what credibility already exists. By credibility is meant the fact of traditional medicine being safe and effective. Thus, there seems to be some acknowledgement of the safety and efficacy of traditional medicine for treating diseases, although there is the need to provide additional knowledge through clinical research in this respect. The pertinent question becomes the suitability of clinical trials for 'increasing credibility' of traditional medicine.

[1494] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 11.
[1495] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1496] ibid.

It does appear that the 'modernised traditional medicine' more readily lends itself to clinical evaluation. It adopts parallel processes to conventional medicine in that it utilises sophisticated machines in transforming plants into soluble granules and tablets in finished and standardised forms.[1497] More, the plants utilised are researched, documented and preserved.[1498] Thus, clinical trials may be used to understand the therapeutic actions and safety of these drugs. What is not clear about modernised traditional medicine is whether the mystical aspect of traditional medicine is reduced or completely exterminated.[1499] However, the area that presents a challenge regarding clinical evaluation is that which is imbued with traditional, esoteric and magico-religious beliefs and practices. In this case, it has been suggested that while performing clinical research, such traditional medicine principles and theories of practice should be strictly adhered to and not ignored in the context of trial design.[1500] How is this possible?

It is yet to be explained how clinical trials would incorporate theories such as instructions or revelations from a deity to a traditional medicine practitioner to, for example, not fetch the herbs for treatment of a patient himself. He might be directed to send 'a young boy or girl who is a virgin or who is "clean"' in his stead.[1501] Occasionally, the deity may require such an errand boy or girl to 'keep mute' until the herbs are delivered to the traditional medicine practitioner.[1502] In the event that such instruction is violated, the herbs could lose their efficacy.[1503] What about theories that deities manifest herbal attributes? Among the *Yorubas* in Nigeria, for example, there is the *Osanyin* (the herbalist and god of traditional medicine), who rules over all wild herbs with medicinal and magical values; and the *Obatala* (the creator and healer of humans), who has priests (*babalawos*) and controls specific herbs, such as sage, kola nut, basil, hyssop, blue vervain, white willow and valerian.[1504] How would science take into account the influences of these deities over these herbs in designing trials? Likewise, there is a strong belief that incantations (if spoken correctly at the right place and time) invoke plants' therapeutic powers to

[1497] Borokini and Lawal (n 779) 29.
[1498] ibid.
[1499] ibid 30.
[1500] World Health Organization, 'Traditional and Modern Medicine: Harmonizing the Two Approaches' (n 1310).
[1501] Borokini and Lawal (n 779) 24.
[1502] ibid.
[1503] ibid.
[1504] ibid 25.

overcome diseases.[1505] It is difficult to imagine how these theories and practices could be verified experimentally.

The reality is that EBM is reductionist and would not emphasise any theory that suggests that life is dependent on forces other than chemical or physical forces.[1506] For this reason, while it lends itself to the understanding of the therapeutic actions of plants, it still grapples with the underlying traditional beliefs and practices.[1507] Besides, EBM is founded on Western knowledge and viewpoints. Does it then seem appropriate to apply Western standards of evidence related to medicine to an entirely different theoretical assumption of traditional health systems and therapies?[1508] The inappropriateness is made more manifest by the fact that traditional beliefs are dismissed by the West as being based on 'superstition and necromancy'.[1509] Hence the need to 'co-opt' it into EBM and 'improve and demystify its therapeutic qualities'.[1510] The politics of knowledge involved in this perspective is clear; it obviously constitutes a valuing of knowledge.[1511] It seeks to repress 'Indigenous ways of knowing and subjectivities, and [represent] Indigenous knowledge as primordial, mythic and, compared with hard line precision of mathematics and science, ephemeral'.[1512] This situation may not be too far from qualifying as a form of neo-colonialism.

Nonetheless, attention is being turned to observational studies as a means of addressing these areas not readily evaluated using the trial methodology and to correctly design and interpret such clinical trials.[1513] According to this approach, it may be assumed that a natural experiment is taking place in traditional medicine, as practitioners are prescribing, and patients are using.[1514] Thus, observational research of existing practices allows for

[1505] ibid 26.
[1506] Ian D Coulter and Evan M Willis, 'The Rise and Rise of Complementary and Alternative Medicine: A Sociological Perspective' (2004) 180(11) *Medical Journal of Australia* 587-589.
[1507] Olajide Oloyede, 'Epistemological Issues in the Making of an African Medicine: Sutherlandia (*Lessertia Frutescens*)' (2010) 14(2) *African Sociological Review*.
[1508] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).
[1509] Aceme Nyika, 'Ethical and Regulatory Issues Surrounding African Traditional Medicine in the Context of HIV/AIDS' (2007) 7(1) *Developing World Bioethics* 25-34; see also Oloyede (n 1507).
[1510] ibid.
[1511] Kathy Bowrey and Jane Anderson, 'The Politics of Global Information Sharing: Whose Agendas are Being Advanced?' (2009) 18(4) *Social and Legal Studies* 479, 483.
[1512] ibid 484.
[1513] Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health' (n 1400).
[1514] ibid.

the first line of data for further clinical research.[1515] It is difficult to see how this approach makes any difference. It remains unclear how metaphysical influences are interpreted in the observation and how they are applied in designing the eventual clinical research. Moreover, why must clinical trials be the only standard to judge the efficacy of all traditional medicine? Although it is considered a 'gold-standard' to validate all knowledge,[1516] this appears to be in theory, as it cannot be used to comprehend traditions, customs and belief systems.

While the fact that traditional medicine has stood the test of time[1517] and is used by the majority of the populations of developing and least-developed countries is evidence of its safety and efficacy, this does not mean that its safety and efficacy cannot be questioned[1518] in view of the negative reports concerning its use. The same can be said for conventional drugs which are subjected to clinical trials, yet there are numerous reports of adverse reactions resulting from their use.[1519] The issue becomes the 'litmus test' suited to verify the safety and efficacy of magico-religious traditional medicine, taking into account its foundational theories and practices. There seems to be a good method in Brazil's GMP Guidelines. Recall that they provide four requirements for proof of safety and efficacy of traditional medicine for purposes of registration. Requiring that it is sufficient to *attest* the safety and efficacy of a traditional medicine product or therapy[1520] is relevant to traditional medicine that is rooted in traditional theories and beliefs. Such attestation may be in the form of observation of traditional use; publication in a literature showing a period of 20 or more years of proven safety and efficacy;[1521] or testimonies of traditional medicine practitioners that are recognised in their communities as having special abilities with regard to traditional medicine, including individual testimonies of elders or other members of a community who have been treated successfully by such practitioners or with such therapy. This system of confirming the safety and efficacy of traditional medicine appears to assimilate traditional theoretical assumptions, whether or not they are explicable, and does not attempt to 'demystify' those

[1515] ibid.
[1516] Tilburt and Kaptchuk (n 785).
[1517] Oloyede (n 1507).
[1518] Oloyede (n 1507).
[1519] ibid.
[1520] Carvalho et al. (n 757) 467-473.
[1521] ibid.

theories or practices, as any system that ventures to do so would only result in deculturation.[1522] Thus, this type of evidence should be acceptable to competent authorities for registration or listing of traditional medicine in the interest of consumer safety.

5.4.3. Ascertaining the Effect of Regulation on the Cost of Traditional Medicine

An additional issue requiring further investigation and discussion is that regulation could adversely affect the cost of traditional medicine. This is particularly troubling as one of the rationales for proposing the integration of traditional medicine into the national health systems of developing and least-developed countries is to provide affordable medicines. Regulatory measures targeted at ensuring quality assurance, safety, efficacy and rational use of traditional medicine, such as labelling, packaging, correct identification of raw materials, pharmacognostic and physio-chemical standardisation, as well as pre-clinical and post-clinical trials, and monitoring of adverse events, will require substantial investments by manufacturers. Certainly, manufacturers would seek to profit from such investment by marketing traditional medicine products at high cost. Already jurisdictions such as China now grant patent monopoly to manufacturers of 'new traditional medicine-based products, methods of process and new uses of traditional medicine, including herbal preparations, extracts from herbal medicines, foods containing herbal medicines and methods for preparing herbal formulas',[1523] in order to reward investment in R&D of new varieties of traditional medicine.

What is more, small and medium-sized enterprises (SMEs) may be put out of business, as they would find manufacturing traditional medicine to be prohibitively expensive.[1524] This is likely to have the consequence of eliminating competition in the market capable of reducing prices. Ultimately, high cost would impede access to traditional products or therapies, as they would be beyond the means of those below the poverty line in developing and least-developed countries. Thus, in the interest of promoting universal healthcare coverage and access to affordable medicines, it is important for governments

[1522] Iroegbu (n 1485).
[1523] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[1524] Abbott, 'Documenting Traditional Medical Knowledge' (n 195) 8.

of developing and least-developed countries to insist through national policies and regulations that practitioners and manufacturers of traditional medicine provide high quality medical services and therapies at low cost. An example of such measure can be seen in Article 9 of China's regulation on traditional medicine, which stipulates that institutions of traditional medicine that provide traditional Chinese medicine services to people must do so at reasonable prices.[1525] While China provides patent protection for new varieties of traditional medicine, there is no evidence suggesting that this has resulted in increased cost of traditional medicine. [1526] Nonetheless, governments of other developing and least-developed countries must beware of the dangers of incentivising investment in R&D of traditional medicine products through the patent regime. The possible consequence of this action on access to traditional medicine can be easily inferred from the problem of access to essential conventional medicines for which the patent regime is partly responsible (as discussed in Chapter two).

In spite of these drawbacks, formulating national policies and regulatory frameworks is necessary if traditional medicine is to be appropriately utilised in providing the much needed health care in developing and least-developed countries. This is because regulation is not only essential for ensuring quality, safety, efficacy and rational use, but also the accessibility and affordability of traditional medicine; hence, the need to investigate the consequences of these drawbacks further when regulating traditional medicine. Added to this, regulation is also fundamental to the full and successful integration of traditional medicine into the national health systems of developing and least-developed countries for achieving sustainable development by 2030. Having discussed strategic policy and regulatory measures for appropriately using traditional medicine, the following section explains how these national policies and regulations facilitate integration.

5.5. Formulation of National Policies and Regulations Essential for Integrating Traditional Medicine into National Health Systems

[1525] Regulations of the People's Republic of China on Traditional Chinese Medicine 2003, art 9.
[1526] Quian Jia, 'Traditional Chinese Medicine Could Make "Health for One" True' (World Health Organization 2005) Document No 18; see also 'Chinese Herbal Medicine' (*Todd Plymale-Mallory*, 2016) <http://www.toddplymalemallory.com/chinese-medicine/> accessed 5 January 2018.

The integration of traditional medicine into a national health system presupposes that traditional medicine is officially recognised and included in all areas of healthcare delivery. [1527] In practice, this means that an integrated system utilises research, conventional medicine, and traditional medicine to diagnose, treat and prevent diseases. [1528] The aim of this strategy is to increase healthcare coverage through collaboration, communication, harmonisation and partnership building between conventional and traditional systems of medicine.[1529] Achieving this state of affairs will entail officially recognising traditional medicine in the national health policy, registration and licencing of traditional medicine practitioners, registration of traditional medicine products, regulation of traditional medicine practices, establishment of national traditional medicine hospitals, inclusion of traditional medicine in national insurance schemes as reimbursable items, establishment of research institutions on traditional medicine, and training traditional medicine practitioners at all levels of education, including universities.[1530] Additionally, integration involves the inclusion of traditional medicine in national health programmes, and its visibility in national planning and budgeting.[1531] For instance, both the integration of traditional medicine into the national healthcare system and the integrated training of traditional medicine practitioners are officially recognised in China.[1532] Article 21 of the Constitution of the People's Republic of China promotes both conventional and traditional medicines.[1533]

The integrated nature of the Chinese health system is seen in healthcare delivery by conventional and traditional medicines alongside each other at every level.[1534] As at the end of 2015, statistics showed that there were 3,966 traditional Chinese medicine

[1527] Adelaide Bela Agostinho, 'Integration of Traditional Medicine in Health Systems in Africa' (2011) 2(2) *Universitas Forum* <http://www.universitasforum.org/index.php/pjs/article/view/68/257> accessed 22 September 2016.
[1528] Cooper et al., Africa's Health Challenges (n 1112).
[1529] ibid.
[1530] Cooper et al., *Africa's Health Challenges* (n 1112); see also Agostinho (n 1527); and S Griffiths, V Chung, E K Yeoh, E Wong and C H Lau, 'Attitude Toward Traditional Chinese Medicine Among Allopathic Physicians in Hong Kong' (2012) 18(6) *Hong Kong Medical Journal*.
[1531] Cooper et al., *Africa's Health Challenges* (n 1112).
[1532] X Zhang, 'Integration of Traditional Medicine into National Health Care Systems' (1998) Paper Presented at the Medicus Mundi Switzerland Workshop on the Integration of Traditional Medicine into Public Health, Lausanne, Switzerland.
[1533] Constitution of the People's Republic of China 1982 (as amended in 2004), art 21.
[1534] World Health Organization, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine' (n 1243).

hospitals across China, including 446 hospitals of integrated Chinese and conventional medicine.[1535] There were also 452,000 practitioners and assistant practitioners of traditional Chinese medicine, including practitioners of Chinese and conventional medicine.[1536] In the same year, 910 million visits to traditional Chinese medicine medical and health services were recorded across the country, as well as 26.9 million inpatients were treated.[1537] This is substantial evidence to support the hypothesis that traditional medicine of good quality that is safe and effective can make a valuable contribution to national and individual health care and the promotion of health equity,[1538] and in this way can be instrumental in promoting universal health coverage and access to essential medicines for eradicating malaria, tuberculosis and HIV/AIDS by 2030 in other developing and least-developed countries. An equally good example, is that the Indian government recognises the immense benefits of traditional medicine and has included it in national health programmes.[1539] The department of AYUSH in the Indian Ministry of Health and Family Welfare is aimed at upgrading education standards and quality control, broadening accessibility and increasing awareness of traditional medicine.[1540] Also, AYUSH institutions across India have an estimated 62,000 hospital beds and over 785,000 health workers, with the government including Ayurveda in its insurance scheme, Rashtra Swastya Bima Yojana (RSBY), in 2014 after petitions from across the country to make it a reimbursable item.[1541]

There is a chance that these recommendations of formulating national policies and regulatory frameworks for ensuring the rational use and appropriate integration of traditional medicine into the national health systems of developing and least-developed countries might seem counter-intuitive in light of the argument made in Chapter two against the practicality of concluding a binding convention on drug R&D in time for progress towards the 2030 Agenda for Sustainable Development. However, they need not

[1535] The State Council, 'Traditional Chinese Medicine in China' (*The State Council, People's Republic of China* 6 December 2016) <http://english.gov.cn/archive/white_paper/2016/12/06/content_281475509333700.htm> accessed 25 April 2017.
[1536] ibid.
[1537] ibid.
[1538] Agostinho (n 1527).
[1539] Carr, 'Traditional Healing: Modern Medicine's Friend or Foe?' (n 942).
[1540] Carr, 'Traditional Healing: Modern Medicine's Friend or Foe?' (n 942).
[1541] ibid.

seem so. Rightly, negotiating an international treaty involves a complex and protracted process, more so where there are multiple stakeholders with conflicting interests. In contrast, the process of formulating national policies and regulations is more straightforward and unexacting, as they are administrative, and thus, usually made by the executive branch of government with less form of the bureaucracy associated with legislative deliberations.[1542] Also, there are not likely to be multiple stakeholders with conflicting interests capable of resulting in an impasse in the context of implementing domestic policy and regulatory measures on the practice of traditional medicine. The only interest that would be considered during the formulation of national policies and regulations on traditional medicine is the rights of the indigenous peoples over traditional medicine and the knowledge associated with it, as this is implicated in the wider application of traditional medicine for public health care.

In this regard, Chapter six will emphasise the need for governments of developing and least-developed countries to protect traditional medical knowledge and adopt measures that subject access by third parties to the prior informed consent, and benefit-sharing with the indigenous peoples in compliance with the Convention on Biological Diversity and its Nagoya Protocol. Moreover, besides the technical guidelines formulated by the WHO, lessons can be learnt from countries such as China and India who have robust policies and regulations on traditional medicine (as mentioned earlier). Therefore, all that other developing and least-developed countries need do is internalise these measures and best practices in a manner suitable to their different realities. Viewed from these perspectives, it will become clear that it is uncomplicated for developing and least-developed countries to appropriately integrate traditional medicine into their national health systems through adequate policies and regulatory frameworks in time to promote universal health coverage and access to medicines in order to pursue the 2030 target for sustainable development.

In conclusion, for traditional medicine to efficiently contribute to realising sustainable development by promoting universal health coverage and access to affordable medicines,

[1542] 'Policy v Regulation: The Difference between' (*Difference Betweeen.com*, 18 August 2012) <http://www.differencebetween.com/difference-between-policy-and-vs-regulation/> accessed 5 January 2018.

developing and least-developed countries must tackle the challenges confronting the appropriate utilisation and integration of traditional medicine into national health systems. Appropriate utilisation and successful integration can only be achieved by formulating national policies and regulatory frameworks on traditional medicine that adequately address issues, such as the education and training of traditional practitioners; collaboration between conventional and traditional medicine practitioners; consumer information on proper use; quality, safety and efficacy of traditional medicine therapies; and regulation and registration of traditional medicine products. Addressing these issues through domestic policies and regulations in time to pursue the 2030 target for achieving sustainable development is straightforward and uncomplicated. The technical guidelines developed by the WHO, and good practices that can be gleaned from other jurisdictions, particularly China and India, who have fully integrated traditional medicine into their national health systems, can serve as templates for other developing and least-developed countries to fashion their own regulations, but in a manner that best suits their circumstances.

In doing this, developing and least-developed countries must carefully consider the drawbacks discussed in this chapter when regulating traditional medicine to have a solid outcome. Equally important, to ensure that traditional medicine serves well as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D, governments must ensure that regulations do not engender red-tapism or promote the interests of one system of medicine over the other. Rather, collaboration, good communication and mutual respect should be encouraged between conventional and traditional medicine practitioners for the ultimate good of patients. In the absence of adequate regulation, the quality, safety and efficacy of herbal medicines and other traditional health practices will be unchecked, and the traditional medicine system will not be utilised to its fullest potential for providing primary health care and affordable medicines for sustainable development.

CHAPTER SIX

ACCESS TO TRADITIONAL MEDICINE: THE NEED FOR CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY, AND THE PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE

Chapter four evaluated the challenges affecting the proper use and integration of traditional medicine into the national health systems of developing and least-developed countries and identified the potential for unsustainable use of biological diversity (commonly 'biodiversity') and uncompensated exploitation of traditional medical knowledge to undermine access to traditional medicine for health care. This chapter considers the exigencies for developing and least-developed countries to adopt legislative, administrative or policy measures for the conservation of biodiversity and the sustainable use of its components, the fair and equitable sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge, and the legal protection of traditional medical knowledge, including how these can be implemented in practice.

The importance of national action in this regard cannot be overemphasised: first, considering that the loss of biodiversity has become one of the crucial environmental conversations within the international community. Human activities in relation to land and natural resources, as well as over-exploitation, production and waste have resulted in the rapid decline of the rich tapestry of life – terrestrial and marine ecosystems, and other complex ecological species. Since traditional medicine depends on genetic resources and other forms of biodiversity as its main ingredients, the loss of biodiversity poses a substantial threat to its availability to promote universal health coverage and access to affordable medicines to achieve the 2030 Agenda for Sustainable Development.

Secondly, developing and least-developed countries have bitterly complained about the collection of large quantities and varieties of genetic resources from their territories, both during the colonial and the post-colonial era, to the Western world. Western biotechnology and pharmaceutical companies have shown an increased interest in genetic resources that lie in the world's biodiversity-rich areas due to the realisation of their actual or potential value for developing plant-derived products. This has resulted in claims of

misappropriation of these resources and the associated traditional knowledge. Traditional knowledge of the medicinal uses of plants aids the industry in locating pharmacologically active plants and serves as a source of initial leads for potential drug discovery, even though its contribution to the process usually becomes less obvious along the way. In cases where the traditional knowledge lead results in commercial success for the industry, the indigenous peoples – owners of traditional knowledge according to the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) – are often not compensated, not to mention recognised as co-inventors, by the patent regime. That said, while research and documentation, development of treatment guidelines, and treatment brochures for traditional medicine preparations are essential for the proper use of traditional medicine in the national health systems of developing and least-developed countries as suggested in Chapter five, these measures will make traditional medical knowledge more accessible and vulnerable to unauthorised and inappropriate uses by anyone, particularly the biotechnology and pharmaceutical industries which find this information useful.

On this note, this chapter explores the provisions and key concepts of the regime of the Convention on Biological Diversity 1992 and its Nagoya Protocol 2010, and the ongoing work at the World Intellectual Property Organization (WIPO) within its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), noted in Chapter two, to determine how developing and least-developed countries can effectively conserve and sustainably use biodiversity, implement access and benefit-sharing requirements in relation to genetic resources and associated traditional knowledge, and protect traditional medical knowledge. On the whole, the aim is to sustain access to quality, safe and effective traditional medicine to complement the use of TRIPS flexibilities and (probably) a convention on drug research and development (R&D) for sustainable development.

6.1. Decline in Biodiversity and its Impact on Access to Traditional Medicine for Sustainable Development

Biodiversity is the variety of life forms on earth, namely: ‘the sum of all plants, animals, fungi and micro-organisms on earth, all of their genetic variations and their phenotypic

variation, and all of the communities and ecosystems that they comprise'.[1543] These components of biodiversity have, for many centuries, provided society with wide ranging goods and services.[1544] For example, humanity has relied on species for subsistence – food, medicines and industrial products; and the ecosystems for services, such as water purification, flood control, pollination and pest control.[1545] Biodiversity-related sectors as, for instance, agricultural, forestry and forestry-related products, have significantly contributed to the economies of most developing and least-developed countries mainly through export trade.[1546] The knowledge, both informative and transformative, regarding the components of biodiversity has stimulated technological innovation and learning about human ecology and biology.[1547] To illustrate, while previously the pharmaceutical, agricultural and industrial R&D largely relied on different methods, nowadays the development of new biotechnologies has enabled the screening of samples of plants or microorganisms for use in these industries.[1548]

Despite its many different values, since the past 200 years, there has been an accelerated decline in biodiversity in every region of the world, thus endangering economies, livelihoods, food security and people's well-being.[1549] Named as the 'sixth extinction wave', the present mass decline is the consequence of human activities.[1550] Population growth and economic development considerably increased human effects on wild populations through environmental change and disturbances, such as increased habitat fragmentation and modification, over-exploitation for subsistence or sport hunting,

[1543] Christian Lévêque and Jean-Claude Mounolou, *Biodiversity* (Chichester: John Wiley & Sons, 2003) 5; see also P Raven, 'The Epic of Evolution and the Problem of Biodiversity Loss' in Ch. MacManis (ed), *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (London: Earthscan 2007) 27; and Ebermann (n 977) 25.
[1544] National Research Council, *Perspectives on Biodiversity: Valuing its Role in an Everchanging World* (Washington DC: National Academic Press 1999).
[1545] ibid; see also Elizabeth Carabine, Courtenay Cabot Venton, Thomas Tanner and Aditya Bahadur, 'The Contribution of Ecosystem Services to Human Resilience: A Rapid Review' (Overseas Development Institute, 2015).
[1546] National Research Council, *Perspectives on Biodiversity* (n 1544).
[1547] ibid.
[1548] ibid.
[1549] UNESCO, 'Biodiversity and Nature's Contributions Continue Dangerous Decline' (*UNESCO*, 23 March 2018) <https://en.unesco.org/news/biodiversity-and-nature-s-contributions-continue-dangerous-decline> accessed 10 January 2019; see also J He, C Yan, M Holyoak, X Wan, G Ren, Y Hou, Y Xie and Z Zhang, 'Quantifying the Effects of Climate and Anthropogenic Change on Regional Species Loss in China' (2018) 13(7) *PLoS ONE*.
[1550] A D Barnosky, N Matzke, S Tomiya, G O Wogan, B Swartz, T B Quental, C Marshall, J L McGuire, E L Lindsey, K C Macguire, B Mersey and E A Ferrer, 'Has the Earth's Sixth Mass Extinction Already Arrived?' (2011) 471(7336) *Nature* 51-57.

pollution, impacts from invasive species, and largely human-introduced pathogens.[1551] In this respect, it has been suggested that humankind has entered a new geological age, the Anthropocene, in which human activity is one of the primary drivers of climate and environmental change.[1552] Taking the rainforest, which is a major source of biodiversity as an example, over two-thirds are no longer in existence.[1553] An estimated 19 out of 20 species lost in the elimination of the rainforest are unknown,[1554] and nearly 17,000 plant and animal species are presently at risk of extinction.[1555] Likewise, indirect anthropogenic pressures such as climate change are implicated in the mass reduction of species, both in range size and abundance.[1556] He et al. have noted that the present distribution of species have been shaped by past climate conditions, 'often through species-specific physiological thresholds of temperature and precipitation tolerance'.[1557]

Thus, at the United Nations (UN) High-level Meeting of the General Assembly during the International Year of Biodiversity 2010, H. E. Mr Joseph Deiss, President of the 65th Session of the General Assembly, stressed that:

> [today] biodiversity is being lost throughout the world, largely as a result of actions of human beings. Climate change is further worsening this problem. What is more, degradation of many of the essential services rendered by the ecosystems is threatening to undermine progress towards the Millennium Development Goals.[1558]

This holds true for the UN 2030 Agenda for Sustainable Development. One of such services rendered by biodiversity is the provision of traditional medicine, as it

[1551] He et al., 'Quantifying the Effects of Climate and Anthropogenic Change on Regional Species Loss in China' (n 1549); see also Fanie Pelletier and David W Coltman, 'Will Human Influences on Evolutionary Dynamics in the Wild Pervade the Anthropocene?' (2018) 16(7) *BMC Biology*.
[1552] Pelletier and Coltman, 'Will Human Influences on Evolutionary Dynamics in the Wild Pervade the Anthropocene?' (n 1551).
[1553] Ebermann (n 977) 26.
[1554] Raven (n 1543) 27, 30.
[1555] 'Biodiversity Loss is Bankrupting the Natural Economy – Ban' (*UN News Centre*, 22 September 2010) <http://www.un.org/apps/news/story.asp?NewsID=36052#.WmXOnyOcZ0s > accessed 15 October 2016.
[1556] He et al., 'Quantifying the Effects of Climate and Anthropogenic Change on Regional Species Loss in China' (n 1549).
[1557] ibid.
[1558] H E Mr Joseph Deiss (n 703).

incorporates plants and animals in treating, diagnosing and preventing diseases, as well as maintaining well-being.[1559] As the examples discussed in Chapter three showed, traditional remedies for treating malaria and tuberculosis, and providing palliative care for HIV/AIDS are derived from local plants. This raises the concern that unsustainable use of biodiversity could undermine access to traditional medicine for eradicating malaria, tuberculosis and HIV/AIDS, and promoting universal health coverage because the loss of biodiversity could mean not only the reduction in available traditional remedies but also the loss of potential plants for enhancing access to medicines in furtherance of the 2030 Agenda for Sustainable Development.[1560] Mindful of this, the World Health Organization (WHO) opined that:

> [if] access to [traditional medicine] is to be increased sustainably, the natural resource base upon which it often depends must be sustained… Since the vast majority of plant genetic resources and other forms of biodiversity are found in or originate from developing countries…such problems [as over-exploitation] are in urgent need of resolution.[1561]

Although seemingly self-contradictory, yet the use of local resources for traditional medicine can equally result in depletion of biodiversity when they are over-harvested. In Eastern and Southern Africa, for example, the sustainability of the wild stocks of African Potato (*Hypoxis hemerocallidea*) faces the threat of extinction because the knowledge that it could be used to treat HIV/AIDS has increased demand for it.[1562] In Ghana also, Garcinia kola (*Garcinia afzelii*), which possesses antiseptic properties, is becoming scarce as a result of over-exploitation for use as chewsticks for dental hygiene.[1563] Accordingly, the use for traditional medicine equally raises the need for sustainably exploiting biodiversity.

[1559] World Health Organization, 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1560] C H Saslis-Lagoudakis, J A Hawkins, S J Greenhill, C A Pendry, M F Watson, W Tuladhar-Douglas, S R Baral, V Savolainen, 'The Evolution of Traditional Knowledge: Environment Shapes Medicinal Plant Use in Nepal' (2014) 281(1780) *Proceedings of the Royal Society B: Biological Sciences*; see also Australian National University, 'Traditional Medicine: Environment Change Threatens Indigenous Know-How' (*ScienceDaily*, 13 February 2014) <https://www.sciencedaily.com/releases/2014/02/140213103517.htm> accessed 1 February 2017.
[1561] World Health Organization, 'WHO Traditional Medicine Strategy 2002-2005' (n 12).
[1562] ibid.
[1563] IUCN, *Ghana: Conservation of Biological Diversity* (Cambridge: World Conservation Monitoring Centre 1988).

Noting, among other things, that as much as 80 per cent of people living in rural areas of developing and least-developed countries rely on 'traditional plant-based medicines' for basic health care and only less than 1 per cent of over 80,000 tree species has been studied for potential use, Goal 15 of the 2030 Agenda for Sustainable Development is to 'sustainably manage forests, combat desertification, halt and reverse land degradation, halt biodiversity loss'.[1564] It aims to achieve this by 2030 through, *inter alia*, the conservation of biodiversity in order to enhance its capacity to provide benefits that are essential for sustainable development, to promote the fair and equitable sharing of benefits arising from the utilisation of genetic resources, and promote appropriate access to such resources, '*as internationally agreed*'.[1565] Thus, while the 2030 Agenda for Sustainable Development does not consider traditional medicine as a viable tool for achieving its health-related goal (Goal 3), as suggested in Chapters one and three, it tacitly recognises that traditional medicine is essential for sustainable development; and consequently, acknowledges that to enhance and ensure sustainable access to traditional medicine, there is a need for the conservation and sustainable use of biodiversity, as well as the promotion of access and benefit-sharing arising from such utilisation.

In pointing out that conservation and benefit-sharing must be achieved 'as internationally agreed', Goal 15 of the 2030 Agenda for Sustainable Development links the realisation of this target to the Convention on Biological Diversity 1992 and its Nagoya Protocol 2010.[1566] The Convention on Biological Diversity 1992 is an international legally-binding treaty that requires its contracting parties to adopt national strategies, plans or programmes, in line with the measures set out in the Convention, for the conservation and sustainable use of biodiversity, and the fair and equitable sharing of benefits arising from the use of genetic resources.[1567] For instance, as will be seen in 6.4.1., Article 8 provides the main set of Convention obligations to conserve biodiversity. The Convention recognises *in-situ* conservation as the primary technique for biodiversity conservation. Article 8 requires each contracting party to promote the protection of the ecosystem,

[1564] United Nations, 'Transforming Our World: The 2030 Agenda For Sustainable Development' (n 3) Goal 15.
[1565] ibid.
[1566] ibid.
[1567] Convention on Biological Diversity 1992, preamble and art 6(a) & (b)

habitats and the maintenance of viable populations, as well as to establish a system of protected areas where special conservation measures need to be taken.[1568] States are also obligated under Article 9 to adopt *ex-situ* conservation measures for biodiversity components, including to establish *ex-situ* facilities for conservation and research on plants, animals and micro-organisms.[1569] In addition, there is a supplementary legal framework to the Convention on Biological Diversity, the Nagoya Protocol, adopted in 2010 by the Conference of Parties (COP) – the governing body of the Convention.[1570] Primarily, the Protocol aims to implement transparent access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation – the third goal of the Convention on Biological Diversity.[1571]

The Convention on Biological Diversity also affirms that the conservation of biodiversity is a common concern of humankind in preambular paragraph 3.[1572] Here, the 'common concern for humankind' suggests that all humanity has an interest in conserving biodiversity because it is essential to sustaining all life forms on earth.[1573] Thus, conservation is not exclusively a national issue, but an affair which requires global cooperation among states and intergovernmental organizations and even the non-governmental sector.[1574] Simultaneously, Article 3 of the Convention recognises, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right of states to exploit '*their*' own resources pursuant to their environmental policies.[1575] It has been suggested that the word 'their' does not refer to property rights, but to biological resources found within the jurisdiction of a particular state.[1576] However, at the domestic level, the principle of sovereign right of states to exploit their resources may have private property rights consequences.[1577] When a state, in exercising sovereignty, asserts control over a particular resource, for example by

[1568] ibid, art 8.
[1569] ibid, art 9.
[1570] 'About the Nagoya Protocol' (n 704).
[1571] ibid.
[1572] Convention on Biological Diversity 1992, preambular paragraph 3.
[1573] Lyle Glowka, Françoise Burhenne-Guilmin, Hugh Synge, Jeffery A McNeely and Lothar Gündling, *A Guide to the Convention on Biological Diversity* (Gland and Cambridge: IUCN 1994) 10.
[1574] ibid.
[1575] Convention on Biological Diversity 1992, art 3.
[1576] Glowka et al. (n 1573) 10, 26.
[1577] Philippe Cullet, 'Property Rights Regimes Over Biological Resources' (2001) 19 *Environment and Planning C: Government and Policy* 651.

nationalising it, the state acquires all the rights that would ordinarily accrue to a private owner.[1578] In such a case, the state's assertion of sovereign rights is conceptually akin to private property rights.[1579] In other words, 'state sovereignty at the domestic level is also a monopoly'.[1580]

Nevertheless, this sovereign right of states is subject to two important limitations. First, the right to exploit carries with it a responsibility to ensure transboundary environmental protection.[1581] States have to ensure that activities within their jurisdiction or control do not cause damage to other states or areas beyond national jurisdiction.[1582] Secondly, the sovereign right must also be exercised in accordance with the UN Charter and the principles of international law.[1583] This means that, in asserting sovereignty, states have to consider the various obligations under the UN Charter to cooperate, including to promote higher standards of living and provide solutions to international socio-economic and health problems.[1584] These obligations cannot be realised without regard for environmental conservation.[1585] Furthermore, reference to 'principles of international law' contemplates principles of environmental protection and conservation derived from numerous international instruments.[1586] They obligate states to protect their environment and prevent environmental damage, and to ensure that when biodiversity is used, the use is sustainable.[1587] This, it has been suggested, provides the critical link between the sovereign right of states over their biological resources and the common concern of humankind in ensuring conservation.[1588] In other words, while conservation is a common concern of humankind because it supports all life on earth, hence the global duty to cooperate in conserving and managing it; states have the responsibility to ensure the conservation and sustainable use of biodiversity and its genetic components found in their environment.[1589] In this light, the principle of state sovereignty is intended to lead to more

[1578] ibid.
[1579] ibid.
[1580] ibid.
[1581] Convention on Biological Diversity 1992, art 3.
[1582] ibid.
[1583] ibid.
[1584] Glowka et al. (n 1573) 26.
[1585] ibid.
[1586] ibid.
[1587] ibid.
[1588] ibid 10.
[1589] Cullet, 'Property Rights Regimes Over Biological Resources' (n 1577) 651.

efficient utilisation of natural resources.[1590] Thus, in order to sustainably increase access to traditional medicine, it is important for developing and least-developed countries to adopt legislative or administrative measures for the conservation and sustainable use of biodiversity, and for regulating access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in accordance with the Convention on Biological Diversity and its Nagoya Protocol – discussed in greater depth later on.

This initiative is particularly crucial for, as Chapter four noted, scientists and pharmaceutical companies have further intensified their search in nature for pharmacologically active plants due to the growing resistance of bacteria to antibiotics, and the realisation that some diseases, for example, some strains of HIV, have become incurable by conventional medicine.[1591] More so, despite burgeoning investments in R&D, the number of new molecular entities admitted into the market has remained minimal.[1592] Developments in biotechnology created the possibility of producing plant-derived pharmaceuticals, genetically modified crops and other products derivable from genetic resources.[1593] Based on this knowledge that research can be applied to life forms to produce commercially viable products, there evolved a genetics supply or life industry that depended on genetic materials from fields, forests and communities.[1594] For instance, in 1966, Dr Jacques Debat – a French entrepreneur – obtained a European patent on Tadenan, a drug for benign prostate hyperplasia (BPH).[1595] Using scientific techniques, this drug was developed with an extract from pygeum bark (*Prunus africanus*) based on the observation that the indigenous Bakwerians in Cameroon had used the bark of pygeum to treat 'old man's disease' or BPH for centuries.[1596] Since the 1970s, developing and least-developed countries have protested the appropriation of genetic resources within their jurisdiction in this manner, especially during the colonial transfer of plant

[1590] Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (Earthscan 2010) 6.
[1591] Ebermann (n 977) 1
[1592] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 238.
[1593] Venbrux (n 1135) 1, 3; see also Downes (n 1135) 1, 8-14.
[1594] Naomi Roht-Arriaza, 'Of Seeds and Shamans: The Appropriation of The Scientific and Technical Knowledge of Indigenous and Local Communities' (1996) 17 *The Michigan Journal of International Law* 919, 926.
[1595] A J Simons, I K Dawson, B Dugumba and Z Tchoundjeu, 'Passing Problems: Prostate and Prunus (1998) 43 *HerbalGram*, 49-53; Eyong, 'Indigenous Knowledge and Sustainable Development in Africa' (n 947) 121, 133.
[1596] ibid.

germ plasm in the era spanning 1492-1992, and the marketing of such resources to them as commodities at a price.[1597]

Under the colonial regime, scientists, breeders, and collectors from the colonising territories accumulated a vast quantity and diversity of commercially useful and rare plant life forms from the colonies to botanic gardens, gene banks, research institutions and breeding programmes.[1598] According to Charles Eyong, for instance, research has explained the existence of more botanic gardens in gene-poor Europe than in gene-rich Africa with the finding that foreign bioprospectors collected indigenous species to the West.[1599] Housing only 11,000 plant species, Europe has 11 times more gardens than Africa, which has over 30,000 known species of plants.[1600] Developed countries, including some environmental activists, non-governmental organisations, and commentators have attempted to rationalise this collection and transfer of genetic resources based on the concept of 'common heritage of mankind'.[1601] Under this regime, biological resources are treated as belonging to the public domain and are not owned by any individual, group or state.[1602] They have argued that during the colonial period and even in post-colonial era, the common heritage of mankind has been the principle governing the diffusion of crops and animal genetic resources from centres of domestication, their exchange among farmers, and their introduction into the colonial territories after 1492.[1603] Besides, this concept of common heritage was accorded legal status in international conventions, such as the 1972 UNESCO Convention on the Protection of World Cultural and Natural Heritage, and the 1983 Resolution of the Food and Agricultural Organization (FAO) Commission, which established the International

[1597] Gurdial Singh Nijar, 'Incorporating Traditional Knowledge in an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects' (2010) 21(2) *The European Journal of International Law* 459.
[1598] Venbrux (n 1135) 1, 3; see also Downes (n 1135) 1, 8-14.
[1599] Eyong, 'Indigenous Knowledge and Sustainable Development in Africa' (n 947) 125-26.
[1600] ibid.
[1601] Patrick R Mooney, *Seeds of the Earth: A Public or Private Resource* (Inter Pares for the Canadian Council for International Co-operation and the International Coalition for Development Action 1979); see also Paul Gepts, 'Who Owns Biodiversity, and How Should the Owners be Compensated?' (2004) 134 *Plant Physiology* 1295, 1295; and Ikechi Mgbeoji, 'Beyond Rhetoric: State Sovereignty, Common Concern, and the Inapplicability of the Common Heritage Concept of Plant Genetic Resources' (2003) 16(4) *Leiden Journal of International Law* 821-837.
[1602] Gepts, 'Who Owns Biodiversity, and How Should the Owners be Compensated?' (n 1601) 1295.
[1603] ibid.

Undertaking of Plant Genetic Resources.[1604] Although the 1983 FAO Resolution, for example, afforded preservation to genetic resources, it nevertheless required that they were made freely available for use as the 'common heritage of mankind'.[1605]

However, this concept has been rejected as applicable to genetic resources within the jurisdiction of a given state, even during the colonial times.[1606] The common heritage concept, it has been noted, 'is of recent vintage and states have always had the right…to determine, regulate, and control access to plant life forms within their own jurisdiction'.[1607] Given the insistence of states on territorial sovereignty, it is only in cases of resources beyond their territories, such as in the Antarctica or deep seabed, that the common heritage concept has received some recognition.[1608] Thus, it appears incorrect, as some commentators have done in the past, to argue that prior to 1992 plant genetic resources were part of the common heritage of mankind.[1609] Any lingering doubts regarding the status of genetic resources within the boundaries of sovereign states have been dispelled by the provisions of the Convention on Biological Diversity. Article 15 of the Convention affirms the authority of states to determine who accesses genetic resources, subject to national legislation, based on prior informed consent and benefit-sharing on mutually agreed terms, and that this authority derives from the sovereign rights of states over their natural resources.[1610] Based on this, developing and least-developed countries contend that the unauthorised and uncompensated commercial use of genetic resources within their jurisdiction or control, including the subsequent acquisition of patent rights by the biotechnology and pharmaceutical industries over products derived from such use, contravene their sovereign rights over their resources.[1611] This has been characterised as 'biopiracy'.[1612] Another instance is the research conducted by the National Cancer Institute (NCI) on the tropical plant, mamala tree (*Homalanthus nutans*),

[1604] Ebermann (n 977) 32.
[1605] David Hunter, James Salzman and Durwood Zaelke, *International Environmental Law and Policy* (Foundation Press, 2011) 1023.
[1606] Mgbeoji, 'Beyond Rhetoric' (n 1601) 821-837; see also Cullet, 'Property Rights Regimes Over Biological Resources' (n 1577) 651.
[1607] Mgbeoji, 'Beyond Rhetoric' (n 1601) 821-837.
[1608] Cullet, 'Property Rights Regimes Over Biological Resources' (n 1577) 651.
[1609] Mgbeoji, 'Beyond Rhetoric' (n 1601) 821-837
[1610] Convention on Biological Diversity 1992, art 15(1), (2), (4), (5) and (7).
[1611] The Commission on Intellectual and Industrial Property, 'TRIPS and the Biodiversity Convention: What Conflict?' (International Chamber of Commerce 1999).
[1612] Dutfield, 'Bioprospecting: Legitimate Research or Biopiracy?' (n 1138).

based on the observation that Western Samoan healers treated hepatitis using the plant.[1613] The research yielded prostratin which showed potential for treating HIV, and several applications were later filed for patent on this active agent.[1614]

The point is that acts of biopiracy could have an impact on access to traditional medicine for sustainable development, as there are cases where such exploitations can lead to depletion of biodiversity. Admittedly, biotechnology can be used to reproduce and manipulate genetic resources at a cellular level away from its place of domestication without resources being over-harvested, although there is still some form of use of genetic resources, but in a small amount, as a sample of the plant is required to start the biotechnology process.[1615] What is more, the world's genes are increasingly existing in the form of free-floating sequences in public databases so that plants no longer need to be harvested.[1616] Thus, the genes of Chinese wormwood (*Artemisia annua*), for example, can now be assembled in a laboratory and inserted into yeast or tobacco to produce a precursor of artemisinin for treating malaria.[1617] However, it is also possible to find multiple corporations collecting a particular plant from the wild for its different therapeutic properties, as plants are known to comprise of numerous compounds that could be pharmacologically active. This was the situation faced by Peru's cat's claw (*Uncaria tomentosa*). The bark of cat's claw – a jungle plant – contains substances which boost the human immunological system and are found to be effective against certain types of cancers.[1618] This plant was used for many centuries by the Ashaninka community of the Peruvian jungle,[1619] but it was at the brink of extinction because of its massive exploitation by pharmaceutical companies as a result of its popularity and demand throughout the world for its medicinal properties.[1620]

[1613] Space Daily, 'Samoa Claims Rights to AIDS-Fighting Gene Found in Pacific Tree Bark' (22 October 2004) <http://www.spacedaily.com/reports/Samoa_claims_rights_to_AIDSfighting_gene_found_in_Pacific_tree_bark.html> accessed 1 January 2016.
[1614] ibid.
[1615] Ebermann (n 977) 19; see also Ong, 'Harnessing the Biological Bounty of Nature' (n 1145) 1,7
[1616] Kelly Servick, 'Rise of Digital DNA Raises Biopiracy Fear' (*Science*, 17 November 2016) <http://www.sciencemag.org/news/2016/11/rise-digital-dna-raises-biopiracy-fears > accessed 21 January 2018.
[1617] ibid.
[1618] Timmermans (n 869).
[1619] Zoraida Portillo, 'Environment – Latin America: Biopirates Threatens the Amazon' *Inter Press Service* (Lima, 4 January 1999).
[1620] Timmermans (n 869); see also Portillo (n 1619).

Similarly, *Pilocarpus jaborandi*, a plant native to North-Eastern Brazil and known by Brazil's indigenous peoples for causing salivation or producing saliva, was under threat as a result of unauthorised and uncompensated exploitation by pharmaceutical companies for producing treatments for, among others, radiation-induced xerostoma (dry mouth syndrome) and angle-closure glaucoma.[1621] In fact, these companies found it more cost-effective to extract pilocarpine, the active ingredient, from the leaves of *Pilocarpus jaborandi* than synthesis.[1622] The German company, Merck and Co, for example, established large plantations in Brazil and incorporated a subsidiary, Vegetex-Extratos Vegetais do Brasil Ltda, to enhance its collection of the plant from the wild.[1623] This potential for biopiracy acts to result in loss of biodiversity reiterates the importance for developing and least-developed countries to adopt national strategies to implement conservation and sustainable use of biodiversity, and regulate access to genetic resources subject to fair and equitable sharing of benefits, as enshrined in the Convention on Biological Diversity and its Nagoya Protocol, in order to sustain access to traditional medicine for progress towards the 2030 Agenda for Sustainable Development.

Nonetheless, it should be pointed out that it is not only biodiversity that is in urgent need of conservation because of biopiracy; implicated in the use of biodiversity to produce plant-derived pharmaceuticals is the traditional knowledge of the indigenous peoples regarding the medicinal uses of plants (otherwise 'traditional medical knowledge'). As defined in Chapter three, traditional medical knowledge is the 'knowledge that local and indigenous peoples hold of the healing properties of plants'.[1624] It is this knowledge, as well as health practices, approaches and beliefs developed experientially that are infused into the practice of traditional medicine.[1625] This knowledge is said to play a vital role in the exploration activities of scientists for pharmacologically active plants, as well as in

[1621] Kerry ten Kate and Sarah A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (Earthscan, 1999) 73; see also Alessandra Delavi, 'Green Piracy' (*RainTree,* 1996) <http://www.rain-tree.com/article5.htm#.V457ojfPU_V > accessed 20 July 2016; and Marc C Stuart, Maria Kouimtzi and Suzanne R Hill, *WHO Model Formulary 2008* (Geneva: Switzerland, World Health Organization, 2009) 439.
[1622] ten Kate and Laird, The Commercial Use of Biodiversity (n 1621) 73.
[1623] ten Kate and Laird, The Commercial Use of Biodiversity (n 1621) 73.
[1624] Ebermann (n 977) 11.
[1625] World Health Organization, 'WHO Traditional Medicine Strategy 2002-2005' (n 12) 7.

providing potentially valuable clues for pharmaceutical R&D.[1626] This forms part of the biopiracy arguments: that third parties commercialise traditional medical knowledge without the prior informed consent of and benefit-sharing with the indigenous peoples. At issue, is the point that the unauthorised and uncompensated commercial use of traditional knowledge of the medicinal uses of plants by scientists and pharmaceutical companies has implications that underscore the importance for developing and least-developed countries to establish national regimes for the protection of traditional knowledge, and ensuring that its utilisation is based on prior informed consent and sharing of benefits with the indigenous peoples, with the principal aim of ensuring access to quality, safe and effective traditional medicine for realising the 2030 Agenda for Sustainable Development. It is on this issue that the next section focuses.

6.2. The Role of Traditional Medical Knowledge in Drug Discovery and Development

Discussions about the role of traditional medical knowledge in drug R&D are often contentious. This is as a result of the difference of opinion between those who argue that traditional knowledge is a potentially valuable source of clues for drug discovery, and others who maintain that while it may have been important in providing leads in the past, it has no 'present and future relevance' in drug discovery, and 'bioprospecting [is] a waste of time and money' due to advances in science and technology.[1627] In laboratories, biotechnology is used to discover potential pharmacologically useful properties in plants by decoding their cellular and molecular structures to use such biological molecules and cells to develop drugs.[1628] Bioprospecting, i.e. the exploration of biodiversity for commercially valuable genetic resources, is usually the first stage in any biotechnological drug R&D process.[1629] Given the variability of life on earth, it is typically a complex and

[1626] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 240; see also Ebermann (n 977).
[1627] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 240; see also Ebermann (n 977) 1; and Graham Dutfield, 'Why Traditional Knowledge is Important in Drug Discovery' (2010) 2(9) *Future Medicinal Chemistry* 1405-1409, 1405.
[1628] Sutton, Law and Biotechnology (n 1139) 4.
[1629] Ebermann (n 977) 19.

complicated exercise to screen a mass collection of plants for pharmacological activity.[1630] In many cases, this complexity results in a low hit rate in drug discovery.[1631]

An alternative methodology would be to begin the research from known medically active compounds, focusing the exploration on finding plants that contain those compounds.[1632] However, the limitation to this approach is that the required compound must be known.[1633] There is a more streamlined approach to conducting bioprospecting – the 'ethnopharmacological approach'. This approach purposefully incorporates the indigenous peoples because of their extensive knowledge of plants that are effective remedies for various diseases, although such knowledge does not identify the active chemical compounds in plants.[1634] Generally, the mandate of the team of expert-bioprospectors when embarking on bioprospecting expeditions is to interview shamans or other traditional healers in indigenous communities to acquire information on plants that have been used successfully as traditional medicine.[1635] This investigation does not only reveal the plant, but also the plant part used, the indication and method of treatment.[1636] It is in this way that traditional knowledge is said to provide biological information that could potentially lead to drug discovery, and which pharmaceutical companies commercialise – in the event that it results in drug discovery – with no recompense to the indigenous peoples for contributing to their commercial success. For instance, recall it was the observation that Western Samoan healers used the tropical plant mamala tree (*Homalanthus nutans*) to treat hepatitis that led the NCI to investigate and develop prostratin – an active agent that could potentially cure HIV.[1637]

As explained by Graham Dutfield, the reason some people in the pharmaceutical industry insist that traditional medical knowledge plays no significant role in drug discovery is

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[1630] ibid.
[1631] Georg Albers-Schönberg, 'The Pharmaceutical Discovery Process' in Timothy Swanson (ed), Intellectual Property Rights and Biodiversity Conservation: An Interdisciplinary Analysis of the Values of Medical Plant (Cambridge, 1998) 62, 67.
[1632] Ebermann (n 977) 20.
[1633] Michael Huft, 'Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights' (1995) 89 *Northwestern University Law Review* 1678.
[1634] Ebermann (n 977) 20.
[1635] Ebermann (n 977) 20.
[1636] Ebermann (n 977) 20; see also Lester Yano, 'Protection of Ethnobiological Knowledge of Indigenous Peoples' (1993) 41 *UCLA Law Review* 443, 448.
[1637] 'Targeting Hidden HIV: Research Group Licenses New Prostratin Technology' (*POZ*, 8 February 2010) < https://www.poz.com/article/hiv-prostratin-reservoirs-17975-2260> accessed 24 March 2017.

that in many cases, its contribution is not readily apparent.[1638] Unlike some imagine, pharmaceutical R&D is not a straightforward process which starts with a single discovery and eventually ends (within 10 -15 years) with a commercially viable product.[1639] In reality:

> progress in pharmaceutical research goes backwards as well as forwards and along complicated pathways often with no beginning or end. Alternatively, one might suggest the complexity of research progress has more in common with trees having many spreading branches than with thoroughfares.[1640]

Thus:

> …the learning trails that have led from traditional knowledge to some highly profitable drugs and classes of drugs can be so long and winding that they become hard to retrace with lengthy sections disappearing from most people's sights. Rediscovering these trails may show past traditional knowledge connections to some of today's best-selling drugs.[1641]

For instance, there is no difficulty in tracing curare, the surgical relaxant, to curare the Amazonian arrowhead poison despite the lengthy time that passed between when Europeans observed that Amazon's indigenous people used the plant extract to asphyxiate their prey during hunting, and 1942 when the use of curare in surgery commenced.[1642] Curare has the effect of blocking the acetylcholine receptors that initiate muscle contraction, and the pharmacological studies that followed this discovery by the Europeans led to the modern muscle relaxants now prescribed by anaesthesiologists in

[1638] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'Why Traditional Knowledge is Important in Drug Discovery' (n 1627) 1405-1409.
[1639] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Graham Dutfield, 'From Traditional Medicines to Modern Drugs' in Tania Bubela and E Richard Gold (eds), *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests* (Edward Elgar Publishing, 2012) 93, 96.
[1640] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 96.
[1641] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 96.
[1642] ibid.

medical surgery.[1643] However, this did not mark the end of the learning trail: further research conducted using curare not only resulted in improved muscle relaxants, but was also useful in enhancing the understanding of physiology and brain function by demonstrating the role of chemicals in transmitting 'messages within the brain, and from the brain to the rest of the body'.[1644] Based on this, numerous spin-off drugs such as ß-blockers, antidepressants such as Prozac, and treatments for Parkinson's disease, asthma and diarrhoea were developed.[1645] The point being made is that while scientific efforts spanning over an extended period resulted in these subsequent developments, the link between Prozac and the Amazonian use of curare as an arrowhead poison is not readily discernible.

The same can be said of the relationship between the observation by the English Chaplain, Rev. Edward Stones, that cinchona tree bark extract (quinine) was used by the Quechua indigenous people to treat fevers such as malaria,[1646] and the development of aspirin and later on, non-steroidal anti-inflammatory drugs (NSAIDs).[1647] Extracts from willow bark, used in ancient Greece and Rome to treat fevers and inflammation, had antipyretic properties which was rediscovered by Edward Stones (misnamed 'Edmund' in his willow bark paper)[1648] in 1763 prompted by the use of the extract (quinine) from the South American cinchona tree bark as an effective therapeutic agent for suppressing shivering as well as treating malaria by the Quechua people.[1649] It is worth noting that Stones had tasted willow bark earlier in 1758.[1650] This enabled him to compare it with the cinchona bark which was more expensive, and then reach the conclusion that willow bark was an inexpensive alternative to cinchona for treating fever.[1651] Subsequently, the German

[1643] Ian Vincent McGonigle, 'Afterword: Ethnopharmacology' in Jane Feaver, Simon Ings, Annie Kirby, Toby Litt, Sara Maitland, Adam Marek, Gregory Norminton, Sean O'Brien, K J Orr, Justina Robson, Jane Rogers, Dilys Rose, Sarah Schofield, Simon van Booy (eds), *Bio-Punk* (Comma Press, 2013).
[1644] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 97.
[1645] ibid.
[1646] Edmund Stone, 'An Account of the Successes of the Bark of the Willow in the Cure of the Augue' (1763) *Philosophical Transactions of the Royal Society of London* 195-200.
[1647] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 97-98.
[1648] W S Pierpoint, 'Edward Stone (1702-1768) and Edmund Stone (1700-1768): Confused Identities Resolved' (1997) 51(2) *Notes and Records: The Royal Society Journal of the History of Science* 211-217.
[1649] Stone (n 1646); see also Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 97-98.
[1650] Stone (n 1646).
[1651] ibid.

company, Bayer, synthesised and marketed the willow bark extract (salicylic acid) as aspirin.[1652] The mass-consumption of aspirin as a treatment for fevers and headaches in the 19th century was not the end of the trail: studies carried out using aspirin as a research tool led to the development of NSAIDs which are useful for treating inflammatory pains and fevers.[1653] Thus, these instances show that traditional medical knowledge plays a valuable role in drug discovery, but its contributions are very often not obvious as they gradually disappear amid many experimentations leading up to the potential discovery of new drugs.

Moreover, the patent regime engenders an environment in which traditional contributions are overlooked. By awarding property rights to only inventors of something new, involving an inventive step, and capable of industrial application, the patent regime does not recognise contributions of existing 'related artefacts', such as traditional medical knowledge from which inventors draw inspiration.[1654] It is even possible for the contribution of such 'related artefacts' to be acknowledged in the written description of the invention (also known as 'patent specification or disclosure'), yet the patent regime would not regard this as co-invention or require a sharing of benefits, as it allows inventors to reference the works or ideas of others.[1655] Besides, it is improbable that the indigenous peoples providing the lead for the discovery of a pharmaceutical compound would have known how to isolate it from their plants or describe it scientifically.[1656] However, a distinction must be made between a situation where the past related artefact was contributory and where it is, in fact, identical to the claimed invention. In the latter case, it is novelty-destroying as the claimed invention belonged to the state of the art before the date the patent application was filed, and therefore, not patentable.

Nevertheless, neglecting traditional contributions in drug discovery, and patenting and commercialising the end product without compensating the indigenous peoples seem far from fair and equitable; more so, where they were of immense assistance to the

[1652] Elizabeth Landau, 'From a Tree, a 'Miracle' Called Aspirin' *CNN* (22 December 2010).
[1653] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 97-98.
[1654] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 96.
[1655] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237; see also Dutfield, 'From Traditional Medicines to Modern Drugs' (n 1639) 93, 96.
[1656] ibid.

scientists.[1657] It has been noted in this regard that while applicants mention the names of plants providing the essential chemical ingredients in patent applications, traditional knowledge clues are usually excluded.[1658] To anti-biopiracy advocates, this makes the patent regime complicit in the unauthorised and uncompensated appropriation and monopolisation of long-held traditional medical knowledge; and, as will be seen later, is at the centre of the conflict between the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), the most comprehensive multilateral agreement that provides for the protection of intellectual property rights, and the objectives of the Convention on Biological Diversity.[1659]

The unauthorised and uncompensated appropriation of traditional medical knowledge has significant implications for access to quality, safe and effective traditional medicine for realising the 2030 Agenda for Sustainable Development. As asserted by WHO:

> While research into [traditional medicine] is essential to ensuring access to safe and effective treatments, the knowledge of indigenous [traditional medicine] practices and products gained by researchers can be a source of substantial benefits to companies and research institutes. Increasingly, it appears that knowledge of [traditional medicine] is being appropriated, adapted and patented by scientists and industry, with little or no compensation to its original custodians, and without their informed consent.[1660]

This means that if, as Chapter five recommended, research and documentation, development of treatment guidelines, and development of treatment brochures for preparing traditional medicine, which are to be made available to the public, are necessary for ensuring the quality, safety and efficacy of traditional medicine, then there is the risk that these measures would have the effect of making traditional medical knowledge easily accessible and open to exploitation by anyone unless it is legally protected. Since

[1657] ibid.
[1658] ibid.
[1659] Teshager W Dagne, Intellectual Property and Traditional Knowledge in the Global Economy: Translating Geographical Indications for Development (Routledge, 2014) 73-74.
[1660] World Health Organization, 'WHO Traditional Medicine Strategy 2002-2005' (n 12); see also United Nations Conference on Trade and Development, 'Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices (Geneva: United Nations Conference on Trade and Development 2000).

traditional medical knowledge plays a significant role in drug discovery and has the potential to contribute to the commercial success of the industry, making publicly accessible documented research that details traditional knowledge of plants and plant parts that are pharmacologically active, their treatment claims, methods of preparation and administration – information sought after during bioprospecting – would be very beneficial to scientists, and could possibly lead to further appropriation and monopolisation of traditional medical knowledge by incorporating it into the subject matter of a patented invention. The following section elaborates on this point.

6.3. Possible Ways in which Traditional Medical Knowledge may be Claimed in Patents

Traditional medical knowledge could be incorporated into a claimed invention in a number of ways. The patent's subject matter may be based upon or identical to traditional medical knowledge.[1661] For instance, *Kava* (*Piper methysticum*), a plant indigenous to the islands in the Pacific Ocean, was traditionally used as a relaxant in rituals, to treat insomnia, stress, anxiety, muscle and back pain, and tension headaches.[1662] Natrol Inc., a US-based company, obtained a patent for 'Kavatrol' – a dietary supplement which consisted of *Kava*, chamomile, hops and schizandra.[1663] In its patent application, Natrol claimed that its supplement served as a relaxant.[1664] Again, two other German companies, Schwabe and Krewel-Werke, acquired patents on *Kava* as a prescription drug for treating strokes and insomnia.[1665] The problem in these instances is that Kava had been traditionally used by the Pacific Ocean cultures for many generations in the ways claimed by these patents; so in patent law terms, the claimed inventions belonged to the state of the art. Thus, these companies should not have been granted patent rights in the first place, as their claimed inventions were neither new nor involved an inventive step.

[1661] Cynthia M. Ho, 'Biopiracy and Beyond: A Consideration of Socio-cultural Conflicts with Global Patent Policies' (2005-2006) 39 *University of Michigan Journal of Law Reform* 433.
[1662] Phillipe Cullet, Christophe Germann, Andrea Nascimento, and Gloria Pasadilla, 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' in Susette Biber-Klemm and Thomas Cottier (eds), *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives* (Wallingford: CABI 2006) 137.
[1663] ibid.
[1664] Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 137.
[1665] ibid.

Another instructive example is the Peruvian maca case. Maca (*Lepidium meyenii*) is an indigenous plant cultivated by the Andeans since ancient times as food and medicines; notably, its traditional use for fertility and sexual potency was well known as it is sometimes called 'natural Viagra'.[1666] However, Pure World Botanicals Inc., a US-based subsidiary of Naturex SA – a France-based company that specialises in the production of natural extracts – obtained a US patent that claimed treatment of cancer and sexual dysfunction with an extract from maca.[1667] In a report submitted to the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC), Peru's delegation to the fifth session of the committee in 2003 listed numerous documents showing the state of the art regarding the use of maca, including its root in treatment especially for fertility and sexual potency.[1668] Based on this, the delegation contended that Pure World's patent merely appropriated traditional knowledge, as the claimed invention neither disclosed anything new nor involved an inventive step.[1669]

In some cases, patents of this nature may be granted in error.[1670] It could be that patent examiners did not thoroughly examine patent applications, and so did not discover that a claimed invention formed part of the state of the art.[1671] This negligence would be hardly surprising as patent examiners are overwhelmed continuously by workload due to the rapid increase in the number of patent applications filed on a yearly basis.[1672] Moreover, it does not seem practicable for patent examiners to have access to all of the state of the art, including undocumented knowledge.[1673] This holds true particularly given that majority of traditional medical knowledge exists in oral form, thereby creating an opportunity for anyone to replicate and claim it as a new invention worthy of patent

[1666] Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (n 1590) 50 see also Daniel Robinson, Confronting Biopiracy: Challenges, Cases and International Debates (Routledge, 2010).
[1667] Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (n 1590) 50.
[1668] WIPO-IGC, 'Patents Referring to *Lepidium Meyenii* (Maca): Responses from Peru' (Geneva: Word Intellectual Property Organization 2003); see also Robinson, *Confronting Biopiracy* (n 1666).
[1669] WIPO-IGC, 'Patents Referring to *Lepidium Meyenii* (Maca)' (n 1667).
[1670] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1671] Lorna Dwyer, 'Biopiracy, Trade, and Sustainable Development' (2008) 19 *Colorado Journal of International Environmental Law & Policy* 219.
[1672] Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (n 1590) 49.
[1673] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.

protection.[1674] In jurisdictions such as Japan[1675] and formerly in the US,[1676] undocumented foreign knowledge was inadmissible as novelty-destroying prior art. That is to say that they only acknowledged prior art of a foreign country if it was described in a printed publication.[1677] Based on this position of the law, patent examiners overlooked any prior custody or traditional use of plants by the indigenous peoples.

For instance, turmeric was 'a classic grandmother's remedy' in India that was applied to wounds because of its antiseptic property.[1678] In 1994, the University of Mississippi obtained a US patent on the use of turmeric for wound healing.[1679] In its patent application, the University merely stated that 'in India turmeric [had] long been used as a traditional medicine for the treatment of various sprains and inflammatory conditions'.[1680] It did not cite any written reference substantiating this information, as patent applicants were under an obligation under the US Patent Law to disclose written sources of information material to patent examination.[1681] In light of this, the patent examiners did not consider the traditional use of turmeric in India which was a novelty-destroying prior art.[1682] To challenge this patent by establishing that the claimed invention belonged to the state of the art, the Indian government had to locate and translate 32 references from Sanskrit, Urdu and Hindi as documented evidence of the use of turmeric as traditional medicine in India, which led to the eventual revocation of the patent.[1683]

It is likely that a similar application for patent on turmeric would not have been successful in the UK. The UK applies absolute novelty: this means that the novelty of an invention

[1674] ibid.
[1675] Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity (Routledge, 2000) 64.
[1676] This was formerly the position of the law under 35 United States Code (U S C), sec 102(a), (b); however, this aspect of the legislation has been changed by the America Invents Act (Bill HR 1249) signed by the US President on 16 September 2011; see Summary of the America Invents Act (n 755); and Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1677] Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 137; Dutfield, *Intellectual Property Rights, Trade and Biodiversity* (n 1675) 64.
[1678] Matthias Leistner, 'Analysis of Different Areas of Indigenous Knowledge' in Silke von Lewinski (ed), *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (Kluwer Law International, 2008); see also Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 137.
[1679] U.S. Patent No. 5,401,504 (filed December 28, 1993).
[1680] Leistner (n 1678) 77.
[1681] ibid.
[1682] ibid.
[1683] Ho, 'Biopiracy and Beyond' (n 1661) 433.

is weighed against all information that is available anywhere in the world, and that exists in whatever form as at the priority date.[1684] In other words, even undocumented evidence of foreign knowledge, for example, is admissible to disprove novelty claims. Thus, the description in the patent application of the traditional use of the turmeric in India for wound healing would have been sufficient to destroy the claim of novelty by the patent. Moreover, the fact that the use of turmeric for wound healing was well known and widely applied, whether or not it was described in a distributed publication, would have sufficed to destroy the claim of novelty.

There are also cases in which the claimed invention in the patent application involves an inventive step over and above the traditional medical knowledge related to it or from which it derives.[1685] Recall the example of mamala tree (*Homalanthus nutans*) which was used by healers in Western Samoa to treat hepatitis. Although this knowledge inspired pharmacological studies on the plant by researchers from the NCI, the application of the active agent (prostratin) developed from the plant as a potential treatment for HIV, differs from the traditional use of mamala by the Samoan healers.[1686] Here, the researchers made a contribution far more technical than the traditional medical knowledge lead, thereby meeting the patentability criteria of new and inventive step.[1687] However, although speculative, it is within the bounds of possibility that patents could equally grant rights to those who can translate traditional medical knowledge into the language of chemistry, irrespective of whether or not such translation involves an inventive step or creates anything new.[1688] What happens, in this case is that, hypothetically, the novelty and inventive step criteria are relaxed.

Nevertheless, this theory was not upheld by the House of Lords (now Supreme Court) in the case of *Merrell Dow v Norton*.[1689] Merrell Dow had patented terfenadine – an antihistamine drug in 1972. Upon further research, it discovered that once terfenadine

[1684] Patent Act 1977, s 2(2); see also Charlotte Waelde, Abbe Brown, Smita Kheria and Jane Cornwell, *Contemporary Intellectual Property: Law and Policy* (4th edn, Oxford University Press, 2016) 436.
[1685] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1686] Ebermann (n 977) 3.
[1687] ibid.
[1688] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1689] Merrell Dow Pharmaceuticals Inc & Another v HN Norton & Co Ltd and Others [1996] RPC 76 (HL)

was taken, it was metabolised by the human liver and produced an acid metabolite.[1690] This metabolite was largely responsible for the antihistamine effect of terfenadine.[1691] In 1980, it obtained patent rights over this acid metabolite.[1692] After the expiration of the 1972 patent on terfenadine, other companies, including Norton started producing the drug. Merrell Dow initiated proceedings against them claiming infringement of the acid metabolite because it was contained in the use of terfenadine.[1693] The issue here is that patent was granted to Merrell Dow over the acid metabolite even though it was part of the state of the art, as it had been anticipated by disclosure in the 1972 patent specification which disclosed information on the chemical composition of terfenadine and that it should be taken for its antihistamine effect.[1694] Merrell Dow justified its patent on the metabolite by arguing that for a substance to belong to the state of the art, anticipation must be provided in the language of chemistry.[1695]

In delivering judgement, Lord Hoffmann of the House of Lords disagreed with Merrell Dow, noting that its argument would have been tenable if patent law had a peculiar epistemology; however, that was not the case.[1696] The House of Lords found that there are several ways to identify a substance in the state of the art by comparing how an Amazonian indigenous person would describe the use of cinchona tree bark extract, quinine, with how a Western scientist would.[1697] The Amazonian indigenous person knows that the bark is useful in treating fevers, and that is a quality of quinine. It does not matter that he describes it in 'animistic' and not in chemical terms.[1698] There are ways people know a particular thing, without knowing about its chemical structure or that it has a molecular structure.[1699] What is important is not the scientific explanation, but the ability to use the technical effect.[1700] Therefore, for an invention to be part of the state of the art by disclosure, the information revealed must be such that enables the public to

[1690] Waelde et al. (n 1684) 441.
[1691] ibid.
[1692] ibid.
[1693] ibid.
[1694] ibid.
[1695] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1696] ibid; see also Bengt Domeij, *Pharmaceutical Patents in Europe* (Martinus Nijhoff Publishers 2000) 155.
[1697] ibid.
[1698] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1699] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 241.
[1700] ibid.

know the invention under a description sufficient to work it.[1701] What the 1972 patent described was terfenadine and its effect on the body, one of such effects being the antihistamine effect which was caused by the acid metabolite.[1702] Lord Hoffman concluded that: 'if the recipe which inevitably produces the substance is part of the state of the art, so is the substance as made by the recipe'.[1703]

This was the position taken earlier by the European Patent Office (EPO) Technical Boards of Appeal in the *Flavour concentrates'* case.[1704] While this case had nothing to do with medicines or traditional knowledge, it sheds more light on the theory of translation. In *Flavour concentrates*, the application was for a patent on the process for making flavour concentrates from vegetable or animal substances by extraction with fat solvents under pressure in the presence of water.[1705] The claim included certain parameters for the ratio between the vapour pressure in the vegetables or meat and the vapour pressure of the free water.[1706] This patent application was challenged with two cookbook recipes for pressure-frying chickens and making stews, which in non-technical terms had the same effect as the claimed process.[1707] The applicant justified the application for patent on the cooking recipe on the grounds that the flavour concentrates could be chemically analysed and identified.[1708] Nevertheless, the board was unconvinced and found that the starting process and the reaction conditions of the claimed process were identical to those of the known process.[1709] Therefore, these identical features would yield the same effects.[1710] It did not matter that a cook did not recognise that he was not only frying chicken but also making a flavour concentrate in the surplus oil.[1711] Rather, it was sufficient that 'some flavour of the fried chicken [was] extracted into the oil during the frying process even if

[1701] Waelde et al. (n 1684) 442.
[1702] ibid.
[1703] ibid 441.
[1704] *CPC/Flavour Concentrates Decision* (T303/86) [1989] 2 European Patent Office Reports 95.
[1705] ibid; see also Martin Adelman, Shubha Gosh, Amy Landers and Toshiko Takenaka, *Global Issues in Patent Law* (West Academic Publishing 2010) 103-4; David I Bainbridge, *Intellectual Property* (Pearson Education 2009) 407.
[1706] CPC/Flavour Concentrates Decision (n 1704) 95; see also Adelman et al., Global Issues in Patent Law (n 1705) 103-4.
[1707] ibid.
[1708] ibid.
[1709] CPC/Flavour Concentrates Decision (n 1704) 95; see also Adelman et al., Global Issues in Patent Law (n 1705) 103-4.
[1710] ibid.
[1711] CPC/Flavour Concentrates Decision (n 1704) 95; see also Adelman et al., Global Issues in Patent Law (n 1705) 103-4.

this [was] not the desired result of that process'.[1712] Thus, to be part of the state of the art, a process for making flavour concentrates was adequately described by a recipe for cooking food, which although not expressly referring to flavour concentrates, inevitably had the effect of making them.[1713]

The fact that the translation theory was not upheld in these cases does not gainsay or negate its plausibility being a jurisprudential theory.[1714] One justification for this assertion is that more often than not, evidence of any anticipatory prior art presented before courts or patent examiners will be in a documented form.[1715] Because the knowledge of the indigenous peoples mostly exists in oral form, and customarily, they do not document or publish it in reputable journals or books, there is a high probability that traditional knowledge would not be considered by courts or patent examiners, except in exceptional cases.[1716] For example, a seed of an insect-resistant cowpea developed by local farmers in Ibadan, Nigeria was collected by a scientist from the University of Durban, Angharad Gatehouse, during one of his bioprospecting expeditions to Nigeria.[1717] Adopting formal techniques, he identified in 'scientific language' the genetic component responsible for the cowpea's insect-resistant attribute.[1718] Following this discovery, he resigned from the University of Durban and joined the Agricultural Genetic Company of Cambridge, which helped him patent the insect-resistant cowpea.[1719] This was mainly possible because 'those local farmers did not "publish" their findings or their results in a reputable academic journal reviewed by their "peers"'; thus, 'their scientific insights counted for nothing'.[1720] The critical question is whether the local farmers knew of the insect-resistant property of the cowpea. Clearly, they did. Following the reasoning of Lord Hoffmann in *Merrell Dow*, it does not seem relevant that the local farmers could not have identified in chemical terms the genetic component of the cowpea that was

[1712] ibid.
[1713] ibid.
[1714] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 242.
[1715] ibid.
[1716] ibid.
[1717] James Buchanan, 'Between Advocacy and Responsibility: The Challenge of Biotechnology for International Law' (1994) 1 *Buffalo Journal of International Law* 221; see also Ikechi Mgbeoji, 'Bio-Cultural Knowledge and the Challenges of Intellectual Property Rights Regimes for African Development' (2012) 35(2) *Dalhousie Law Journal* 397-424, 408.
[1718] ibid.
[1719] ibid.
[1720] ibid; see also Ikechi Mgbeoji, Global Biopiracy: Patents, Plants and Indigenous Knowledge (UBC Press, 2014) 14.

responsible for the insect-resistant effect if they were asked to do so. As a matter of fact, the insect-resistant characteristic of the cowpea was their invention. In light of this, the invention claimed by Gatehouse was not new and did not involve an inventive step, as it belonged to the state of the art. Nevertheless, because the traditional knowledge was not documented, and Gatehouse could translate it into the language of science, patent law accorded him recognition as the inventor of the insect-resistant cowpea with the attendant rights.

Appropriating and monopolising traditional knowledge in the ways just described raises two issues: a legal issue and a moral issue. First, the legal issue arises from the provisions of international law and human rights which recognise the sovereignty of the indigenous peoples over genetic resources, and as custodians and owners of associated traditional knowledge. Owing to their close relationship with traditional lands and territories, international law and human rights vest title over lands and territories, which they traditionally used and occupied, on the indigenous peoples.[1721] Title over lands includes the right to use, own, manage and control the natural resources found within such lands and territories.[1722] Article 1(1) of both the International Covenant on Economic, Social and Cultural Rights (mentioned in Chapter one) and the International Covenant on Civil and Political Rights (mentioned in Chapter three) state that *all peoples* have the right to self-determination by virtue of which they determine their political status and freely pursue their economic, social and cultural development.[1723] The United Nations (UN) Charter, the foundational treaty of the UN – an intergovernmental organisation with 193 parties, also recognises 'the principle of equal rights and self-determination of *peoples'*.[1724] These provisions imply that *all peoples* (bar none) are entitled to this inalienable right to self-determination, including the indigenous peoples. [1725] Fundamental to enjoying this right is the exercise of permanent sovereignty over natural

[1721] Erica-Irene Daes, 'Prevention of Discrimination and Protection of Indigenous Rights: Indigenous Peoples' Permanent Sovereignty Over Natural Resources, Final Report of the Special Rapporteur' (United Nations Economic and Social Council, E/CN.4/Sub.2/2004/30) para 6.
[1722] ibid.
[1723] International Covenant on Economic, Social and Cultural Rights 1966, art 1(1); International Covenant on Civil and Political Rights 1966, art 1(1).
[1724] Charter of the United Nations 1945, art 1(2).
[1725] Miguel Alfonso Martinez, 'Study on Treaties, Agreements and other Constructive Arrangements Between States and Indigenous Populations: Final Report of the Special Rapporteur' (E/CN.4/Sub.2/1999/20) para 256.

resources.[1726] Thus, the basis upon which the indigenous peoples claim sovereignty over land and natural resources is the right to self-determination.

Indigenous peoples' sovereignty over land and resources is also acknowledged by the United Nations Declarations on the Rights of Indigenous Peoples (UNDRIP 2007), which Chapter three noted to be the most representative instrument on the thoughts and participation of the indigenous peoples.[1727] Article 26 establishes the right of the indigenous peoples to own, develop, and control the lands, territories and resources that they have traditionally possessed or used.[1728] From these stipulations of international law and human rights, one can take the analytical position that the Convention on Biological Diversity does not reflect the international consensus on the rights of the indigenous peoples to own, manage and control natural resources found on traditional lands and territories. This is because, while it recognises the sovereign right of states to exploit their natural resources, the Convention does not articulate such right on the part of indigenous peoples. However, Articles 5 and 6 of its Nagoya Protocol distinguish between genetic resources over which states can exercise sovereign right, and those 'held' by indigenous and local communities, regarding which bioprospectors must obtain their prior informed consent before access.[1729] As will be discussed later on, while the Nagoya Protocol seems to recognise the right of the indigenous peoples to self-determination given Articles 5 and 6, it nevertheless subjects the implementation of this right to domestic legislation. This means that for the indigenous peoples to assert sovereign right over genetic resources, and consent or approve access and partake in sharing benefits derived from utilising genetic resources found within their traditional lands and territories, these rights must be established under domestic laws.[1730]

The relationship between the indigenous peoples and their lands and territories is said to form a core part of their identity and spirituality, and is deeply rooted in beliefs, customs,

[1726] Debra Harry and Le à Malia Kanehe, 'The BS in Access and Benefit Sharing (ABS): Critical Questions for Indigenous Peoples' in Beth Burrows (ed), *The Catch: Perspectives on Benefit Sharing* (Edmonds Institute, 2005) 2.
[1727] ibid; Sharon Venne, Our Elders Understand Our Rights: Evolving International Law Regarding Indigenous Rights (Theytus Books Ltd 1999) 137.
[1728] United Nations Declarations on the Rights of the Indigenous Peoples (UNDRIP 2007), art 26.
[1729] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity 2010, arts 5 & 6.
[1730] ibid.

traditions and culture.[1731] Based on this 'intimate connection with land',[1732] they have nurtured and sustained their environments for generations.[1733] In turn, the flora, fauna, and other resources found on traditional lands and territories have been a source of livelihood and sustenance to their communities, providing them with food, clothing and medicines.[1734] It is from this cultural interaction with land and natural resources that the traditional knowledge of the medicinal uses of plants evolves. Therefore, traditional medical knowledge passes as the intellectual creation of the indigenous peoples, and this entitles them to maintain and control its wider application. Article 31 of the UNDRIP encapsulates this by recognising the right of the indigenous peoples to 'maintain, control, protect and develop' their traditional knowledge, including 'manifestations of sciences, technologies and cultures', as well as human and genetic resources, seeds, medicines, and knowledge of the properties of flora and fauna.[1735]

This right contained in Article 31 also covers the right to maintain, control, protect and develop their intellectual property rights over such traditional knowledge[1736] – that is, the right to earn recognition and economic benefit from their knowledge and protect it against unauthorised use by third parties. Added to this, UNDRIP's Article 24(1) endorses the indigenous peoples' rights to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals.[1737] Thus, the combined effect of these provisions of international law and human rights is that unauthorised and uncompensated use of genetic resources and associated traditional knowledge, whether for drug R&D or in any other subject matter of patents, contravenes the indigenous peoples' inalienable right to self-determination, as well as their property rights over traditional knowledge.

[1731] Erica-Irene A Daes, 'Prevention of Discrimination and Protection of Indigenous Peoples and `Minorities: Indigenous Peoples and their Relationship with Land, Final Working Paper Prepared by the Special Rapporteur' (United Nations Economic and Social Council, EN/CN.4/Sub.2/2001/21) para 16.
[1732] Cultural Survival and the Indigenous Peoples' Caucus, 'Our Land, Our Identity, Our Freedom' 5(2) *Cultural Survival Voices* (March 2007).
[1733] Backgrounder, 'Indigenous Peoples – Land, Territories and Natural Resources' (n 739).
[1734] ibid.
[1735] UNDRIP 2007, art 31.
[1736] ibid.
[1737] ibid, art 24(1).

Secondly, the moral issue stems from indigenous peoples' outlook on the world as a social and spiritual interaction between all life forms.[1738] To them, all life forms are interdependent, and other elements not less superior to human life.[1739] On this basis, they have cared for, protected and respected biodiversity, as well as used it for subsistence for centuries.[1740] This dependence on biodiversity resulted in the evolution of the body of knowledge associated with genetic resources, which is communally held and passed down from generation to generation according to customary values. Within their communities, both genetic resources and associated traditional knowledge are at the core of spiritual and communal well-being.[1741] Indigenous peoples perceive some plants as having religious significance and for that reason as sacred and beyond commodification.[1742] For instance, the neem tree (*Azadirachta indica*) is regarded as home to *Shitala* (goddess of smallpox) in India, and through its leaves the goddess cures and staves off smallpox and chickenpox.[1743] Due to its religious and cultural significance, it was thought of as beyond commodification.[1744] Nonetheless, a search of US patents related to traditional knowledge and associated genetic resources revealed that between 1976 to 2005, the US Patent and Trademark Office (USPTO) had granted 255 patents based on properties of neem.[1745]

Further, community developments based on genetic resources and traditional knowledge are viewed as 'co-creation' and 'co-development', as opposed to inventions.[1746] Private ownership of property – an essential characteristic of intellectual property rights – is anathema to the indigenous sense of communality.[1747] This accounts for the practice of

[1738] Martha Johnson, 'Research on Traditional Environmental Knowledge: Its Development and Its Role', in Martha Johnson (ed), *LORE: Capturing Traditional Environmental Knowledge* (DIANE Publishing, 1998) 3.
[1739] ibid.
[1740] Emily Marden, 'The Neem Tree Patent: International Conflicts Over Commodification of Life' (1999) 22 *Boston College International & Comparative Law Review* 279, 292-293.
[1741] Peter-Tobias Stoll and Anja von Hahn, 'Indigenous Peoples, Indigenous Knowledge and Indigenous Resources in International Law', in von Lewinski (ed) (n 1678).
[1742] Marden (n 1740) 292-293.
[1743] Matthew Hall, *Plants as Persons: A Philosophical Botany* (SUNY Press 2011) 74; see also Anil Kolluri, 'Neem Tree' (*Sacred Trees & Plants*, 3 January 2014) <http://sacredtress.blogspot.co.uk/2014/01/neem-tree.html> accessed 31 January 2018.
[1744] Marden (n 1740) 292-293.
[1745] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 240.
[1746] Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge (South End Press 1999) 67.
[1747] Keith Aoki, 'Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection' (1998) 6 *Indian Journal of Global Legal Studies* 11, 46.

disseminating knowledge and freely exchanging new developments amongst themselves. For example, in many developing and least-developed countries, indigenous farmers who develop new plant varieties share such knowledge with other members of their community, and even across communities and cultures.[1748] This state of affairs underlies the indigenous perception of the wider application of traditional knowledge and genetic resources, particularly through the patent regime, as morally offensive.[1749] More so, it is deemed unfair and inequitable where genetic resources, which they have spent centuries respecting, nurturing and conserving, and the associated traditional knowledge, are accessed and utilised by third parties without permission, incorporated into the subject matter of patents, and commercialised without any form of benefits accruing to them. As the argument goes, ideally, if anyone were to claim ownership of biodiversity or its derivatives, it should be these peoples who cared for it and developed the knowledge regarding its uses; and even so, this ownership would not be exclusive as such a notion is incompatible with their customs and traditions.[1750] Thus, it is only equitable given their stewardship and diligence, for the indigenous peoples to be the rightful beneficiaries of any commercial development of genetic resources and traditional knowledge.[1751]

To avoid romanticising about indigenous peoples and biopiracy, there is no doubt that there are instances where the indigenous peoples have shared their knowledge of medicinal uses of genetic resources based on an agreement to share benefits derived from such utilisation – a *quid pro quo*. In South India, the Kani tribes divulged their medicinal knowledge regarding the anti-fatigue properties of a wild plant, Arogyapaacha (*Trichopus zeylanicus*), to scientists at the Tropical Botanic Garden and Research Institute (TBGRI).[1752] The scientists isolated 12 active ingredients from the plant and developed an anti-stress and anti-fatigue drug named Jeevani for sports.[1753] After filing two patent applications on the drug, TBGRI established a trust fund where 50 per cent of the fee

[1748] Erin Kathleen Bender, 'North and South: The WTO, TRIPS, and the Scourge of Biopiracy' (2004) 11 *Tulsa Journal of Comparative & International Law* 281, 295.
[1749] Ho, 'Biopiracy and Beyond' (n 1661) 436.
[1750] Marden (n 1740) 279, 292.
[1751] Shiva (n 1746) 69.
[1752] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1490) 7.
[1753] ibid.

derived from the licencing of the technology to Arya Vaidya Pharmacy Ltd was to be deposited for the tribes' welfare.[1754]

In contrast to this situation, the key issue in relation to access to quality, safe and effective traditional medicine for achieving the 2030 Agenda for Sustainable Development is that because the research and documentation of traditional medicine, development of treatment guidelines, and development of treatment brochures for preparing traditional medicine, would have the effect of causing traditional medical knowledge to be freely available for others to use, this is likely to enable further unauthorised and uncompensated use of genetic resources and associated traditional knowledge. While one may argue that documentation and public disclosure of traditional medical knowledge will make it available for patent rejection and invalidation,[1755] documentation does not adequately protect the underlying knowledge against unauthorised use by third parties.[1756] In this regard, 'protection' is used in the intellectual property sense of legally ensuring that traditional knowledge is not misappropriated, copied and used without authorisation, as traditional knowledge in this research is dealt with in its narrow sense, i.e. referring to the know-how, skills, practices and technical knowledge relating to health.[1757] This is distinguishable from traditional cultural expressions (TCEs) which refer 'to tangible and intangible manifestations of culture and knowledge in artistic forms, such as designs, music, performances, arts and symbols', which require material protection – safeguarding and preservation – as envisaged in the 2003 UNESCO Convention.[1758]

Thus, to ensure access to quality, safe and effective traditional medicine which would complement the use of TRIPS flexibilities and (probably) a convention on drug R&D to promote universal health coverage and access to medicines, it is all-important for developing and least-developed countries to establish national regimes for the protection of traditional knowledge. In this respect, the WIPO[1759] is the body primarily responsible

[1754] Tobias Kiene, The Legal Protection of Traditional Knowledge in the Pharmaceutical Field: An Intercultural Problem on the International Area (Waxmann Verlag, 2009) 18.
[1755] Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge' (n 192) 237, 242.
[1756] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[1757] Wendland (n 1142) 97-107; see also Lixinski (n 1142).
[1758] ibid.
[1759] Introduced in chapter two as one amongst 17 specialised agencies of the United Nations created in 1967 to encourage creative activity and to promote the protection of intellectual property throughout the world with a membership of 191 states.

for the intellectual property protection of traditional knowledge.[1760] Negotiations are presently in progress within its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to develop an international instrument (or instruments) that would effectively protect traditional knowledge, genetic resources and TCEs.[1761] Such instrument could range from recommendations to WIPO members, to a treaty which would be binding on countries which elect to ratify it.[1762] Along similar lines, Article 8(j) of the Convention on Biological Diversity, Articles 5(5) and 7 of the Nagoya Protocol, contain provisions that obligate contracting parties to take legislative, administrative or policy measures that establish traditional knowledge as a subject matter for access and benefit sharing. In the next section, this chapter examines the regime of the Convention on Biological Diversity and the ongoing work at WIPO-IGC to ascertain how developing and least-developed countries can effectively: conserve biodiversity and ensure sustainable use of its components; implement the access and benefit-sharing system of the Convention and its Nagoya Protocol in relation to genetic resources and associated traditional knowledge; and protect traditional medical knowledge.

6.4. Effective Conservation and Sustainable Use of Biodiversity, Implementation of Access and Benefit-Sharing, and Protection of Traditional Medical Knowledge

6.4.1. The Convention on Biological Diversity 1992

The United Nations' Convention on Biological Diversity became available for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio 'Earth Summit') and entered into force on 4 June 1993.[1763] As already stated, it is a binding international framework treaty[1764] with three main objectives: the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.[1765] It is comprised of 196 parties,

[1760] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143).
[1761] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143).
[1762] ibid.
[1763] 'History of The Convention' (*Convention on Biological Diversity*) <https://www.cbd.int/history/> accessed 19 January 2016.
[1764] Philippe Cullet, Intellectual Property Protection and Sustainable Development (LexisNexis Butterworths, 2005) 92.
[1765] 'History of The Convention' (n 1763).

which includes 195 states and the European Union (EU).[1766] Although the US has signed, it is yet to ratify the Convention and has expressed no intention to do so.[1767] The regulation of biodiversity became important to the international community partly as a result of the concern that biodiversity 'is being significantly reduced by human activities',[1768] and the awareness that conservation and sustainable use of biodiversity 'is of critical importance for meeting the food, *health*, and other needs of the growing world population'.[1769] Being a framework treaty, the 1992 Convention sets out general principles to guide states' decisions regarding biodiversity management and establishes a number of broad obligations and institutional frameworks to enable continued cooperation, as well as the development of more commitments and areas of work.[1770]

As noted earlier, the Convention on Biological Diversity adopts an approach to conservation and sustainable use, which is rooted in the international law principle of permanent sovereignty.[1771] Under international law, the proclamation of permanent sovereignty has many antecedents – for example, the United Nations General Assembly in 1962 affirmed '[t]he right of peoples and nations to permanent sovereignty over their natural wealth and resources', inclusive of the right to dispose of such resources as national interest dictates.[1772] While this has only a declaratory force, it is often taken to be a statement of existing law and has been restated in other declarations.[1773] In the Convention on Biological Diversity, states' sovereign right over their biodiversity is recognised; but accompanying this right is the responsibility of the individual states to conserve and sustainably use the resources that lie within their territorial boundaries.[1774] This means that states' exercise of sovereign right is central to the Convention's 'reach

[1766] ibid.
[1767] Sanjoy Hazarika, 'India Presses U.S to Pass Biotic Treaty' *The New York Times* (23 April 1995) <https://www.nytimes.com/1995/04/23/world/india-presses-us-to-pass-biotic-treaty.html> accessed 7 January 2019.
[1768] Convention on Biological Diversity 1992, 7th preambular citation.
[1769] ibid, 21st preambular citation.
[1770] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 92.
[1771] Christine Willmore, 'Sovereignty, Conservation and Sustainable Use' in Elisa Morgera and Jona Razzaque (eds), *Biodiversity and Nature Protection Law* (Edward Elgar Publishing Limited, 2017) 31.
[1772] UN General Assembly, 'General Assembly resolution 1803 (XVII) of 14 December 1962, "Permanent sovereignty over natural resources"' (17th session: 1962).
[1773] Willmore (n 1771); see also Nico Schrijver, *Sovereignty Over Natural Resources* (Cambridge University Press 2008).
[1774] Convention on Biological Diversity 1992, 5th and 6th preambular citations, and art 3.

and effectiveness'.[1775] As a result, the implementation of the Convention's objectives takes place at the national level principally through the development of National Biodiversity Strategies and Action Plans (NBSAPs) as provided by Article 6.[1776] Article 6 of the Convention on Biological Diversity states that:

> Each Contracting Party shall, in accordance with its particular conditions and capabilities:
>
> (a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and
>
> (b) Integrate, *as far as possible and as appropriate*, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.[1777]

Thus, to prevent the loss of biodiversity with the aim of ensuring sustainable access to traditional medicine, it is crucial for developing and least-developed countries to develop NBSAPs that would lay down the measures for conservation set out in the Convention. These measures cover both *in situ* and *ex situ* conditions: according to the Convention on Biological Diversity Article 2, *in situ* relates to the conservation of plants, animals and micro-organism communities, including natural habitats, and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.[1778] In this connection, states are required, among other things, to formulate guidelines for protected areas – areas designed, regulated or managed to achieve specific conservation objectives;[1779] develop legislation or other regulatory

[1775] Willmore (n 1771).
[1776] Shannon M Hagerman and Ricardo Pelai, '"As Far as Possible and as Appropriate": Implementing the Aichi Biodiversity Targets' (2016) 9(6) *Conservation Letters*, Special Issue: Achieving the Targets of Global Biodiversity Conventions 469-478.
[1777] Convention on Biological Diversity 1992, art 6.
[1778] ibid, art 2.
[1779] ibid.

policies for the protection of threatened species and populations; prevent the introduction of, control or eradicate, those alien species which threaten ecosystems, habitats or species; and respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity.[1780]

Concerning *ex situ*, this involves conservation outside the natural habitats of protected biodiversity components [1781] and is meant to be only complementary to *in situ* conservation. [1782] States are required to adopt measures for *ex situ* conservation, preferably in the country of origin, including: to establish and maintain *ex situ* facilities such as gene banks, zoological and botanical gardens for conservation and research on plants, animals and micro-organisms; and to adopt rehabilitative and recovery measures for threatened species and the process of reintroducing them into their natural habitats under good conditions.[1783] For example, a traditional remedy of indigenous healers in Cameroon, *Ancistrocladus korupensis*, a rare plant which grows in the rainforest, was successfully conserved by the Korup National Park – one of Africa's 'oldest and richest' tropical forests located in the Southwest Province of Cameroon[1784] – by transplanting the young plants from the rainforest, domesticating them in a nursery, and subsequently planting them on a farm.[1785] This was necessary because based on observations of its traditional uses, scientists had discovered that the plant contained an important alkaloid (Michellamine B) for drug R&D for HIV/AIDS.[1786] As a result, the government was concerned that exploitation for R&D could lead to the plant becoming extinct.[1787]

[1780] ibid, art 8.
[1781] Convention on Biological Diversity 1992, art 2.
[1782] ibid, art 9.
[1783] ibid.
[1784] Oishimaya Sen Nag, 'The Wonders of the Nine National Parks of Cameroon' (*World Atlas*, 1 August 2017) <https://www.worldatlas.com/articles/the-wonders-of-the-nine-national-parks-of-cameroon.html> accessed 7 January 2019.
[1785] Charles Takoyoh Eyong, 'Why Ignore Ekpwe Rules? The Regulation of Forest Use by a Secret Society in Korup National Park, Cameroon' in Irit Eguavoen and Wolfram Laube (eds), *Negotiating Local Governance: Natural Resource Management at the Interface of Communities and the State* (LIT Verlag Münster, 2010) 87; see also Tansa Musa, 'Cameroon-Environment: Saving a Valuable Medicinal Plant' *Inter Press Service* (14 February 1997) <http://www.ipsnews.net/1997/02/cameroon-environment-saving-a-valuable-medicinal-plant/> accessed 14 March 2016.
[1786] Eyong, 'Why Ignore Ekpwe Rules?' (n 1785) 87.
[1787] Musa (n 1785).

It is noteworthy that while the Convention on Biological Diversity articulates these processes for conservation, it does not give the term 'conservation' any definition.[1788] This has been explained as intentional, as it was a concession to developing and least-developed countries which were apprehensive that the global conservation scheme might preclude them from exploiting their resources.[1789] Essentially, this policy space allows countries to define activities that might constitute 'use' of biodiversity as conservation.[1790] Nevertheless, a core injunction of the Convention is that use of biodiversity and its components should be 'sustainable'. In particular, Article 10 of the Convention requires parties to '*as far as possible and as appropriate*' 'integrate consideration of the conservation and sustainable use of biological resources into national decision-making'.[1791] That being so, 'sustainable' requires a 'more efficient, ethical, humane use' of biodiversity components.[1792] This can be gleaned from the Convention's definition of 'sustainable' to mean 'the use of components of [biodiversity] in a way and at a rate that does not lead to [its] long-term decline…thereby maintaining its potential to meet the needs and aspirations of present and future generations'.[1793] In this regard, it has been suggested that the concept of 'sustainable use' of biodiversity components relates to sustainable development,[1794] which was defined in Chapter one as 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs'.[1795] Thus, to sustainably use biodiversity components with the aim of ensuring access to traditional medicine for realising the 2030 Agenda for Sustainable Development, Article 10 requires developing and least-developed countries to adopt measures to avoid or minimise adverse impacts on biodiversity; to cooperate with the private sector in developing methods for achieving sustainable use; and to protect and encourage traditional cultural practices that are compatible with conservation or sustainable use of biodiversity.[1796]

[1788] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 93.
[1789] ibid 94.
[1790] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 94.
[1791] Convention on Biological Diversity 1992, art 10.
[1792] Secretariat of the Convention on Biological Diversity, *Addis Ababa Principles and Guidelines for the Sustainable Use of Biodiversity* (Montreal: Secretariat of the Convention on Biological Diversity 2004) principle 11.
[1793] Convention on Biological Diversity 1992, art 2.
[1794] Willmore (n 1771) 31.
[1795] Brundtland (n 23).
[1796] Convention on Biological Diversity 1992, art 10.

It is equally worth mentioning the International Treaty on Plant Genetic Resources for Food and Agriculture (also referred to as 'FAO Plants Treaty'), a legally binding instrument, which was adopted on 3 November 2001[1797] to work in harmony with the Convention on Biological Diversity for the 'conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use…for sustainable agriculture and food security'.[1798] A successor to the earlier referenced International Undertaking on Plant Genetic Resources for Food and Agriculture which legitimised the common heritage of mankind,[1799] the Plants Treaty was likewise adopted under the aegis of the Food and Agriculture Organization (FAO) – a specialised agency of the UN which is at the forefront of global efforts to defeat hunger – and is comprised of 139 parties, including the European Union (EU) and the US.[1800] This treaty is significant because as explained in Chapter three, some plant species are traditionally used as both food and medicine – for instance, recall the herb, *Udah,* used for soup and administered for maternal health following the four-week period after childbirth by the *Ibos* in Nigeria.[1801] Besides, the COP, the governing body of the Convention on Biological Diversity,[1802] recognised in its COP 6 Decision VI/6 the vital role of the Plants Treaty, in harmony with the Convention, for the conservation and sustainable utilisation of biodiversity; for facilitated access to plant genetic resources for food and agriculture; and for sharing of benefits arising out of their utilisation.[1803]

Importantly, the FAO Plants Treaty contains useful provisions regarding the conservation, exploration, collection, evaluation and documentation of plant genetic resources,[1804] and requires its contracting parties to adopt policy and legal measures to

[1797] 'International Treaty on Plant Genetic Resources for Food and Agriculture: Overview' (*Food and Agricultural Organization*) <http://www.fao.org/plant-treaty/overview/en/> accessed 28 February 2018.
[1798] International Treaty on Plant Genetic Resources for Food and Agriculture 2001, art 1(1).
[1799] Shawn N Sullivan, 'Plant Genetic Resources and the Law: Past, Present and Future' (2004) 135(1) *Plant Physiology* 10-15.
[1800] Gerald Moore and Witold Tymowski, Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture (Gland, Switzerland and Cambridge, UK: IUCN 2005).
[1801] IK Program, 'Traditional Knowledge Case Studies' (n 1062); see also Helaine Selin, *Encyclopaedia of the History of Science, Technology and Medicine in Non-Western Cultures* (Springer Science and Business Media 1997) 679.
[1802] 'Conference of Parties (COP)' (*Convention on Biological Diversity*) < https://www.cbd.int/cop/> accessed 2 January 2016.
[1803] Secretariat to the Convention on Biological Diversity, 'COP 6 Decision VI/6 2002' <https://www.cbd.int/decision/cop/default.shtml?id=7180> accessed 8 March 2018.
[1804] International Treaty on Plant Genetic Resources for Food and Agriculture 2001, art 5.

promote the sustainable use of plant genetic resources.[1805] Moreover, it provides for Farmers' Rights as a concession for 'the enormous contribution' of indigenous and local farmers in every region of the world, particularly those in developing and least-developed countries, to the conservation and development of genetic resources which serve as the basis for food and agricultural production throughout the world.[1806] Thus, since the goals of the FAO Plants Treaty are harmonious with the objectives of the Convention on Biological Diversity, the Treaty is also relevant to developing and least-developed countries for ensuring sustainable access to traditional medicine for sustainable development through the conservation of biodiversity and sustainable use of its components.

Besides the need to prevent the increasing loss, it has been posited that regulating biodiversity through the Convention on Biological Diversity became necessary in order to reach a compromise between developed countries, on the one hand, which wanted access because they possessed most of the technologies to exploit genetic resources, and developing countries, on the other hand, which held most of the biodiversity and demanded to restrict access to it.[1807] These two inequalities – unequal distribution of the world's biodiversity and uneven distribution of scientific and technological capacity – underlie claims of biopiracy; with scientific and technological advantage, the biotechnology and pharmaceutical industries from developed countries appropriate genetic resources and associated traditional knowledge without compensating developing and least-developed countries and the indigenous peoples within their territories, which house the majority of the world's resources but lack scientific and technological know-how to exploit them.[1808]

To establish a balance between these competing interests, Article 15 of the Convention while recognising the sovereign right of states over their resources and the authority to determine access to genetic resources lying within their jurisdiction, encourages

[1805] ibid, art 6.
[1806] ibid, art 9.
[1807] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 91.
[1808] Keith E Maskus, Intellectual Property Rights in the Global Economy (Peterson Institute, 2000) 222; see also Venbrux (n 1135) 6-7; and Sophia Twarog and Promila Kapoor, Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions (United Nations Publications, 2004).

contracting parties to facilitate access to genetic resources for environmentally sound uses and not to impose restrictions that are contrary to the objectives of the Convention.[1809] As preconditions, access to genetic resources must be based on the prior informed consent of the country providing such resources. Where granted, access must be on mutually agreed terms and sharing of benefits in a fair and equitable way, the results of R&D and the benefits arising from the commercial and other utilisation of genetic resources with the provider-country upon mutually agreed terms as well.[1810] This is referred to as the access and benefit-sharing (ABS) system of the Convention on Biological Diversity.

Furthermore, the Convention on Biological Diversity Article 16 requires parties to facilitate access to and transfer of technology, which includes biotechnology, that is relevant to the conservation and sustainable use of biodiversity, or that makes use of genetic resources to developing countries on fair and most favourable terms, and to adopt legislative, administrative or policy measures to ensure the private sector facilitates the access to, joint development and transfer to developing countries.[1811] While calling for recognition and respect of patents or other intellectual property rights over technologies, this Article provides for transfer to developing countries, which provide resources, of such technologies that make use of those resources where necessary and on mutually agreed terms.[1812] This provision has been finessed as imposing a moral duty on developed countries to assist developing, and least-developed countries bridge the development gap.[1813] Also, it is aimed at addressing one of the inequities in the global biotechnology trade.[1814]

However, the US, being a strong advocate for stringent intellectual property standards, has maintained that Article 16 is irreconcilable with intellectual property rights, notwithstanding that it calls for access and transfer of technologies on terms that 'recognise and are consistent with the adequate and effective protection of intellectual

[1809] Convention on Biological Diversity 1992, art 15(1), (2).
[1810] ibid, art 15(4), (5), (7).
[1811] Convention on Biological Diversity 1992, art 16.
[1812] ibid.
[1813] Gaetan Verhoosel, 'Beyond the Unsustainable Rhetoric of Sustainable Development: Transferring Environmentally Sound Technologies' (1998) 11 *Georgetown International Environmental Law Review* 49, 50.
[1814] Venbrux (n 1135).

property rights'.[1815] Essentially, the US is greatly concerned that it would be obligated to facilitate the transfer of not only the products of technology but also the technology itself to developing and least-developed countries.[1816] That being so, the desire to protect its intellectual property stance and the interests of its biotechnology and pharmaceutical industries explains why the US has refused to ratify the Convention.[1817] The concern with this is that being one of the key players in the global biotechnology trade, the US' failure to ratify could undermine the objectives of the Convention on Biological Diversity.[1818]

As for the compromise struck in relation to traditional knowledge, 'recognising the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biodiversity', and the need to share benefits arising from the utilisation of traditional knowledge as a reward for their contribution to conservation,[1819] Article 8(j) urges parties to '*as far as possible and as appropriate*' 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity'.[1820] However, contracting parties are, at the same time, required to promote the wider application of such knowledge with the *approval and involvement* of such knowledge holders and encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.[1821] In similar vein, Article 10 calls on parties to protect traditional cultural practices relating to the customary use of biodiversity that are compatible with conservation or sustainable use requirements.[1822] It must be noted that whereas Chapter three identified the key characteristics of indigenous peoples, neither the UNDRIP nor the Convention on Biological Diversity and its Nagoya Protocol defines 'local communities'. In international law, they are a group of people with unclear status, but nevertheless enjoy human rights protection against acts or

[1815] Robert F Blomquist, 'Ratification Resisted: Understanding America's Response to the Convention on Biological Diversity' (2002) 32 *Golden Gate University Law Review* 526-527; see also Convention on Biological Diversity 1992, art 16(2).
[1816] Blomquist (n 1815) 526-527.
[1817] ibid.
[1818] Darren Smyth, 'We Need to Talk About Nagoya' (*Chemistry World,* 24 May 2014).
[1819] Convention on Biological Diversity 1992, 13th preambular citation; see also Doris Schroeder, 'Justice and Benefit Sharing' in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San Hoodia Case* (Springer Science & Business Media 2009) 11.
[1820] Convention on Biological Diversity 1992, art 8(j).
[1821] ibid.
[1822] ibid, art 10(c).

omissions that may adversely interfere with their customary relations with knowledge, land and natural resources, and share many attributes with indigenous peoples.[1823]

What is noticeable from the provisions of Articles 8(j) and 10 is that the Convention seems only to deal with knowledge, innovations and practices of indigenous and local communities relevant to the conservation and sustainable use of biodiversity, and not with traditional knowledge related to R&D.[1824] On this note, some commentators have opined that the Convention on Biological Diversity establishes relations between the state and the indigenous and local community whose traditional knowledge is utilised for the conservation and sustainable use of biodiversity.[1825] In other words, in the case of traditional knowledge, benefit-sharing references 'an internal, state-to-community contribution to sustainable development, social justice and equity'.[1826] Even so, unlike in the case of genetic resources under Article 15, the Convention on Biological Diversity does not expressly link traditional knowledge with the concept of access and benefit-sharing.[1827]

In this connection, there have been remarkable discussions suggesting an interpretation beyond the wordings of the Convention in view of interest from the biotechnology and pharmaceutical industries in genetic resources and the commercial benefits derived from their utilisation owing to the leads provided by the associated traditional knowledge regarding potentially useful properties of genetic resources.[1828] Based on this close connection between genetic resources and traditional knowledge, a combined reading of

[1823] Elisa Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (2016) 27(2) *European Journal of International Law* 353-383.
[1824] Elisa Morgera, Elsa Tsioumani and Matthias Buck, Unravelling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity (Brill Online Books and Journals 2014) 25.
[1825] Morgera et al., Unravelling the Nagoya Protocol (n 1824) 25.
[1826] Elisa Morgera and Elsa Tsioumani, 'Evolution of Benefit-Sharing: Linking Biodiversity and Community Livelihoods' (2010) 19(2) *Review of European, Comparative & International Environmental Law* 150-173, 150-151; see also Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 25.
[1827] Morgera and Tsioumani, 'Evolution of Benefit-Sharing' (n 1826) 155-156; see also Geoff Burton, 'Implementation of the Nagoya Protocol in JUSCANZ Countries: The Unlikely Lot' in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Martinus Nijhoff Publishers 2012) 295, 316.
[1828] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 28; see also Elisa Morgera and Elsa Tsioumani, 'Yesterday, Today and Tomorrow: Looking Afresh at the Convention on Biological Diversity' (2011) 21(1) *Yearbook of International Environmental Law* 3-40.

Articles 15 and 8(j) would effectively subject traditional knowledge to access and benefit-sharing negotiations.[1829] This interpretation was reinforced by paragraph 48 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization, a non-legally binding set of guidelines adopted by parties to the Convention on Biological Diversity in 2002 to assist governments in developing legislative, administrative or other policy measures for access and benefit-sharing,[1830] which states that 'benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process'.[1831] According to the Bonn Guidelines, such beneficiaries in the access and benefit-sharing process may include the indigenous and local communities.[1832] As will be seen subsequently, the Nagoya Protocol provides, for the first time, legally binding obligations on access and benefit-sharing for the use of 'associated traditional knowledge' in R&D.[1833]

The majority of the contracting parties have operationalised the objectives of the Convention on Biological Diversity by developing, revising or updating their NBSAPs especially since the adoption of the Strategic Plan for Biodiversity 2011-2020, a ten-year framework adopted in 2010 by parties to the Convention 'for action by all countries and stakeholders to safeguard biodiversity and the benefits it provides to people' and to serve as a flexible framework for establishing national and regional targets and promoting the coherent and effective implementation of the objectives of the Convention.[1834] Adopted as part of the Strategic Plan are 20 ambitious but achievable targets known as Aichi Biodiversity Targets, which are grouped under five strategic goals that aim to: (a) address the underlying causes of biodiversity loss by mainstreaming biodiversity across government and society; (b) reduce the direct pressures on biodiversity and promote

[1829] Morgera et al., Unravelling the Nagoya Protocol (n 1824) 28.
[1830] Secretariat of the Convention on Biological Diversity, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation* (Montreal: Secretariat to the Convention on Biological Diversity) IV.
[1831] Bonn Guidelines 2002, para 48.
[1832] ibid.
[1833] Nagoya Protocol 2010, arts 5(5) and 7; see also Guardial Singh Nijar, 'Traditional Knowledge Systems, International Law and National Challenges: Marginalization or Emancipation?' *European Journal of International Law* 24 (2013) 1205; and Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 28.
[1834] Secretariat of the Convention on Biological Diversity, 'Strategic Plan for Biodiversity 2011-2020 and the Aichi Targets: Living in Harmony with Nature' <https://www.cbd.int/doc/strategic-plan/2011-2020/Aichi-Targets-EN.pdf> accessed 2 March 2018.

sustainable use; (c) improve the status of biodiversity by safeguarding ecosystems, species and genetic diversity; (d) enhance the benefits to all from biodiversity and ecosystem services; and (e) enhance implementation through participatory planning, knowledge management and capacity building.[1835]

In 2015, South Africa for instance, a party to the Convention since 1996[1836] and the third most biologically diverse country in the world,[1837] aligned its NBSAP, first developed in 2005, with the Strategic Plan for Biodiversity 2011-2020 and the Aichi Targets to cover a period of 10 years (2015-2025).[1838] Some of the pressing issues the NBSAP seeks to address include: improving the management of biodiversity assets and their contribution to the economy, rural development, job creation and social well-being; enhancing resilience and ensuring benefits to society through investments in ecological infrastructure; mainstreaming biodiversity considerations into policies, strategies and practices of a range of sectors; mobilising people to adopt practices that sustain the long-term benefits of biodiversity; improving the conservation and management of biodiversity through the development of an equitable and suitably skilled workforce; and, supporting the management, conservation and sustainable use of biodiversity through effective knowledge foundations, including indigenous knowledge and citizen science.[1839] The preparation, coordination and monitoring of the NBSAP are led by the Department of Environmental Affairs (DEA) and supported by the South African National Biodiversity Institute (SANBI) in the areas of, *inter alia*, research, monitoring, knowledge and information, planning and policy advice.[1840] Meanwhile, preparations are being made by the government of South Africa to revise its Biodiversity Act of 2004, which provides for the management and conservation of biodiversity; the protection of species and ecosystems that warrant national protection; the sustainable use of indigenous

[1835] ibid.
[1836] 'List of Parties' (*Convention on Biological Diversity*) <https://www.cbd.int/information/parties.shtml> accessed 2 March 2018.
[1837] Susie Brownlie, Amrei von Hase, Mark Botha, Jeffrey Manuel, Zoe Balmforth and Nicky Jenner, 'Biodiversity Offsets in South Africa – Challenges and Potential Solutions' (2017) 35(3) *Impact Assessment and Project Appraisal* 248-256, 248.
[1838] Government of South Africa, 'National Biodiversity Strategy and Action Plan' (Pretoria: Department of Environmental Affairs 2015).
[1839] Government of South Africa, 'National Biodiversity Strategy and Action Plan'(n 1838).
[1840] ibid.

biological resources; and the fair and equitable sharing of benefits arising from bioprospecting involving indigenous natural resources.[1841]

Similarly, India, a contracting party to the Convention since 1994[1842] and a megadiverse country, developed a National Biodiversity Action Plan (NBAP) through a comprehensive inter-ministerial process in 2008.[1843] Indian NBAP 2008 identifies threats and constraints in biodiversity conservation, based on which it outlines national action points which include: strengthening and integration of *in situ*, on-farm and *ex situ* conservation; augmentation of natural resource base and its sustainable utilisation, i.e. ensuring inter- and intra-generational equity; regulation of introduction of invasive alien species and their management; integration of biodiversity concerns in economic and social development; minimising and eliminating activities leading to loss of biodiversity due to pollution and promoting development of clean technologies; building national capacities for biodiversity conservation and appropriate use of new technologies, among others.[1844] In 2014, India developed 12 new National Biodiversity Targets in alignment with the Strategic Plan 2011-2020 and its Aichi Targets, which now form an addendum to the NBAP 2008.[1845] Notable among these new targets are that: by 2020, the genetic diversity of cultivated plants, farm livestock, and their wild relatives, including other socio-economically as well as culturally valuable species, is maintained, and strategies have been developed and implemented for minimising genetic erosion and safeguarding their genetic diversity; by 2020, national initiatives using communities' traditional knowledge relating to biodiversity are strengthened, with a view to protecting this knowledge in accordance with national legislation and international obligations; and ensuring that access to genetic resources and fair and equitable sharing of benefits are operational.[1846]

[1841] National Environmental Management: Biodiversity Act 2004.
[1842] 'List of Parties' (Convention on Biological Diversity) (n 1836).
[1843] Ministry of Environment, Forests & Climate Change, 'National Biodiversity Action Plan (NBAP): Addendum 2014 to NBAP 2008' (Ministry of Environment, Forests & Climate Change Government of India).
[1844] Ministry of Environment, Forests & Climate Change, 'National Biodiversity Action Plan (NBAP' (n 1843).
[1845] ibid.
[1846] ibid.

It is also worth pointing out that in 2002, India adopted a Biodiversity Act in response to concerns over biopiracy.[1847] Taking the approach of the Convention on Biological Diversity, India's Biodiversity Act aims to achieve the conservation of biodiversity, sustainable use of its components and the fair and equitable sharing of benefits arising out of the use of biodiversity and associated knowledge, based on the state's exercise of sovereign right to control natural resources.[1848] In facilitating access to genetic resources, the Act distinguishes between citizens and non-citizens of India, prescribing relatively stricter conditions for the latter to access genetic resources.[1849] For instance, non-citizens can only access genetic resources and associated traditional knowledge for research, commercial utilisation, bio-survey or bio-utilisation subject to the prior approval of the National Biodiversity Authority (NBA) – the competent authority responsible for the implementation of the Biodiversity Act.[1850] In respect of intellectual property rights, the Act mandates all patent applicants to obtain the consent of the NBA where their inventions are based on any biological resources acquired in India.[1851] Where patent rights have already been obtained outside India, the Biodiversity Act authorises the NBA to take steps to lodge post-grant oppositions (explained in Chapter two) to such granted patents.[1852]

While these provisions represent significant attempts to curb biopiracy, first: because intellectual property rights are territorial, the idea of consent by the Authority is limited to patent applications made in India – it is doubtful whether the Authority's jurisdiction extends to foreign applications; and secondly: the cost of challenging granted patents abroad is prohibitively expensive; thus, it is questionable whether it is a sustainable long-term strategy to solve the problem of biopiracy.[1853] Nonetheless, India has successfully challenged a few granted patents that were based on its genetic resources and incorporated the associated traditional knowledge. For instance, recall the government's opposition to

[1847] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 101.
[1848] Biodiversity Act 2002, Preamble.
[1849] ibid, s 3; see also Christian Prip and Kristin Rosendal, 'Access to Genetic Resources and Benefit-Sharing from their Use (ABS) – State of Implementation and Research Gaps' (2015) FNI Reports; and Cullet, *Intellectual Property Protection and Sustainable Development* (n 1764) 101-102.
[1850] Biodiversity Act 2002, s 3; see also 'Biodiversity Act' (*Ministry of Environment, Forests and Climate Change*) <http://www.moef.nic.in/division/national-biodiversity-authority-nba> accessed 3 March 2018.
[1851] Biodiversity Act 2002, s 6.
[1852] Biodiversity Act 2002, s 18(4).
[1853] Cullet, Intellectual Property Protection and Sustainable Development (n 1764) 102.

the US patent on the use of turmeric for wound healing which was upheld by the USPTO having received documentary evidence supporting the traditional use of turmeric in India.[1854] Also, the Opposition Division of the EPO overturned a patent for a pesticide from a neem tree extract following a legal challenge by the Indian government and conclusive evidence of the long prior use of neem to make pesticides in India.[1855] Nonetheless, other patents on the properties of neem still exist in the US and across Europe,[1856] thus, highlighting the weakness of India's strategy to curtail biopiracy.

While global progress regarding the development of NBSAPs, as well as domestic biodiversity laws to achieve the objectives of the Convention on Biological Diversity, is well documented, less is known about the nature and extent of national implementation in practice.[1857] The concern with this is that, much as the Convention is legally binding, it possesses the nature of soft law in that its wordings accentuate the importance of contextualised solutions.[1858] With the provision of general and highly qualified commitments, such as 'as appropriate' and 'as far as possible', the Convention on Biological Diversity leaves each contracting party with discretion as to the manner of implementation,[1859] including the scope to 'construct wholly different approaches'.[1860] For instance, while its provisions on conservation and sustainable use identify processes and strategies, they do not articulate 'rigorous inputs' or substantive outcomes.[1861] With the absence of any form of monitoring – except the one requirement to submit NBSAPs under Article 6 which hardly qualifies as monitoring – and a mechanism for ensuring consistency in interpretation of these terms, parties are allowed considerable space to determine what is 'appropriate' or 'possible'.[1862]

[1854] Ho, 'Biopiracy and Beyond' (n 1661) 433.
[1855] Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 136; see also Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n 1590) 50.
[1856] ibid.
[1857] Hagerman and Pelai (n 1776) 469-478.
[1858] Willmore (n 1771); see also Oguamanam, *International Law and Indigenous Knowledge* (n 69); Mrinalini Kochupillai, *Promoting Sustainable Innovations in Plant Varieties* (Springer, 2016) 29; and Stuart R Harrop and Diana J Pritchard, 'A Hard Instrument Goes Soft: The Implications of the Convention on Biological Diversity's Current Trajectory' (2011) 21 *Global Environmental Change* 474, 475.
[1859] Oguamanam, *International Law and Indigenous Knowledge* (n 69); see also Kochupillai (n 1858) 29; and Harrop and Pritchard (n 1858) 474, 475.
[1860] Willmore (n 1771).
[1861] ibid.
[1862] ibid.

In the same vein, given the non-existence of an independent judiciary or appellate body or dispute mechanism (similarly to the World Trade Organization's Dispute Settlement Understanding noted in Chapter two) to determine the reasonableness or appropriateness of specific approaches, or sanctions when parties default on their commitments, 'states are not effectively obliged to do anything specific'.[1863] The point is that while the provisions of the Convention may be enabling for those states willing to take action, it may equally permit others to take minimal 'appropriate and reasonable' action.[1864] Consequently, 'contextualisation conjoined with an open-textured Convention', may 'produce little practical change on the ground'.[1865] This result is even more likely when the myriad of well-known challenges facing the implementation of multilateral agreements, especially in developing and least-developed countries, is considered. For example, lack of institutional, financial and technological resources and capacity to implement; data and information deficiencies; national budgetary constraints;[1866] poor involvement of civil society; political instability; and lack of political will.[1867] In this connection, midway global assessments suggest that the Strategic Plan 2011-2020 and its Aichi Targets are unlikely to be realised.[1868] Thus, the success or failure to achieve the objectives of the Convention on Biological Diversity is strongly dependent on the social-political context at the national level.[1869]

Furthermore, a point of considerable debate under international law has been the intersection between the Convention on Biological Diversity and the TRIPS Agreement, as well as the implications of such intersection for achieving the objectives of the Convention. Developing and least-developed countries, including indigenous groups and biopiracy advocates, have contended that the TRIPS Agreement fosters biopiracy because it facilitates the utilisation of genetic resources and associated traditional knowledge for R&D without requiring prior informed consent and sharing of benefits arising from such

[1863] ibid; see also Kochupillai (n 1858) 29; and Ho, 'Biopiracy and Beyond' (n 1661) 481.
[1864] Willmore (n 1771).
[1865] ibid.
[1866] UNEP-WCMC, 'The State of Biodiversity in Africa: A Mid-Term Review of Progress Towards the Aichi Biodiversity Targets' (Cambridge, UK: UNEP-WCMC 2016).
[1867] Hagerman and Pelai (n 1776) 469-478.
[1868] ibid.
[1869] ibid.

utilisation. As mentioned in Chapter two, TRIPS is the most comprehensive multilateral agreement under the supervision of the World Trade Organization (WTO) which requires, *inter alia*, patent protection for inventions in all fields of technology that are new, involve an inventive step and are capable of industrial application.[1870] That said, it provides for notable exceptions to this general rule: WTO member states may exclude from patentability any invention they deem necessary in order to protect '*ordre public* or morality' and may equally exclude methods of medical diagnosis and treatment for humans and animals.[1871]

TRIPS, in addition, allows the exclusion from patentability plants, animals and essentially biological processes for the production of plants and animals, but not micro-organisms, non-biological and microbiological processes.[1872] Moreover, member states are required to protect plant varieties either through patents or an effective *sui generis* system or if preferable, a combination of both.[1873] In relation to this, because of the lack of specificity as to what system is most suitable for such protection, most WTO member states have promulgated national legislation based on the 1991 International Convention for the Protection of New Varieties of Plants (UPOV), which provides for Plant Breeders' Rights (PBRs).[1874] Plant Breeders' Rights is a type of intellectual property rights that protect plant varieties by giving breeders legal rights to the varieties they develop, which could otherwise be reproduced by other farmers or competing breeders.[1875] This is rationalised by the need to encourage private investment in the R&D of new and improved plant varieties that ensure better yields and adaptability to changing climatic conditions, thereby contributing to long-term food security.[1876] Under the UPOV, new plant varieties are granted protection if they meet the criteria of novelty, distinctness, uniformity and stability.[1877]

[1870] World Trade Organization, The Legal Texts: The Results of The Uruguay Round of Multilateral Trade Negotiations 320 (Cambridge University Press 1999), art 27(1).
[1871] ibid, arts 27(2) and 27(3)(a).
[1872] ibid, arts 27(3)(b).
[1873] ibid.
[1874] Michael Blakeney, 'Food Security: Patenting of Plant Varieties and Plant Breeding Methods' (2012) 63(3) *Journal of Experimental Botany* 1069-1074, 1069.
[1875] Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 112-154.
[1876] Graham Dutfield, 'Food, Biological Diversity and Intellectual Property: The Role of the International Union for the Protection of New Varieties of Plants (UPOV)' (2011) Quaker United Nations Office 3.
[1877] International Convention for the Protection of New Varieties of Plants 1991, art 19 stating that protection is granted for a period not shorter than 20 years from the date of the grant of the breeder's right.

At issue is the concern that by requiring protection for plant varieties and genetic materials such as micro-organisms, the TRIPS Agreement allows private property rights over materials regarding which the Convention on Biological Diversity affirms the rights of states to exercise sovereignty.[1878] More, while states are allowed to exclude plants, animals and biological processes for the production of plants and animals, there is some degree of flexibility inherent in these exceptions. As previously explained in Chapter two, the TRIPS Agreement merely sets a minimum standard for intellectual property protection to which every member must conform; thus, states wishing to exceed the minimum are not precluded from doing so.[1879] Likewise, there is no definition of what constitutes an 'invention' under TRIPS Article 27(1); the provision only requires protection for '*any inventions*, whether products or processes, in all fields of technology provided they are *new*, *involve an inventive step* and *are capable of industrial application*' – terms which the TRIPS Agreement also did not define.[1880] This considerable space has worked mostly to the benefit of patent applicants who have gained from broad interpretations of these terms in a manner that lowers the threshold of patentability, particularly in developed countries, to award erroneous patents based on genetic resources and associated traditional knowledge (as demonstrated earlier).[1881] Adding to this possibility, TRIPS neither protects nor even explicitly mentions traditional knowledge.[1882] Thus, to the extent that the Agreement allows protection for plant varieties, genetic materials and associated traditional knowledge without recognising the desirability for prior informed consent and fair and equitable sharing of benefits, developing and least-developed countries argue that TRIPS is incompatible with the Convention on Biological Diversity and impedes the realisation of its objectives.[1883]

For trees and vines, the said period shall not be shorter than 25 years from the said date; see also Blakeney, 'Food Security: Patenting of Plant Varieties and Plant Breeding Methods' (n 1874) 1069; see also Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 112-154.

[1878] Waelde et al. (n 1684) 387; see also Camena Guneratne, *Genetic Resources, Equity and International Law* (Edward Elgar Publishing, 2012) 185; and Bernard O'Connor, *The Law of Geographical Indications* (Cameron May 2004) 382.

[1879] Guneratne (n 1878) 175-176.

[1880] Ho, Access to Medicines in the Global Economy (n 222) 63-65.

[1881] Guneratne (n 1878) 176, 182-184.

[1882] O'Connor, *The Law of Geographical Indications* (n 1878) 380; see also Ebermann (n 977) 61.

[1883] Waelde et al. (n 1684) 387; see also Guneratne (n 1878); and O'Connor, *The Law of Geographical Indications* (n 1878) 382.

To bring TRIPS in line with the objectives of the Convention, a group of developing countries, i.e. Bolivia, Brazil, Colombia, Cuba, India and Pakistan proposed an amendment to the TRIPS Agreement to include Article 29*bis* to provide that applicants for patents relating to genetic materials and associated traditional knowledge must: (a) disclose the source and country of origin of the genetic material and associated traditional knowledge used in the claimed invention; (b) disclose evidence of prior informed consent; and (c) disclose evidence of a benefit-sharing agreement.[1884] Underlying these amendments was the desire to ensure more transparency in the use of genetic resources, and responsibility to share benefits arising out of such use.[1885] If entrenched in the TRIPS Agreement, the disclosure requirement would minimise the grant of erroneous patents[1886] since they would form additional requirements for assessing the patentability of biotechnological inventions.[1887] This proposal provoked an impassioned debate in the TRIPS Council, the body responsible for the administration of the Agreement,[1888] within the context of the review of Article 27(3)(b).

Arguments in this debate were principally divided along economic lines, with developed countries led by the US strongly opposing the idea of any amendments because, in their view, TRIPS did not conflict with the Convention on Biological Diversity.[1889] According to the US, that TRIPS does not cover misappropriation of genetic resources and associated traditional knowledge makes clear that such issue falls outside its scope, and therefore rightly belongs to a separate regulatory system.[1890] In its opinion, contracts between states regulated by national laws on access and benefit-sharing would best address issues of

[1884] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communications from Bolivia, Brazil, Columbia, Cuba, India and Pakistan: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge' (IP/C/W/459, 2005).
[1885] Jonathan Carr, 'Agreements that Divide: TRIPS vs CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications' (2008) 18 *Journal of Transnational Law & Policy* 131,141.
[1886] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communications from Bolivia, Brazil, Columbia, Cuba, India and Pakistan' (n 1884) para 6.
[1887] ibid para 7.
[1888] 'Council of TRIPS' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm> accessed 15 May 2016.
[1889] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communication from the United States: Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement' (IP/C/W/257, 2001).
[1890] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communication from the United States: Article 27(3)(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore' (IP/C/W/469, 2006) para 4.

misappropriation, prior informed consent and sharing of benefits rather than disclosure requirement, which may disrupt 'the careful balance created by the patent system to promote innovation'.[1891] As for the EU (formerly 'European Communities and their member states'), while acknowledging that the concerns voiced by developing and least-developed members within the context of the review of Article 27(3)(b) merited proper consideration, it was of the view that the amendment was not a vehicle capable of producing definitive solutions to all the issues raised.[1892] To date, nothing concrete has resulted from this debate, and the TRIPS Agreement is yet to undergo any amendment to include the disclosure requirement.[1893] (More reflection on this later.)

Significantly, despite the strong disagreement between both sides in this debate, they seem to have agreed on one issue: that there are cases where it would be impossible for states to enforce the access and benefit-sharing requirements of the Convention on Biological Diversity. Part of the argument advanced by developing and least-developed countries was that a nation-based contract system was not sufficient to deal with illegal bioprospecting, misappropriation, and erroneous patents;[1894] they insisted that the ideal system to combat these problems was one that created an international obligation and ensured international enforcement.[1895] This was necessary to cover situations where genetic resources are no longer within the jurisdiction of the state, or in cases of states with overlapping resources, or where corporations apply for patents based on genetic resources and associated traditional knowledge abroad.[1896]

On the part of developed countries, the US observed that origin or source of some genetic materials might be difficult to trace, given the existence of a world market for many

[1891] ibid paras 5, 7, 35 and 36.
[1892] Council for Trade-Related Aspects of Intellectual Property Rights, 'Review of the Provisions of Article 27(3)(b) of the TRIPS Agreement: Communication by the European Communities and their Member States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement' (3 April 2001).
[1893] Daniel Gervais, 'Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach' (2005) *Michigan State Law Review* 137, 139.
[1894] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communications from Bolivia, Brazil, Columbia, Cuba, India and Pakistan' (n 1884) para 4.
[1895] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communications from Bolivia, Brazil, Columbia, Cuba, India and Pakistan' (n 1884) para 10.
[1896] ibid.

biological resources for purposes of industrial processing.[1897] In this regard, it suggested improvement upon the existing post-grant opposition procedure and re-examination practices, as well as the general requirement that applicants disclose all information material to patentability.[1898] Thus, although they did not agree on a solution, it would appear that both sides, wittingly or unwittingly, conceded that in cases where genetic resources are no longer within the jurisdiction of the state; or where they have lost the link to their place of origin or source; or where genetic resources or associated traditional knowledge are transboundary; or where patent applications based on genetic resources and traditional knowledge have been filed abroad, it would be impracticable to enforce access and benefit-sharing requirements.

These problems partly stem from the absence of an international enforcement mechanism under the Convention on Biological Diversity. As previously indicated, the Convention requires that the implementation of its objectives takes place at the national level. That being so, even though it subjects genetic resources and associated traditional knowledge to the national access and benefit-sharing laws of a country, this does not preclude international companies or paradoxically, national companies from seeking patent protection elsewhere.[1899] A case that illustrates this point is that of India and patents on the properties of the neem tree: recall that despite requiring through national law that all inventors obtain consent before applying for intellectual property rights where the invention is based on any biological resource obtained in India,[1900] W. R. Grace – a multinational chemical corporation – was able to obtain a European patent for a pesticide derived from neem extract.[1901] Even after the subsequent revocation of this patent, there are still existing neem-related patents held by Indian and foreign companies in the US and Europe.[1902] On these grounds, it would appear that an effective means of enforcing

[1897] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communication from the United States' (n 1890) para 13.
[1898] ibid para 29.
[1899] Patricia Covarrubia, 'Genetic Resources and the Debate Over Legacy: Chilean Constitutional Reform' (2015) *European Intellectual Property Review* 2; see also Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 136.
[1900] Biodiversity Act 2002, s 6.
[1901] Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (n 1590) 50.
[1902] Cullet et al., 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' (n 1662) 136; see also Ho, 'Biopiracy and Beyond' (n 1661) 439; see also Marianne Beisheim, Ernst U von Weizsa¨cker, Oran R Young, Matthias Finger, *Limits to Privatization: How to Avoid Too Much of a Good Thing: A Report to the Club of Rome* (Earthscan 2012) 53; Linda Bullard, 'Freeing the Free Trade: A Briefing Paper on the Neem Biopiracy Case' (2005) NW Resistance Against Genetic Engineering

access and benefit-sharing requirements with regard to genetic resources and associated traditional knowledge is not through a case-by-case challenge, but rather an integrated approach.[1903] This substantiates the importance of an international enforcement mechanism as proposed by developing and least-developed countries.

These problems are also rooted in the fact that the Convention on Biological Diversity Article 15 (access to genetic resources) envisages bilateral access and benefit-sharing situations. In other words, it recognises a single resource provider as being entitled to receive all the benefits.[1904] Because it is possible to find that some genetic resources are located in more than one country or region, or that particular traditional knowledge is held by different indigenous groups located in more than one country, implementing Article 15 in these situations could be challenging.[1905] As will be seen later, it could potentially lead to a 'race to the bottom' which provides corporations with the lowest compensation, thereby excluding other providers from sharing the same resource or knowledge.[1906] Regarding this, it has been suggested that a multilateral access and benefit-sharing approach may be a preferable option in a transboundary situation.[1907]

Again, while the Convention on Biological Diversity asserts state sovereignty over natural resources and seeks to enforce distributive justice, it does not address situations where genetic resources have lost their link to the place of origin or source.[1908] As correctly noted by the US, the origin or source of some genetic resources may be difficult to trace, given that they have become widely available and used for industrial processes[1909] or agribusiness.[1910] Where such a link cannot be established or uncovered, it would be impracticable to enforce the sharing of benefits derived from the use of such

<http://nwrage.org/content/freeing-free-tree-briefing-paper-neem-biopiracy-case> accessed 14 August 2016.

[1903] Kruger (n 552) 169, 175.

[1904] Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch, Natasha Ali and China Williams, *An Explanatory Guide to The Nagoya Protocol on Access and Benefit-Sharing* (IUCN, 2012).

[1905] ibid.

[1906] ibid; see also Gaia Foundation, Genetic Resources Action International, 'Biodiversity for Sale: Dismantling the Hype About Benefit-sharing' (2000) 4 Global Trade and Biodiversity in Conflict.

[1907] Greiber et al. (n 1904).

[1908] Covarrubia, 'Genetic Resources and the Debate Over Legacy' (n 1899) 2.

[1909] Council for Trade-Related Aspects of Intellectual Property Rights, 'Communication from the United States' (n 1890) para 13.

[1910] Covarrubia, 'Genetic Resources and the Debate Over Legacy' (n 1899) 2.

genetic resources. Consider the case of rosy periwinkle (*Catharanthus roseus*): in the late 1950s, a US pharmaceutical company, Eli Lilly, isolated, tested and marketed two cancer-fighting drugs – vincristine and vinblastine – from rosy periwinkle which yielded massive profits estimated at US$100 million.[1911] However, evidence suggests that Eli Lilly shared no part of the benefits derived from using this plant with the country of origin or source.[1912] This was because the origin of the plant was largely contentious. By 1957, French explorers had introduced rosy periwinkle around the globe.[1913] The plant was grown mostly in the Tropics where it was used by many indigenous peoples for treating various illnesses including sore throats, diabetes, dysentery and pleurisy.[1914]

As evidence of its wide availability, Eli Lilly collected the first specimen for R&D in India; whereas Robert Noble, a Canadian scientist whose independent research on rosy periwinkle contributed enormously to subsequent developments, obtained his first specimen from a physician in Jamaica.[1915] Nevertheless, commentators agree that rosy periwinkle originated from Madagascar.[1916] They confirm as a matter of fact that the plant was used for centuries as a treatment for diabetes by traditional healers of the Malagasy group, an Austronesian [1917] ethnic group native to the island and country of Madagascar.[1918] That it became available across international borders through the French explorers was possible due to the common heritage regime of the 1950s (as previously mentioned) which treated biological resources as part of the public domain and free for everyone.[1919] Because the plant had naturalised in other parts of the world, it became

[1911] Michael F Brown, *Who Owns Native Culture?* (Harvard University Press, 2003) 135-138; see also Michael Hassemer, 'Genetic Resources' in von Lewinski (ed) (n 1678).
[1912] Paul Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy' (2015) 17(1) *San Diego International Law Journal*, 9-10; see also Venbrux (n 1135) 8.
[1913] Brown (n 1911).
[1914] ibid.
[1915] ibid 135-138.
[1916] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (1912) 9-10; see also James A R Nafziger, Robert K Patterson and Alison D Renteln, *Cultural Law: International, Comparative, and Indigenous* (Cambridge University Press, 2014) 624; Smithsonian Institution, 'A Traditional Brew Leads to Cancer Cure'. *Migrations in History: Medical Technology*. Smithsonian Institution; Brown (n 1911) 135-138; and Hassemer (n 1911).
[1917] *The Oxford English Dictionary*, 'Austronesian: relating to or denoting a family of languages spoken in an area extending from Madagascar in the west to the Pacific islands in the east' (Oxford University Press 1884).
[1918] Brown (n 1911) 135-138; see also James Odek, 'Biopiracy: Creating Proprietary Rights in Plant Genetic Resources' (1994) 2 *Journal of Intellectual Property Law* 141, 143.
[1919] Hassemer (n 1911).

difficult to trace its origin (to Madagascar) for purposes of identifying the country entitled to partake in benefit-sharing.[1920] Thus, it can be problematic to untangle property rights claims particularly in situations where resources have become available to all, not to mention, enforce benefit-sharing obligations.

It was to remedy these deficiencies, and primarily, to clarify the uncertainties regarding the scope of access and benefit-sharing which the Convention on Biological Diversity failed to elaborate upon, that the COP commenced the process that culminated in the adoption of the 2002 Bonn Guidelines (mentioned earlier).[1921] In addition to assisting governments to develop and draft legislative, administrative and policy measures on access and benefit-sharing and contracts and other arrangements under mutually agreed terms,[1922] the Guidelines were adopted to inform the practices of users and providers of genetic resources in access and benefit-sharing arrangements; improve capacity-building in developing and least-developed countries; promote transfer of technology; and engender the formulation of laws that protect customary laws of indigenous communities.[1923] Notably, the Bonn Guidelines urged countries to develop measures to encourage the disclosure of the country of origin of genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights.[1924]

However, irrespective of the useful provisions they contained, the voluntary character of the Bonn Guidelines rendered it ineffective, particularly in the case of states that lacked the political will to take any reasonable steps.[1925] Similarly to the Convention, the Guidelines' contract-based solutions were mostly national strategies, and for that reason inadequate for addressing certain problems with an international dimension.[1926] This situation re-emphasised the need for a legally binding international framework that levied specific commitments on states with the aim of realising the objectives of the Convention

[1920] Brown (n 1911) 135-138.
[1921] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (n 1912) 21.
[1922] Secretariat to the Convention on Biological Diversity, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation* (Montreal: Secretariat to the Convention on Biological Diversity 2002) 1.
[1923] ibid 11(g).
[1924] ibid 16(d)(ii).
[1925] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (n 1912) 26.
[1926] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (n 1912) 26.

on Biological Diversity.[1927] After long and winding negotiations, parties to the Convention adopted the Nagoya Protocol at the Tenth Meeting of the COP held in Nagoya, Japan on 29 October 2010, which entered into force on 12 October 2014 and is comprised of 104 parties, including the EU.[1928] In the main, its objective is the fair and equitable sharing of benefits arising from the utilisation of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.[1929] As previously mentioned, it is a legally binding agreement attached to the Convention on Biological Diversity that aims to establish legal certainty and transparency, as well as more predictable conditions for operating the access and benefit-sharing mechanism.[1930]

6.4.2. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2010

While the former United Nations Secretary-General, Mr Ban Ki-moon, heralded the adoption of the Nagoya Protocol as epoch-making in that it 'provides an innovative approach to conserving and protecting the world's rapidly diminishing living resources, while providing benefits to all, in particular, local communities in developing countries',[1931] many developing, and least-developed countries held a contrary view. For instance, Bolivian delegates, during the closing plenary session of the Tenth Meeting of the COP in 2010, remarked that the Protocol did not fully incorporate the views of many countries.[1932] Venezuela was more assertive: it claimed that the Protocol had 'suffered departures from its initial objectives', and in no way reflected 'the fundamental principles' and 'spirit' in which it was conceived.[1933] As opposed to preventing biopiracy, Venezuela noted that the Nagoya Protocol showed 'a marked tendency towards

[1927] ibid.
[1928] 'About the Nagoya Protocol' (n 704).
[1929] ibid.
[1930] ibid.
[1931] United Nations Secretary-General, 'Statement Attributable to the Spokesperson for the Secretary-General on the Adoption of a Protocol to the Convention on Biological Diversity' (*United Nations*, 1 November 2010) < https://www.un.org/sg/en/content/sg/statement/2010-11-01/statement-attributable-spokesperson-secretary-general-adoption> accessed 16 March 2018.
[1932] International Institute of Sustainable Development, 'Summary of the Tenth Conference of the Parties to the Convention on Biodiversity' (2010) 9 *Earth Negotiations Bulletin*; see also Siswandi (n 705).
[1933] International Institute of Sustainable Development (n 1932); see also Siswandi (n 705); and Secretariat of the Convention on Biological Diversity, 'Report of the Tenth Meeting of the Conference of Parties to the Convention on Biological Diversity' (UNEP/CBD/COP/10/27 98, 2010).

commercialization of [biodiversity] and the conversion of nature into a market product'.[1934] This was the hallmark of the environment that surrounded the negotiation and eventual adoption of the Nagoya Protocol: conflict, tension, pessimism and 'political undercurrents'.[1935] As discussed in Chapter two, this environment was engendered by first, the proliferation of international instruments and fora relating to genetic resources since the adoption of the Convention on Biological Diversity; and secondly, the existence of conflicting interests between multiple stakeholders in the context of genetic resources utilisation. [1936] Ultimately, these factors resulted in complicated and protracted negotiations, intermittently collapsing, until a compromise was reached nearly 10 years later.[1937]

In respect of the first issue, questions regarding the interaction between obligations of parties to the Convention under the Protocol,[1938] and their obligations under existing international instruments that deal with legal issues relating to the utilisation of genetic resources, proved to be highly contentious during negotiations. For example, it was important to some countries that the Protocol did not impede the implementation of existing mechanisms related to genetic resources, such as the Multilateral System of Access and Benefit-sharing under the FAO Plants Treaty; more so, as the Protocol was likely to affect the status of genetic resources, particularly those that were not covered by the Multilateral System.[1939] Also, as noted in Chapter two, the interface between the Nagoya Protocol and the WTO and its TRIPS Agreement resulted in moments of heated debates and conflict. In particular, the question of whether or not the Protocol should require inventors to disclose all information regarding the use of genetic resources and associated traditional knowledge in their inventions led to the occasional meltdown of negotiations.[1940] Eventually, the proposal to include the disclosure requirement in the Nagoya Protocol did not survive the negotiations.[1941]

[1934] Secretariat of the Convention on Biological Diversity, 'Report of the Tenth Meeting of the Conference of Parties' (n 1933); see also Siswandi (n 705).
[1935] Siswandi (n 705).
[1936] ibid.
[1937] Kohsaka (n 702) 56.
[1938] Nagoya Protocol 2010, 1st and 2nd preambular citations, noting that parties to the Protocol are parties to the Convention.
[1939] Siswandi (n 705).
[1940] Greiber et al. (n 1904).
[1941] ibid.

Regarding the second issue, the participation of multiple stakeholders with competing interests meant that reaching compromises at various times was difficult. On the one hand, there were the developing countries, indigenous and local communities and non-governmental organisations (NGOs) whose standing in relation to the Nagoya Protocol was to ensure that it was significant in stopping biopiracy, promoting effective benefit-sharing and guaranteeing the sovereign right of states, as well as the indigenous right to self-determination.[1942] On the other hand, the developed countries, biotechnology and pharmaceutical industries and researchers needed to ensure that whatever legal measures were taken under the Protocol would not hinder access to genetic resources for R&D and 'add great uncertainty into the intellectual property system'.[1943] Needless to say, the US remained uninvolved with anything relating to the Convention on Biological Diversity.[1944]

Owing to these factors, the final agreement between these conflicting groups produced soft and ambiguous provisions in the Nagoya Protocol. For instance, most provisions in the Protocol require parties to take 'appropriate, effective and proportionate' 'legislative, administrative or policy measures', or perform certain obligations if 'established in' or 'in accordance with' 'domestic legislation'.[1945] There is also the recurring use of 'as appropriate' and the requirement that certain actions be taken within 'a reasonable time'.[1946] Some other provisions merely obligate parties to 'take into consideration' or 'endeavour to support' specific measures or subject matters.[1947] In relation to the latter, it is considered that such provisions do not connote 'a meaningful commitment on anybody to do anything'.[1948] Thus, it has been argued that because the Nagoya Protocol lacks strong enforcement provisions, the realisation of its objectives would largely depend on

[1942] Siswandi (n 705); see also Schindel (n 716) 779-781.
[1943] Siswandi (n 705); see also Biotechnology Innovation Organization, 'Biological Diversity: Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity' (*Bio*, 14 October 2010) < https://www.bio.org/advocacy/letters/biological-diversity-draft-protocol-access-genetic-resources-and-fair-and-equitable> accessed 16 March 2018.
[1944] Siswandi (n 705).
[1945] Nagoya Protocol 2010, art 5, 6, 7.
[1946] ibid, art 6, 11, 15, 16, 17.
[1947] ibid, art 8, 10, 12.
[1948] Graham Dutfield, 'Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What's Left to Discuss?' in M David and D Halbert (eds), *THE SAGE HANDBOOK ON INTELLECTUAL PROPERTY* (Sage 2014) 9.

the formulation of national legislation, administrative or policy measures; and the effective cooperation among stakeholders that have significant interest in the utilisation of genetic resources and associated traditional knowledge[1949] – and this applies to the context of ensuring access to traditional medicine for realising the 2030 Agenda for Sustainable Development.

Nevertheless, the Protocol comprises some useful provisions that could serve as practical means to enforce compliance with access and benefit-sharing requirements, as well as prevent misappropriation of genetic resources and associated traditional knowledge. For example, Articles 15 and 16 of the Nagoya Protocol provide for a compliance mechanism. This measure was one of the very controversial issues in the meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS) which was mandated by the COP in 2004 to elaborate and negotiate an international regime on access and benefit-sharing.[1950] It was one of the core outcomes sought by developing and least-developed countries, indigenous peoples and NGOs, to lay the foundation for these countries to enforce stronger national legislation to curb biopiracy.[1951] That said, this mechanism was vigorously challenged by developed countries which pushed for a limited scope of the proposed compliance provision.[1952]

However, the mechanism survived negotiations and is embodied in Article 15 which obligates each party to take 'appropriate, effective and proportionate legislative, administrative or policy measures' to ensure that users within its jurisdiction have accessed genetic resources in accordance with prior informed consent, mutually agreed terms as required by domestic legislation or regulatory requirements of the other party;[1953] and Article 16 which requires each party to take similar measures to provide that users in its jurisdiction have complied with domestic laws in accessing traditional knowledge associated with genetic resources.[1954] To ensure compliance with mutually agreed terms, the Protocol encourages providers and users of genetic resources and associated

[1949] Siswandi (n 705).
[1950] Secretariat of the Convention on Biological Diversity, 'Working Group on Access & Benefit Sharing' (*Convention on Biological Diversity*) < https://www.cbd.int/abs/wgabs/> accessed 9 March 2018.
[1951] Siswandi (n 705).
[1952] ibid.
[1953] Nagoya Protocol 2010, art 15.
[1954] Nagoya Protocol 2010, art 16.

traditional knowledge to include dispute resolution provisions in mutually agreed terms, including jurisdiction, applicable law and options for alternative dispute resolution, such as mediation or arbitration.[1955] In furtherance of this, parties are required to establish means of seeking redress under their legal systems in case of disputes arising from mutually agreed terms, and to take effective measures regarding access to justice and the utilisation of mechanisms regarding mutual recognition and enforcement of foreign judgements and arbitral awards.[1956]

By imposing an obligation on states to ensure that genetic resources and associated traditional knowledge are accessed based on prior informed consent and mutually agreed terms, these provisions are valuable to cases of biopiracy with international dimensions.[1957] In practice, parties to whose jurisdictions a user of genetic resources and associated traditional knowledge has relocated after leaving the country of origin or source, are required to take appropriate steps to verify that relevant consent was obtained, and that mutually agreed terms were negotiated before access to such resources and knowledge as required by domestic legislation or regulatory requirements of the other party.[1958] Where there has been non-compliance, parties are obligated to take appropriate, effective and proportionate measures to address such violations based on cooperation with one another.[1959] This is crucial, particularly in cases where a user has moved to the user-country to avoid compliance with the laws of the provider-country or to evade liability for violation of domestic access and benefit-sharing legislation or regulatory requirements. [1960] Nevertheless, while noting the utility of these provisions, it is imperative to point out that their effectiveness will depend on the political will and capacity of each party to adopt the necessary measures, as they contain ambiguous language, such as 'appropriate, effective and proportionate'.

Furthermore, to support compliance, the Nagoya Protocol includes another significant provision that requires monitoring and enhancing transparency about the utilisation of

[1955] ibid, art 18(1).
[1956] ibid, art 18(2).
[1957] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (n 1912) 34.
[1958] ibid.
[1959] Nagoya Protocol 2010, art 15(2) -(3), 16(2) -(3).
[1960] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (n 1912) 34.

genetic resources.[1961] Parties are required to implement this obligation by adopting measures, such as designating one or more checkpoints and encouraging users and providers of genetic resources to include provisions, in mutually agreed terms, to share information on the implementation of their obligations, including through reporting requirements.[1962] The responsibility of the checkpoint is to collect or receive relevant information related to prior informed consent, source of the genetic resource, establishment of mutually agreed terms, and to the utilisation of genetic resources; and each party may require users of genetic resources to provide such information at a designated checkpoint, as well as adopt measures to address situations of non-compliance.[1963] Such information obtained by the checkpoints would in turn be transferred to national authorities of the party providing prior informed consent, including the Access and Benefit-Sharing Clearing-House[1964] – which is established by the Protocol under Article 14 to serve as a means of sharing information made available by each party regarding domestic measures on access and benefit-sharing; certificates showing decision to grant prior informed consent and establish mutually agreed terms; and national focal points and competent authority.[1965] The tendering of an internationally recognised certificate of compliance to the designated checkpoint by a user would be sufficient evidence to prove that the genetic resource, which it covers, has been accessed in compliance with prior informed consent and mutually agreed terms.[1966]

In addition, where genetic resources and associated traditional knowledge occur in transboundary situations or when it is impracticable to grant or obtain prior informed consent, the Nagoya Protocol in Article 10 calls on parties to consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from their utilisation.[1967] The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism are to be used to support the conservation of biodiversity and the

[1961] Nagoya Protocol 2010, art 17.
[1962] ibid, art 17 (a), (b).
[1963] ibid, art 17 (a) (i), (ii).
[1964] ibid, art 17 (a) (iii).
[1965] ibid, art 14.
[1966] ibid, art 17(3).
[1967] ibid, art 10.

sustainable use of its components.[1968] Also, in cases where genetic resources and associated traditional knowledge occur in transboundary situations, Article 11 calls on those parties with significant interests in such resources and traditional knowledge to endeavour to cooperate with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.[1969]

Though these features of the Nagoya Protocol provide international obligations and enforcement measures (called for by developing and least-developed countries within the context of the review of TRIPS Article 27(3)(b)) to address biopiracy, thereby compensating for some of the deficiencies of the Convention on Biological Diversity, the use of recurring discretionary and ambiguous language remains a challenge to their effectiveness, particularly with regard to stimulating parties to take action.[1970] For example, in spite of the provision that obligates parties to 'consider' the need for a global multilateral mechanism, the problem of benefit-sharing in transboundary situations and in cases where it is impossible to grant or obtain prior informed consent would persist until such time that a workable mechanism is in place, supposing it is politically possible and practicable in view of the disruptions that have characterised such negotiations owing to the political undercurrents between developing and developed countries[1971] – a similar situation envisaged in respect of the proposed convention on drug R&D as discussed in Chapter two. Besides, it is noticeable that while the Nagoya Protocol provides for monitoring the utilisation of genetic resources, there is no corresponding provision for traditional knowledge associated with genetic resources.[1972] Moreover, the responsibilities of the designated checkpoints do not include acting as mandatory checkpoints for patent applications – the purpose for which the disclosure requirement is needed.[1973] These gaps create the opportunity for further misappropriations of genetic resources and associated traditional knowledge.

[1968] Nagoya Protocol 2010, art 10.
[1969] ibid, art 11.
[1970] Siswandi (n 705).
[1971] Graham Dutfield, 'Transboundary Resources, Consent and Customary Law' (2013) 9/2 *Law, Environmental and Development Journal* 259, 260.
[1972] Konstantia Koutouki, 'The Nagoya Protocol: Status of the Indigenous and Local Communities' (2011) Center for International Sustainable Development Law 14.
[1973] Siswandi (n 705).

On the positive side, parties have begun to take measures in user-countries to ensure compliance with domestic access and benefit-sharing legislation or regulatory requirements in provider-countries. In 2014, the EU adopted Regulation No. 511/2014 which entered into force on 9 June 2014, but its provisions became applicable from 12 October 2015.[1974] This regulation places a significant burden on users within the EU to exercise 'due diligence' to ensure that genetic resources and associated traditional knowledge have been accessed in accordance with the access and benefit-sharing requirements in the provider-country.[1975] The regulation requires researchers of genetic resources and associated traditional knowledge to obtain, keep, and transfer to subsequent users of the genetic resources and traditional knowledge, an internationally recognised certificate of compliance, including information on the content of mutually agreed terms relevant to subsequent users.[1976] In the event that no internationally recognised certificate is available, researchers shall transfer to subsequent users information and relevant documents that contain the date and place of accessing genetic resources and associated traditional knowledge, their description, their source, the existence of any rights and obligations relating to them, including rights and obligations regarding subsequent applications and commercialisation, access permits, mutually agreed terms, and benefit-sharing.[1977]

In order to monitor user compliance, recipients of research funding or researchers seeking marketing approval for a product that involves genetic resources and associated traditional knowledge (e.g. pharmaceuticals) must file a 'compliance declaration' to the appropriate authority prior to seeking such approval.[1978] Also, each EU member state is required to establish checkpoints to monitor compliance and impose fines for non-

[1974] EU Environment, 'Sharing Nature's Genetic Resources – ABS' (*European Commission*, 11 December 2015) <http://extranet.novacomm-europa.eu/environment/nature/biodiversity/international/abs/index_en.htm> accessed 30 January 2016.
[1975] Regulation (EU) No. 511/2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, art 4(1).
[1976] ibid, art 4(3)(a).
[1977] ibid, art 4(3)(b).
[1978] Bruce Manheim, 'Contributors: Freedom to Utilize Genetic Resources? The Nagoya Protocol Two Years Later' (*Intellectual Property Watch*, 24 October 2016) < https://www.ip-watch.org/2016/10/24/freedom-utilize-genetic-resources-nagoya-protocol-two-years-later/> accessed 31 March 2017; see also Covington, 'Global Enforcement of the Nagoya Protocol in the Life Sciences Industries' (*Covington Alert*, 7 December 2016).

compliance.[1979] Presently, corporations have reported audits taking place in the UK and the Netherlands, which have enacted a Nagoya Protocol compliance regulation to implement EU Regulation No. 511/2014.[1980] Nonetheless, the plant breeding industry has expressed the concern that the due diligence requirement is in conflict with the 'open access' principle of the 1991 International Convention for the Protection of New Varieties of Plants (UPOV) under which protected varieties can be freely exploited by subsequent breeders without any obligation to the first breeder.[1981] This was the contention of the Dutch and German plant breeders when they challenged the validity of the regulation before the EU General Court.[1982] The Court rejected this challenge without considering the merits because an objection was raised regarding the standing of the industry to bring this claim.[1983] Notwithstanding, the development of the EU Regulation is a step in the right direction to ensure compliance with domestic access and benefit-sharing legislation or regulatory requirements in provider-countries.

On another front, the Nagoya Protocol contains compromise provisions on access and benefit-sharing aimed at establishing cooperation between developed countries, which are considered primarily as users; and developing and least-developed countries, including indigenous and local communities found within their territories, which are mainly providers.[1984] Article 8 provides for special considerations when parties are developing and implementing their access and benefit-sharing legislation or regulatory requirements.[1985] These considerations include: (a) creating conditions to promote research which contributes to the conservation and sustainable use of biodiversity,

[1979] ibid.
[1980] Manheim (n 1978); see also Covington (n 1978).
[1981] Adrian Toutoungi, 'EU General Courts Rejects Plant Breeders' Challenge to Implementation in EU of Nagoya Protocol Access to Genetic Resources and Benefit Sharing' (*Evershed*s, 3 September 2015) <http://www.eversheds.com/global/en/what/articles/index.page?ArticleID=en/Healthcare/EU_General_Court_rejects_plant_breeders_challenge> accessed 2 February 2016; see also Darren Smyth, 'German Plant Breeders Challenge EU Nagoya Regulation – Allege Threatens Biodiversity' (The *IPKat*, 6 August 2014) <http://ipkitten.blogspot.co.uk/2014/08/german-plant-breeders-challenge-eu.html> accessed 21 August 2016.
[1982] ibid.
[1983] ibid.
[1984] Hartmut Meyer, Joji Carino, Chee Yoke Ling, Michael Frein, Francois Meyenborg and Christine von Weizsäcker, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation* (Berne Declaration, Bread for the World, Ecoropa, Tebtebba and Third World Network, 2013) < http://www.ecoropa.info/files/NagoyaProtocolonAccesscomplete.pdf> accessed 12 May 2017.
[1985] Nagoya Protocol 2010, art 8.

including through access for non-commercial research purposes; (b) considering the need for expeditious access and benefit-sharing in cases of present or imminent emergencies that threaten or damage human, animal or plant health as determined nationally or internationally; and (c) considering the importance of genetic resources for food and agriculture and their special role for food and security.[1986] These provisions were aimed at addressing concerns that access and benefit-sharing requirements may impede non-commercial scientific research, interfere with public health efforts as regards developing much needed pharmaceutical products, and not take into account the importance of genetic resources for food security, and mitigation and adaptation to climate change.[1987]

In addition, while reaffirming national sovereignty over natural resources, the Protocol asserts the authority of states to regulate access to genetic resources and require prior informed consent as a prerequisite for access.[1988] Following access, the Protocol in Article 5(1) requires benefits arising from the utilisation of genetic resources as well as 'subsequent applications and commercialisation' to be shared with the state providing such resources based upon mutually agreed terms, thereby reinforcing the legal obligation provided under Article 15 of the Convention on Biological Diversity.[1989] Further, a significant development under the regime of the Convention, and from an international human rights perspective, is the legally binding provision in the Nagoya Protocol Article 6(2) relating to the prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources 'held' by them.[1990] Also, benefits arising from the utilisation of genetic resources that are held by them are to be shared in a fair and equitable way with the communities concerned, based on mutually agreed terms under Article 5(2).[1991] As mentioned earlier, while it can be argued that the Convention on Biological Diversity does not reflect the international consensus on the rights of the indigenous peoples to own, manage and control natural resources found on traditionally owned lands and territories, these provisions of the Protocol seem to bring it in harmony with the internationally recognised rights of indigenous peoples.[1992]

[1986] ibid.
[1987] Nagoya Protocol 2010, 16th preambular citation.
[1988] ibid, art 6(1).
[1989] ibid, art 5(1).
[1990] ibid, art 6(2).
[1991] ibid, art 5(2).
[1992] UNDRIP 2007, art 26.

However, communities' exercise of prior informed consent and benefit-sharing arising from the utilisation of genetic resources is heavily qualified in the Nagoya Protocol by reference to 'in accordance with domestic law' and 'where they have the established right to grant access'.[1993] As previously noted, this presupposes that unless such right has been established in accordance with domestic law, indigenous and local communities are not entitled to any right to prior informed consent and benefit-sharing. Notwithstanding, in the light of international human rights standards, a broad interpretation has been suggested for states' obligation to take measures to ensure communities' right to prior informed consent and benefit-sharing 'in accordance with domestic law' and 'where they have the established rights', to imply an obligation to recognise the rights of communities in national legislation, based on good-faith consultation, taking into account their customary laws, and enacting domestic measures to ensure community participation in access and benefit-sharing.[1994]

Also, it is noticeable that, unlike the case of state benefit-sharing under Article 5(1), the Protocol in Article 5(2) does not require sharing benefits arising from 'subsequent applications and commercialisation' of genetic resources held by indigenous and local communities. This would effectively exclude indigenous and local communities from partaking in benefits from subsequent applications and commercialisation related to genetic resources held by them.[1995] Instead of a literal interpretation, reading 'Article 5(2) as addressing a sub-set of benefit-sharing under Article 5(1) would support an understanding of benefit-sharing from subsequent applications and commercialisation both for genetic resources held by states and for those held by indigenous and local communities'; thus, conforming with international human rights standards.[1996]

More, the Protocol breaks new ground in that it exceeds the text of the Convention on Biological Diversity to require states to develop domestic measures on access and benefit-sharing for the use of traditional knowledge 'associated with genetic resources'.[1997] As

[1993] Nagoya Protocol 2010, art 6(2), 5(2).
[1994] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 120-127.
[1995] ibid.
[1996] ibid.
[1997] Nagoya Protocol 2010, art 7, 5(5).

already noted, this is the first of its kind as the Nagoya Protocol imposes legally binding obligations on states to adopt measures that reward indigenous and local communities for creating and preserving traditional knowledge associated with genetic resources, and for their contribution to scientific advancement which has benefitted global health.[1998] In Article 7, states are obligated to take measures to ensure that traditional knowledge 'held' by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these communities, and that mutually agreed terms have been established.[1999] States shall also, under Article 5(5), take measures in order that the benefits arising from its utilisation are shared in a fair and equitable way with indigenous and local communities holding such knowledge.[2000] Nonetheless, while the obligation under Article 5(5) is not qualified by reference to 'in accordance with domestic law', the right to community prior informed consent in Article 7 is. Even so, 'in accordance with domestic law', as previously stated, should be interpreted to imply an obligation on the part of states to take into account relevant communities' customary laws while implementing measures in national legislation, as well as respect related international human rights obligations.[2001]

Again, the language of Article 7 is further qualified by the inclusion of 'held'. The obligation to take measures to ensure prior informed consent and that mutually agreed terms have been established is restricted to traditional knowledge 'held' by indigenous and local communities.[2002] This suggests that the Protocol does not provide prior informed consent for access to traditional knowledge that is, as for instance, documented in traditional knowledge registries, databases or digital libraries, if it is 'held' by a state or other entity.[2003] An illustration of this is India's Traditional Knowledge Digital Library (TKDL) established in 2001 under the auspices of the Council of Scientific and Industrial Research (CSIR) and Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), which documents existing literature related to Indian traditional medical knowledge systems, including Ayurveda, Unani, Siddha and Yoga.[2004]

[1998] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 127.
[1999] Nagoya Protocol 2010, art 7.
[2000] ibid, art 5(5).
[2001] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 176.
[2002] ibid 175.
[2003] ibid 129-130.
[2004] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).

What is more, the Protocol does not address the situation discussed in Chapter five where traditional knowledge is still held by indigenous and local communities, yet publicly available in the form of treatment guidelines or brochures for traditional medicine preparations.[2005] In this light, developing and least-developed countries would be well advised to clarify these issues in their national legislation on access and benefit-sharing.[2006] Particularly, in order to ensure access to quality, safe and effective traditional medicine for sustainable development in a manner that conforms with international human rights standards, national legislation should require prior informed consent and benefit-sharing derived from the utilisation of traditional knowledge associated with genetic resources held by indigenous and local communities, but also publicly available.

In connection with this, it should be understood that it is the acts of 'utilisation of traditional knowledge associated with genetic resources' and the 'utilisation of genetic resources' that trigger the obligation of benefit-sharing under the Nagoya Protocol. In the context of the Protocol, 'utilisation of genetic resources' means 'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'.[2007] In practice, this imposes an obligation of benefit-sharing on the biotechnology and pharmaceutical industries, especially in cases of misappropriation. However, the Protocol leaves the 'utilisation of traditional knowledge associated with genetic resources' undefined, and this creates interpretational difficulties, being that it also requires sharing of benefits when traditional knowledge is utilised.[2008] That said, the same definition as 'utilisation of genetic resources' has been suggested for 'utilisation of traditional knowledge associated with genetic resources' since it provides the 'lead information' for the use of genetic resources in R&D.[2009] In other words, utilisation of traditional knowledge associated with genetic resources should be understood to connote the use of traditional knowledge to conduct R&D on genetic resources, as well as through the application of biotechnology.

[2005] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 175.
[2006] ibid 130.
[2007] Nagoya Protocol 2010, art 2(c).
[2008] Elisa Morgera and Miranda Geelhoed, 'Consultancy on the Notion of 'Utilisation' in the Nagoya Protocol and the EU ABS Regulation for the Upstream Actors' (2016) *Luxembourg* 6.
[2009] ibid.

Irrespective of the presence of the conjunction '*and*', 'research *and* development' should not be given a cumulative interpretation for the occurrence of utilisation of genetic resources and associated traditional knowledge.[2010] While '*and*' gives weight to that interpretation, and indeed the scientific community has in the past,[2011] it has been argued that such restrictive interpretation may be incompatible with the ordinary denotation of these terms as '*two intimately related processes* by which new products and new forms of old products are brought into being through technological innovation'.[2012] What is more, a 'systematic interpretation' and 'analysis' of the provisions of the Nagoya Protocol[2013] and its preparatory and explanatory documents favour the interpretation of R&D as alternative requirements for utilisation to occur; so that, research with or without a development objective falls within the subject matter scope of the Nagoya Protocol.[2014]

Also, the Protocol in Article 6(3)(a) calls on each party requiring prior informed consent to take the necessary legislative, administrative or policy measures, as appropriate, to clarify its domestic access and benefit-sharing legislation or legislative requirements.[2015] This is important because, as noted previously, early attempts to implement the access and benefit-sharing provisions of the Convention on Biological Diversity uncovered a lack of conceptual clarity.[2016] Similarly, there is a notable lack of clarity regarding the meaning and requirements of the concepts of 'prior informed consent'[2017] and 'fair and equitable benefit-sharing' in international law.[2018] On this basis, the following sections

[2010] ibid.
[2011] Gerard Verkley, 'How will the Nagoya Protocol Affect Our Daily Work? (2015) 6(1) *IMA Fungus* 3, 4 <http://www.imafungus.org/Issue/61/02.pdf> accessed 6 February 2018.
[2012] Morgera and Geelhoed, 'Consultancy on the Notion of 'Utilisation' (n 2008) 6-7; see also *The Encyclopaedia Britannica*, 'Research and Development' (15th edn, Encyclopaedia Britannica Inc. 2010) <https://www.britannica.com/topic/research-and-development> accessed 6 February 2018.
[2013] Notably Nagoya Protocol 2010, arts 2(c), 5(4), 8(a), 17 and the Annex to the Protocol.
[2014] Morgera and Geelhoed, 'Consultancy on the Notion of 'Utilisation' (n 2008) 6-7; see also Caroline von Kries and Gerd Winter, 'Defining Commercial and Non-commercial Research and Development Under the Nagoya Protocol and in other Contexts' in Evanson Chege Kamau, Gerd Winter and Peter-Tobias Stoll (eds), *Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya protocol* (Routledge 2015) 65; and Gurdial Singh Nijar, 'The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries' (2011) South Centre 15.
[2015] Nagoya Protocol 2010, art 6(3)(a).
[2016] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 138.
[2017] Sarah Sargent, 'What's in a Name? The Contested Meaning of Free, Prior and Informed Consent in International Financial Law and Indigenous Rights' in Valentina Vadi and Bruno de Witte (eds) *Culture and International Economic Law* (Routledge 2014).
[2018] Elisa Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (2016) 27(2) *European Journal of International Law* 353-383.

attempt to provide clarification regarding their meaning and requirements in the context of the Convention on Biological Diversity and its Nagoya Protocol, since it is imperative for developing and least-developed countries to implement access and benefit-sharing requirements in relation to genetic resources and associated traditional knowledge in national legislation, in order to ensure access to quality, safe and effective traditional medicine for achieving sustainable development.

6.4.2.1. Prior Informed Consent

It is difficult to determine the origin of this concept; however, literature agrees that prior informed consent first appeared in the mid-1980s amid the struggle of the indigenous peoples for self-determination.[2019] From that time on, it has become well-known in international law and applied in different contexts. Different from the indigenous rights context, it has been widely used in international instruments in the field of chemical and hazardous waste; for example, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade 1998, which is a UN multilateral treaty to promote shared responsibilities in relation to importation of hazardous waste, comprised of 158 parties.[2020] In this context, it was used to ensure that those likely to be affected and authorised to decide on an activity involving risks were given prior information in detail about such potential risks, and to protect importing countries from environmental and health hazards.[2021] Having said that, prior informed consent has meant other things and been used differently in other contexts. As has been argued, 'discussions on what meaning should be given to [prior informed consent] abound and there is no agreement or consensus on what the meaning of [prior informed consent] should be'.[2022]

In the Convention on Biological Diversity and its Nagoya Protocol, prior informed consent is required in three different situations, with different significance: state prior informed consent requirement; community prior informed consent concerning genetic resources; and community prior informed consent concerning traditional knowledge. First, Article 15(5) of the Convention on Biological Diversity and its Nagoya Protocol Article 6(1) require access to genetic resources for their utilisation to be subject to the prior informed consent of the party providing such resources ('state prior informed consent requirement'). In this context, the concept is employed as a tool to safeguard

[2019] Marcus Colchester and Maurizio Farhan Ferrari, 'Making FPIC Work: Challenges and Prospects for Indigenous Peoples' (2007) Moreton-in-Marsh: Forest Peoples Programme (FPP); see also Philippe Hanna and Frank Vanclay, 'Human Rights, Indigenous Peoples and the Concept of Free, Prior and Informed Consent' (2013) 31(2) *Impact Assessment and Project Appraisal* 146-157, 150.
[2020] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 144; see also Secretariat of the Rotterdam Convention – UNEP, 'Overview of the Convention' <http://www.pic.int/TheConvention/Overview/tabid/1044/language/en-US/Default.aspx > accessed 12 February 2017.
[2021] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 144.
[2022] Sargent (n 2017).

countries' sovereignty over natural, as well as genetic resources.[2023] These provisions mean that, before accessing genetic resources, the party acquiring them must inform the provider-country in advance and detail about the proposed research or bioprospecting activity for it to give its consent to the request for access.[2024] Based on this information, the competent authority of the provider-country provides a 'clear and transparent' written decision regarding the request for access and issues a permit at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.[2025]

Secondly, the Nagoya Protocol Article 6(2) requires each party to take measures with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources ('community prior informed consent concerning genetic resources'). Community prior informed consent for access to genetic resources is based on international human rights law which recognises 'indigenous peoples inherent and prior rights to their lands and resources and respects their legitimate authority to require that third parties enter into an equal and respectful relationship with them based on the principle of informed consent'.[2026] Procedurally, it aims to ensure processes that permit and encourage indigenous peoples to make meaningful choices about their developmental objectives.[2027] In this regard, prior informed consent is intrinsically connected to the notion of self-determination, which principally suggests that 'human beings, individually and as groups, are equally entitled to be in control of their destinies, and to live within governing institutional orders that are devised accordingly'.[2028]

[2023] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 144.
[2024] ibid.
[2025] Nagoya Protocol 2010, art 6(d), (e).
[2026] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the Working Group on Indigenous Populations on its twenty-second session' (E/CN.4/Sub.2/2004/28) <http://www.refworld.org/docid/42d7b72f4.html> accessed 16 February 2018.
[2027] ibid.
[2028] James Anaya, 'The Right of Indigenous Peoples to Self-Determination in the Post-Declaration Era' in Claire Charters and Rodolfo Stavenhagen (eds), *Making the Declaration Work: The United Nations Declaration on the Rights of Indigenous Peoples* (Copenhagen: International Work Group for Indigenous Affairs, 2009) 184-199, 187; see also, Hanna and Vanclay (n 2019) 146.

Regarding its operationalisation, parties to the Convention on Biological Diversity are yet to provide any guidance on community prior informed consent. In this connection, it has been submitted that an international human rights paradigm on community prior informed consent for access to natural resources or development and extractive activities on their lands may prove useful in providing normative standards for the principle in the context of the Convention on Biological Diversity and its Nagoya Protocol.[2029] However, even under international human rights law, there is a remarkable lack of conceptual clarity regarding the meaning and requirement of prior informed consent.[2030] At the core of its lack of clarity are questions whether prior informed consent entails a *consultation* process with indigenous groups, or a *substantive right* of indigenous peoples to *veto* proposed projects.[2031] In turn, these questions bring to the fore issues concerning the relationship between the state, business enterprises and indigenous peoples: whether it is the prerogative of the state to own and control natural resources, or whether there is a superseding indigenous claim; and whether the relations between the state, business enterprises and indigenous peoples qualify as a partnership and are bereft of socio-political power asymmetries, or whether indigenous interests are perceived as subservient to either those of the state or business interests, are issues at the centre of the usage of the prior informed consent principle.[2032] Two cases present good illustrations: the cases of *Saramaka People v Suriname*,[2033] and *Kichwa Indigenous People of Sarayaku v Ecuador*.[2034]

The *Saramaka* case addressed the rights of the indigenous peoples and their struggles against encroachment by companies carrying out mining and logging activities on their territories based on concessions granted by the state without their consent.[2035] While noting the significant impact that mining and logging activities could have on the human rights of the Saramaka tribal people – inhabiting the upper Suriname river region – the

[2029] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 149.
[2030] Sargent (n 2017).
[2031] ibid; see also Hurst Hannum, Dinah L Shelton, James Anaya and Rosa Celerio, *International Human Rights: Problems of Law, Policy and Practice* (6th edn, Wolters Kluwer Law & Business 2017) 172-173.
[2032] Sargent (n 2017).
[2033] *Saramaka People v Suriname* (2007) Inter-Am Ct H R (Series C) No 172 (Preliminary Objections, Merits, Reparations, and Costs).
[2034] *Kichwa Indigenous People of Sarayaku v Ecuador* (2012) Inter-Am Ct H R (Series C) No 245 (Preliminary Objections, Merits, Reparations, and Costs).
[2035] Hayley Garscia, 'Saramaka People v Suriname, Case Summary' (2014) 36(2305) *Loyola of Los Angeles International and Comparative Law Review* 2305.

Inter-American Court of Human Rights[2036] held that in cases of large-scale development or investment projects capable of major impacts on indigenous territories, the state had the duty to not only *consult* with the Saramakas but also to obtain their *free, prior and informed consent* [2037] according to their customs and traditions. [2038] By this pronouncement, the court articulated on the part of indigenous peoples a right to not merely be consulted, but also a right to give or withhold consent in cases where there exists a potentially major impact to a community's cultural and physical well-being.[2039] However, in the subsequent case of *Kichwa Indigenous People of Sarayaku* where the Ecuadorian state permitted a private oil company to carry out exploration and exploitation activities (which led to the introduction of high-powered explosives) in the territory of Kichwa indigenous people of Sarayaku, who live in the area along the Bobonaza river in the province of Pastaza in the Southern part of Ecuadorean Amazon,[2040] without obtaining their consent, the Inter-American Court only recognised the general duty of states to *consult* with indigenous peoples on matters affecting them; but 'remained silent on *consent* as a required outcome and consequently did not expand on the substantive dimension of [free, prior and informed consent]'.[2041] Thus, while both cases seem to agree that as a general principle of international human rights law, states are under an obligation to consult when specific interests of indigenous peoples are about to be affected, it is much less certain the extent to which they are required to not only consult but obtain free, prior and informed consent.[2042]

[2036] The Inter-American Court of Human Rights is an independent judicial institution based in San José, Costa Rica. In Conjunction with the Inter-American Commission on Human Rights, it makes up the human rights protection of system of the Organization of American States (OAS), which serves to uphold and promote basic rights and freedoms in the Americas – comprising the totality of the continents in North and South America. See Cicilia Medina Quiroga, 'The Inter-American Court of Human Rights: 35 Years' (2015) 33(2) *Netherlands Quarterly of Human Rights* 118-122.

[2037] A variant of prior informed consent as provided in the UNDRIP.

[2038] Hannum et al. (n 2031) 173.

[2039] Cathal Doyle, *Indigenous Peoples, Title to Territory, Rights and Resources: The Transformative Role of Free, Prior and Informed Consent* (Taylor & Francis Group, 2017) 129, 132; see also Hannum et al. (n 2031) 173.

[2040] 'Confirming Rights: Inter-American Court Ruling Makes Key Victory for Sarayaku People in Ecuador' in 'Defending Life First: Indigenous Voices in Protecting Human Rights and the Environment' 36-3 *Cultural Survival Quarterly Magazine* (September 2012) 10-11.

[2041] Doyle (n 2039) 129; see also Hannum et al. (n 2031) 173; and John Kelly, 'Kichwa Indigenous People of Sarayaku v Ecuador, Case Summary' (2017) 40(3) Loyola of Los Angeles International and Comparative Law Review 1469.

[2042] Hannum et al. (n 2031) 172-173.

There is an argument that, more than any other forum on indigenous rights, the community prior informed consent required by Article 6(2) of the Nagoya Protocol establishes the UNDRIP standard of free, prior and informed consent, especially as it concerns genetic resources used in R&D.[2043] Specifically, UNDRIP Article 32(2) is the relevant provision:

> States shall *consult* and cooperate in good faith with Indigenous peoples concerned through their own representative institutions in order to obtain their free and informed *consent* prior to the approval of any project affecting their…resources, particularly in connection with the development, utilization or exploitation of mineral, water or *other* resources.[2044] (Italics added for emphasis.)

However, similarly to other provisions on free, prior and informed consent in international human rights law, there is to a considerable extent confusion, as well as disagreement regarding the meaning and usage of this principle under Article 32(2) of the UNDRIP. What is more, the UNDRIP does not define, or at least clarify, the normative content of free, prior and informed consent.[2045] This has created a problem of great complexity in applying the principle since many Articles within the UNDRIP require the free, prior and informed consent of indigenous peoples.[2046] For example, free, prior and informed consent is required: in relation to the relocation of indigenous peoples from their lands;[2047] with respect to the utilisation of their cultural, intellectual, religious and spiritual property;[2048] before states adopt or implement legislative or administrative measures that may affect the indigenous peoples;[2049] with regard to taking lands that indigenous peoples have traditionally owned or otherwise used;[2050] and in relation to storage or disposal of hazardous materials in the lands or territories of indigenous peoples.[2051] In 2012, the International Law Association's Committee on Rights of Indigenous Peoples released an Expert Commentary that attempted to provide

[2043] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 146.
[2044] UNDRIP 2007, art 32(2).
[2045] Sargent (n 2017).
[2046] ibid.
[2047] UNDRIP 2007, art 10.
[2048] ibid, art 11.
[2049] ibid, art 19.
[2050] ibid, art 28.
[2051] ibid, art 29.

authoritative clarification and reduce confusion on the normative status of the UNDRIP provisions and indigenous rights in general.[2052] The committee was established in 2006 by the International Law Association – which is a 'non-profit organisation that promotes the study, clarification and development of international law'[2053] – to 'undertake research and then to report' on the area of indigenous peoples' human rights.[2054] However, the committee was dissolved in 2012 after issuing its final report on the rights of indigenous peoples.[2055]

In the commentary, the Committee opined that a right to veto seems to exist with respect to all the UNDRIP provisions that contain free, prior and informed consent, except Article 19 relating to the adoption or implementation of legislative or administrative measures that may affect the indigenous peoples;[2056] and Article 32(2) in connection with the 'development, utilisation or exploitation of mineral, water, or *other* resources'.[2057] This line of interpretation would mean that, in the context of the Nagoya Protocol, Article 6(2) establishes a *consultation* process with the indigenous peoples for access to genetic resources held by them since UNDRIP Article 32(2) does not confer an indigenous right or power to veto. Having said that, former United Nations Special Rapporteur on the Rights of Indigenous Peoples, Professor James Anaya (who is also a former chair of the International Law Association's Committee on Rights of Indigenous Peoples),[2058] while endorsing the commentary, seemed to dissent from the Committee's views by suggesting that within the scope of Article 32(2) UNDRIP, there are also situations that can give rise to an indigenous right to veto.[2059]

Anaya pointed out that other indigenous rights are, in fact, undermined during the 'development, utilisation or exploitation of mineral, water, or other resources', such as 'the rights to property, culture, religion and non-discrimination in relation to their lands,

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[2052] 'Committee on Rights of Indigenous Peoples (2006-2012)' (*International Law Association*) <http://www.ila-hq.org/index.php/committees> accessed 19 February 2018.
[2053] Constitution of the International Law Association, 2016 <http://www.ilahq.org/images/ILA/docs/constitution_english_adopted_johannesburg_2016.pdf> accessed 19 February 2018.
[2054] 'Committee on Rights of Indigenous Peoples (2006-2012)' (n 2052).
[2055] ibid.
[2056] UNDRIP 2007, art 19.
[2057] ibid, art 32(2).
[2058] 'Committee on Rights of Indigenous Peoples (2006-2012)' (n 2052).
[2059] Sargent (n 2017).

territories and natural resources'; and that the Committee has identified some of these rights as conferring a right to veto.[2060] Based on this reasoning, can it then be asserted in situations where biotechnology and pharmaceutical companies request access to utilise genetic resources that possess cultural or religious significance that Article 6(2) of the Nagoya Protocol confers a right to veto the request on the part of indigenous peoples? This is at the very least confusing and represents 'the complexity and lack of agreement on the situational definitions that have been given to [free, prior and informed consent]'.[2061] Thus, neither Anaya nor the International Law Association's Committee on Rights of Indigenous Peoples succeeded in clarifying where free, prior and informed consent requires a consultation process and where it connotes a substantive right to veto, especially with respect to UNDRIP Article 32(2),[2062] thereby leaving the interpretation of prior informed consent in the Nagoya Protocol Article 6(2) unclear.

There is also lack of clarity regarding the normative status of the principle in the third situation where the Nagoya Protocol requires prior informed consent, i.e. concerning traditional knowledge. Article 7 of the Nagoya Protocol requires parties to take measures with the aim of ensuring that access to traditional knowledge associated with genetic resources is based on the prior and informed consent or approval and involvement of the indigenous and local communities ('community prior informed consent concerning traditional knowledge').[2063] This is in recognition of the indigenous peoples' rights to cultural identity, and as mentioned earlier, their right to maintain, control, protect and develop traditional knowledge.[2064] Nonetheless, neither the Protocol nor any other international process provides clarification in respect of the specific procedural and substantive requirements for community prior informed consent concerning traditional knowledge associated with genetic resources; although guidance may be sought in the consensus interpretation developed by parties to the Convention on Biological Diversity within the framework of the Working Group on Article 8(j) (relating to the respect and

[2060] ibid.
[2061] Sargent (n 2017).
[2062] ibid.
[2063] Nagoya Protocol 2010, art 7.
[2064] UNDRIP 2007, arts 3, 4, and 3.1

preservation of traditional knowledge relevant to the conservation and sustainable use of biodiversity).[2065]

For instance, the Convention on Biological Diversity's Akwé: Kon Guidelines, named with a Mohawk term meaning 'everything in creation' and adopted in 2004 to provide a collaborative framework for ensuring the full involvement of indigenous and local communities in the assessment of cultural, environmental and social impact of proposed development on sacred sites and on traditional lands and waters,[2066] notes that where prior informed consent of indigenous and local communities is required, the process should 'consider the rights, knowledge, innovations and practices of indigenous and local communities; the use of appropriate language and process; the allocation of sufficient time and the provision of accurate, factual and legally correct information'.[2067] Also, where the initial proposal to the community has been modified, there will be a need for additional prior informed consent.[2068] Along similar lines, the Convention on Biological Diversity's Tkarihwaié:ri Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity adopted by the Conference of the Parties (COP) in 2010, states that where consent of the indigenous and local communities is required with respect to traditional knowledge, it is within the rights of the indigenous and local communities, as provided by their customary laws and procedures, to identify relevant holders of their knowledge.[2069] Moreover, 'such consent…should not be coerced, forced or manipulated'.[2070] 'Tkarihwaié:ri' is another Mohawk term meaning 'the proper way'; 'Mohawk' referring to the traditional custodians (Mohawk Community of Kahnawake) of the area of Montreal in the Canadian province of Quebec, where the code was negotiated.[2071]

[2065] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 172-173.
[2066] Secretariat of the Convention on Biological Diversity, 'Akwé: Kon Guidelines – Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessments' <https://www.cbd.int/traditional/guidelines.shtml> accessed 13 February 2018.
[2067] Convention on Biological Diversity, Akwé: Kon Guidelines 2004, para 53.
[2068] ibid.
[2069] Secretariat of the Convention on Biological Diversity, The Tkarihwaié:ri Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity 2010 <https://www.cbd.int/traditional/code.shtml> accessed 13 February 2018, para 4.
[2070] ibid, para 11.
[2071] ibid.

To this extent, it is inferable from this consensus, soft law interpretations of parties to the Convention on Biological Diversity, that community prior informed consent over traditional knowledge associated with genetic resources in the context of Nagoya Protocol Article 7, does not provide a substantive right to veto requests for access to traditional knowledge, but rather seems to imply a consultation process with indigenous and local communities. Yet, the Tkarihwaié:ri Code, at paragraph 30, notes that ethical conduct in relation to activities or interactions touching upon biodiversity should recognise that there are some legitimate circumstances where indigenous and local communities can '*restrict* access to traditional knowledge'.[2072] Also recall that the International Law Association's Committee on Rights of Indigenous Peoples and former United Nations Special Rapporteur, Anaya, seemed to agree, at least, that an indigenous right to veto exists with respect to the utilisation of cultural, intellectual, religious and spiritual property. Can it then be argued that an indigenous right to restrict access exists in respect of traditional knowledge with cultural, religious or spiritual significance?

What can be extrapolated from the body of existing human rights processes is that community prior informed consent, whether in relation to genetic resources or associated traditional knowledge, implies a consultation procedure with indigenous and local communities based on good faith, in accordance with their customs and traditions, conducted with the aim of partnership building, that is legitimate based on communities' perception, and results in benefit-sharing that must be congruent with the indigenous notion of benefits.[2073] In light of this, equating community prior informed consent to a substantive right or power to veto is an 'oversimplification'.[2074] According to Anaya:

> …it must be emphasized that the consent is not a free-standing device of legitimation. The principle of free, prior and informed consent, arising as it does within a human rights framework, does not contemplate consent as simply a yes to a predetermined decision, or as means to validate a deal that disadvantages affected indigenous peoples. When consent is given, not just freely and on an

[2072] ibid, para 30.
[2073] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 150.
[2074] ibid.

> informed basis, but also on just terms that are protective of indigenous peoples' rights, it will fulfil its human rights safeguard role.[2075]

Thus, for purposes of adopting national strategies and measures for implementing the Convention on Biological Diversity and its Nagoya Protocol, with the aim of ensuring access to traditional medicine for sustainable development, the requirements for access to genetic resources and associated traditional knowledge based on prior informed consent, in accordance with Nagoya Protocol Articles 6(2) and 7, should be seen as a procedural safeguard for the realisation of indigenous substantive right to self-determination, including the rights to property, culture, religion, non-discrimination and the right to pursue their own path to development.[2076] Focusing on the highly contentious *consultation* and *consent* dichotomy would effectively blur understanding about the human rights framework by which biotechnology and pharmaceutical industries seeking access to genetic resources and associated traditional knowledge may legitimately operate within or near indigenous territories.[2077]

Furthermore, there is a reference to 'or approval and involvement' in Articles 6(2) and 7 of the Nagoya Protocol, and the Convention on Biological Diversity Article 8(j), relating to traditional knowledge relevant to the conservation and sustainable use of biodiversity. While Nagoya Protocol Articles 6(2) and 7 require states to 'take measures, as appropriate, with the aim of ensuring that prior informed consent *or approval and involvement* of indigenous and local communities are obtained for access' to genetic resources and associated traditional knowledge,[2078] Article 8(j) of the Convention on Biological Diversity requires each contracting party to 'promote the wider application of knowledge, innovations and practices' of indigenous and local communities relevant to the conservation and sustainable use of biodiversity with the *approval and involvement* of such knowledge holders.[2079] One can argue, considering the wordings of Articles 6(2) and 7, that the Nagoya Protocol vests on states the discretion to determine whether or not

[2075] Human Rights Council, 'Report of the Special Rapporteur on the Rights of Indigenous Peoples, James Anaya: Extractive Industries and Indigenous Peoples' (UN Doc A/HRC/24/41, 2013) 10.
[2076] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 150-151.
[2077] Human Rights Council, 'Report of the Special Rapporteur on the Rights of Indigenous Peoples, James Anaya' (n 2075) 12.
[2078] Nagoya Protocol 2010, art 6(2) and 7.
[2079] Convention on Biological Diversity 1992, art 8(j).

access to genetic resources and associated traditional knowledge should be subject to the 'prior informed consent *or* approval and involvement' of indigenous and local communities. This interpretation is supported by the presence of the disjunctive conjunction '*or*', which creates the impression that 'prior informed consent' and 'approval and involvement' are expressed as alternatives.

While this may be so, the inclusion of 'approval and involvement' in both the Convention on Biological Diversity and its Nagoya Protocol has been explained by the lack of enthusiasm on the part of some parties to fully endorse the right of indigenous and local communities to grant prior informed consent as developed in international human rights law.[2080] This lack of enthusiasm is equally mirrored by the 'timid preambular reference'[2081] by the Nagoya Protocol to the UNDRIP which reads: 'Noting the United Nations Declaration on the Rights of Indigenous Peoples'.[2082] The purpose of the reference to 'approval and involvement' was to create room for flexibility in national implementation, particularly given the different, and in many cases contentious, legal arrangements that govern relations between indigenous and local communities and their governments.[2083] Moreover, the unwillingness to endorse community prior informed consent can also be understood from the perspective of the motivations of developed countries and the biotechnology and pharmaceutical industries during the negotiation of the Nagoya Protocol to ensure that any legal measures taken would not impede access to genetic resources and associated traditional knowledge.[2084]

The critical concern with regard to this alternative expression, 'approval and involvement,' is the uncertainty as to whether it guarantees similar procedural and substantive safeguards for indigenous and local communities as the concept of prior informed consent.[2085] In this connection, commentators have proposed that in practice, 'prior informed consent' and 'approval and involvement' be considered to have primarily

[2080] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 152.
[2081] ibid.
[2082] Nagoya Protocol 2010, preamble, the 26th recital.
[2083] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 152; see also Jeff Corntassel, 'Toward Sustainable Self-Determination: Rethinking the Contemporary Indigenous Indigenous-Rights Discourse' (2008) 33 Alternatives 105-132, 111-112.
[2084] Siswandi (n 705) 347-349.
[2085] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 153.

the same meaning.[2086] Along similar lines, former United Nations Special Rapporteur, Anaya, has suggested that even though the terms employed in various instruments may not be identical, relevant international environmental treaties should be interpreted and implemented in a manner compatible with the UNDRIP.[2087] This consensus regarding the interpretation to be given to these two expressions is further substantiated by the clarification of 'prior and informed consent', 'free, prior and informed consent' and 'approval and involvement' in the context of the Mo'otz Kuxtal[2088] Voluntary Guidelines for Traditional Knowledge, adopted by parties to the Convention in 2016 for the development of mechanisms, legislation or other appropriate initiatives to ensure the 'prior and informed consent', 'free, prior and informed consent' and 'approval and involvement' of indigenous and local communities for access to and benefit-sharing derived from the utilisation of their knowledge, innovations and practices relevant to the conservation and sustainable use of biodiversity, and for reporting and preventing unlawful appropriation of traditional knowledge.[2089]

These voluntary guidelines interpret 'consent' and 'approval' to both mean the agreement of the indigenous and local communities or their competent authorities to grant access to a potential user, and includes the right not to grant such consent or approval.[2090] As for 'involvement', the guidelines explain that the term refers to 'full and effective participation' of these communities in decision-making processes related to access.[2091] The Mo'otz Kuxtal Voluntary Guidelines adds that '[c]onsultation and full and effective participation of Indigenous peoples and local communities are crucial components of a consent or approval process'.[2092] While the Mo'otz Kuxtal Voluntary Guidelines apply

[2086] ibid 152-153; see also Greiber et al. (n 1904) 110-111; Gurdial Singh Nijar, 'The Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources: An Analysis' (2011) CEBLAW 26; and Matthais Buck and Claire Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Resources' (2011) 20(1) Review of European, Comparative & International Environmental Law 47-61, 55.
[2087] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 152-153.
[2088] Meaning 'roots of life' in Maya language. Mayans are a group of Indigenous peoples of Mesoamericans, inhabiting southern Mexico, Guatemala, Belize, El Salvador and Honduras. See Conference of Parties to the Convention on Biological Diversity, Mo'otz Kuxtal Voluntary Guidelines 2016, CBD/COP/DEC/XIII/18; and James D Nations, *The Maya Tropical Forest: People, Parks and Ancient Cities* (University of Texas Press 2010).
[2089] Mo'otz Kuxtal Voluntary Guidelines 2016.
[2090] ibid, para 6(d).
[2091] ibid, para 6(e).
[2092] ibid.

only to the knowledge, innovations and practices of indigenous and local communities relevant to the conservation and sustainable use of biodiversity under the Convention on Biological Diversity Article 8(j),[2093] they provide guidance for the interpretation of 'prior informed consent' and 'approval and involvement' in the context of access to genetic resources and associated traditional knowledge in Nagoya Protocol Articles 6(2) and 7. Thus, developing and least-developed countries should ensure that for all practical purposes, 'approval and involvement' still effectively guarantees the indigenous right to self-determination and rights to genetic resources and associated traditional knowledge, as well as the right to participate in and determine the outcome of their decision-making processes.[2094]

6.4.2.2. Fair and Equitable Benefit-Sharing

Regarding the concept of benefit-sharing, there is a prevalent view that it is not completely understood, still in its evolutionary stage, and has not 'become satisfactorily operational'. [2095] At various times in international law, 'benefit-sharing' has been perceived, rightly or wrongly, as a 'treaty objective', 'a right', 'a safeguard', 'an international obligation', or a 'mechanism'.[2096] The lack of clarity regarding the concept is such that it has been questioned whether there exist just one or many concepts of benefit-sharing.[2097] In attempting to clarify its normative content, '*sharing*' has been argued to involve a process of long-term consultation between stakeholders – as opposed to a 'one-off exercise' – based on good faith, which aims to reach a mutual understanding regarding the nature of benefits to be shared and how they would be allocated.[2098] In almost all cases, this 'dialogic' engagement establishes a form of partnership between the

[2093] ibid, paras 1 and 5.
[2094] Morgera et al., *Unravelling the Nagoya Protocol* (n 1824) 152.
[2095] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2096] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383; see also Convention on Biological Diversity 1992, art 1, 15(7), 8(j); Nagoya Protocol 2010, art 1, 5, 10; International Treaty on Plant Genetic Resources 2001, art 1, 9, 10; ILO Convention No 169, art 15(2); and United Nations Convention on Law of the Sea (UNCLOS) 1982, art 140.
[2097] Bram De Jonge, 'What is Fair and Equitable Benefit-sharing?' (2011) 24 *Journal of Agriculture & Environmental Ethics* 127; see also Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2098] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.

stakeholders involved.[2099] Within the partnership, the '*benefits*' to be shared are generally of a monetary or non-monetary nature.[2100] According to the Nagoya Protocol, monetary benefits include profits in the form of access fees, up-front or milestone payments, royalties or licence fees, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, and joint ownership of relevant intellectual property rights;[2101] whereas, non-monetary benefits include sharing of R&D results, participation in product development, admittance to *ex situ* facilities and databases, and collaboration, cooperation and contribution to education and training.[2102] Although the Nagoya Protocol is the only international instrument containing benefit-sharing obligations that provides a detailed list of benefits, the list is non-exhaustive.[2103]

As for the '*beneficiaries*' of the benefit-sharing agreement, benefit-sharing applies to relations between countries (inter-state), between a government and a community part of its territory (intra-state), communities and private companies, and within communities (intra-community).[2104] Accordingly, in the context of the Convention on Biological Diversity and its Nagoya Protocol, the beneficiaries are the 'provider-countries' (based upon the understanding that all countries are potentially both users and providers of genetic resources; although developing and least-developed countries are primarily considered the providers), and indigenous and local communities.[2105] Thus, with respect to the use of genetic resources and associated traditional knowledge, benefit-sharing seems to represent a reward for the contributions of traditional knowledge holders and ecosystem stewards in preserving, maintaining and restoring the ecosystem, as well as for the scientific advances and innovations that build on their traditional knowledge.[2106]

[2099] ibid.
[2100] Nagoya Protocol 2010, art 5(4).
[2101] ibid, Annex.
[2102] ibid.
[2103] Nagoya Protocol 2010, art 5(4); see also Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2104] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383; see also Morgera and Tsioumani, 'The Evolution of Benefit-sharing' (n 1826) 150.
[2105] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383; see also Convention on Biological Diversity 1992, arts 15(7), 16(2); and Nagoya Protocol 2010, art 5(1), (2), (5).
[2106] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.

Primarily, the concept of benefit-sharing considers that developing and least-developed countries and indigenous and local communities should participate in the benefits that users derive from their genetic resources and traditional knowledge.[2107] While that may be so, existing empirical evidence[2108] suggests that, more often than not, benefit-sharing works against rather than achieves this stated objective. This is attributed to the *de facto* socio-political power asymmetries which characterise relations to which benefit-sharing applies, inevitably resulting in loss of control and reallocation of genetic resources and traditional knowledge.[2109] Under the Convention on Biological Diversity and its Nagoya Protocol, apportioning benefits is based on mutually agreed terms,[2110] i.e. through *ad hoc* private-law contracts, as against standard agreements carefully drafted by an international decision-making body. [2111] Basically, mutually agreed terms reflect the agreement between providers of genetic resources/traditional knowledge and the users regarding the conditions of access, utilisation of the resources and traditional knowledge, benefits to be shared between both parties, as well as restrictions of use, third party transfer and reporting requirements, among others.[2112] In the absence of standard agreements, these contracts are governed by domestic rules without specific substantive criteria and an international oversight on how benefits are distributed.[2113] Because partnership building is left to contractual freedom, the party wielding bargaining power in the dialogue and negotiation of the benefit-sharing agreement may arbitrarily renegotiate rights, resulting in an actual shift of authority over genetic resources and traditional knowledge from the vulnerable party – usually developing and least-developed countries (in inter-state relations) and the indigenous and local communities (in relations with states or private companies).[2114] This is undesirable since, in principle, benefit-sharing ought to empower

[2107] De Jonge (n 2097) 1.
[2108] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2109] ibid; see also Adrian Martin, Anne Akol and Jon Phillips, 'Just Conservation? On Fairness of Sharing Benefits' in Thomas Sikor (ed) *The Justices and Injustices of Ecosystem Services* (Routledge, 2013) 69, 84-88.
[2110] Convention on Biological Diversity 1992, art 15(4); and Nagoya Protocol 2010 art 5(1), (2), (5).
[2111] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2112] K Barker, C Butler, M da Silva, G Droege, C Lyal, D Schindel, O Seberg and B Zimkus, 'ABS Fact Sheet and Answers to Frequently Asked Questions' (2017) Global Genome Biodiversity Network.
[2113] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.
[2114] ibid.

developing and least-developed countries and the indigenous and local communities, and in fact, safeguard their rights over natural resources and traditional knowledge.[2115]

Besides, benefit-sharing could be a force of division and controversies among members of indigenous and local communities. Compensation, either in monetary or non-monetary form, is a Western concept that is incompatible with the sacred status accorded to some genetic resources and traditional knowledge.[2116] Because of their sacredness, some indigenous peoples do not consider them tradable commodities, not to mention participating in the profits derived from their commercialisation.[2117] However, money, by its nature, has the potential to cause degeneration in societies.[2118] It is not inconceivable that awarding monetary compensation for something shared and freely utilised according to customs and traditions would breed corruption and avarice in a community. For instance, in situations where genetic resources or traditional knowledge is transboundary, there may be a 'race to the bottom' which provides Western companies with the lowest compensation and excludes other communities which share the same resource or knowledge.[2119] A rivalry between communities may also ensue because of commercial prospects and end the tradition of sharing, which may have a long-term negative social impact.[2120]

Even within a single community, animosity may equally arise between those who want the compensation and others who oppose it.[2121] Take the benefit-sharing agreement mentioned earlier between the Kani tribes of the South Indian region of Kerala and the Indian Tropical Botanical Garden and Research Institute (TBGRI) that heightened an already existing acrimony between the tribes.[2122] The TBGRI after discussion agreed to share 50 per cent of the licence fee and royalties relating to the Jevaani drug with a section

[2115] ibid.
[2116] De Jonge (n 2097) 134.
[2117] Ho, 'Biopiracy and Beyond' (n 1661) 459; see also De Jonge (n 2097) 134.
[2118] Thomas Greaves, 'Tribal Rights', in Stephen B Brusch and Doreen Stabinsky (eds), *Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights* (Island Press, 1996) 29.
[2119] Gaia Foundation, Genetic Resources Action International, 'Biodiversity for Sale: Dismantling the Hype About Benefit-sharing' (n 1906).
[2120] Corinna Heineke and Franziska Wolff, 'Access to Genetic Resources and the Sharing of Benefits: Private Rights or Shared Use for Biodiversity Conservation?' (2004) 2 *Environmental Law Network International* 26, 28.
[2121] Ho, 'Biopiracy and Beyond' (n 1661) 460.
[2122] Shane P Mulligan, 'For Whose Benefit? Limits to Sharing in the Bioprospecting 'Regime" (1999) 8 *Environmental Politic*s 35.

of the Kani tribes – the Kanis from the Kuttichal Gram Panchayat area – in exchange for the traditional knowledge relating to the anti-fatigue properties of Arogyapaacha (*Trichopus zeylanicus*) which the Kani tribes (in general) considered sacred and a tribal secret.[2123] However, the Kanis in other Panchayat areas objected to the agreement for the 'sale of their knowledge to "private companies"' by the Kuttichal Kanis.[2124] They felt overlooked and believed the benefit-sharing agreement was defective because it was not inclusive and participatory.[2125] Recognising this tension, TBGRI deposited the 50 per cent licence fee in a trust to be collectively managed by the Kani tribes, and the interest it accrued was to be used for the tribes' welfare.[2126]

These instances bring to the fore the concern of how *fairness* and *equity* – other normative elements of the concept – can be realised in benefit-sharing. Indeed, the Convention on Biological Diversity and its Nagoya Protocol require the sharing in a 'fair and equitable way' benefits derived from the utilisation of genetic resources and traditional knowledge.[2127] Even so, they do not specify how to determine what is fair and equitable, thereby leaving such determination to access and benefit-sharing dialogues and negotiations.[2128] In this light, it has been argued that fair and equitable benefit-sharing should not be comprehended as merely relating to an ethical distribution or exchange of benefits; the principles of procedural and cognitive justice are essential preconditions that must be integrated into the processes of multilateral or bilateral benefit-sharing negotiations in order to realise fairness and equity.[2129] While it is not concerned with the allocation of benefits, procedural justice is useful in the context of benefit-sharing as it aims for fairness and accuracy in legal processes and equal participatory rights of stakeholders involved. [2130] This is particularly important in view of the power asymmetries that characterise inter-state and intra-state relations in benefit-sharing negotiations. Thus, procedural justice will entail long-term investments in negotiation

[2123] Michael J Finger and Philip Schuler, *Poor People's Knowledge: Promoting Intellectual Property in Developing Countries* (World Bank Publications, 2004) 153; see also Kiene (n 1754) 18; and Cullet, *Intellectual Property Protection and Sustainable Development* (n 1764) 167-170.
[2124] Finger and Schuler (n 2123) 153; see also Kiene (n 1754) 18.
[2125] Finger and Schuler (n 2123) 153.
[2126] ibid.
[2127] Convention on Biological Diversity 1992, arts 8(j), 15(7); and Nagoya Protocol 2010, art 5.
[2128] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383; see also De Jonge (n 2097) 127.
[2129] De Jonge (n 2097) 140.
[2130] ibid.

capacities, expansion of knowledge base and adequate legal services for developing and least-developed countries, and indigenous and local communities.[2131] It will also require a thorough analysis of the complex relationships, especially between states and the indigenous and local communities within their territories, and (in transboundary cases) between communities, in order to ascertain their respective rights to various resources and associated knowledge with the aim of facilitating a fair process and equitable outcome of benefit-sharing negotiations.[2132]

Along similar lines, there is a need to acknowledge the cultural differences between stakeholders, as well as the fundamental dissimilitude in understandings regarding core issues, such as genetic resources, traditional knowledge, property, and sharing.[2133] In this respect, cognitive justice principally demands that these different conceptualisations are afforded equal status from the commencement of debates and dialogues about benefit-sharing.[2134] This would mean, for instance, that if a party to a benefit-sharing agreement is apprehensive about the application of patent protection to products based upon or derived from genetic resources and associated traditional knowledge, this should be respected and not taken for granted.[2135] Thus, benefit-sharing should seek to balance competing rights and interests by introducing notions of justice into relationships regulated by international law; consequently, it is argued that its emergence in international law can be traced to the doctrine of equity.[2136] Fair and equitable benefit-sharing can then be conceptualised 'as the concerted and dialogic process aimed at building partnership in identifying and allocating economic and non-economic benefits among state and non-state actors, with emphasis on the vulnerable'.[2137] In the context of traditional medicine for sustainable development, it would emphasise the sharing of benefits in a fair and equitable manner with developing and least-developed countries,

[2131] ibid.
[2132] ibid.
[2133] ibid.
[2134] ibid.
[2135] ibid.
[2136] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383; see also Roland Kläger, *Fair and Equitable Treatment in International Investment Law* (Cambridge University Press, 2013) 130; and Elisa Morgera, 'Fair and Equitable Benefit-sharing: History, Normative Content and Status in International Law' (2017) BENELEX Working Paper N 12.
[2137] Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit-sharing' (n 1823) 353-383.

and the indigenous and local communities whenever genetic resources and associated traditional knowledge are utilised.

Noticeably thus far, although the Convention on Biological Diversity and its Nagoya Protocol comprise significant provisions on access and benefit-sharing in relation to traditional knowledge associated with genetic resources, both instruments remain silent as regards its legal protection. Whereas Article 8(j) of the Convention on Biological Diversity calls on parties to preserve the knowledge, innovations and practices of indigenous and local communities, and Article 10 encourages the protection of the traditional practices relating to the customary use of biodiversity, these provisions say nothing concerning the appropriate means to put preservation and protection into practice.[2138] Also, while the obligations that users should access associated traditional knowledge based on prior informed consent having established mutually agreed terms and benefit-sharing, including the obligation to establish a compliance mechanism, are essential for dealing with cases of misappropriation, they do not relate to patent applications.[2139] That is to say, the measures prescribed by the regime of the Convention do not directly prevent third parties from acquiring intellectual property rights based upon or derived from traditional knowledge associated with genetic resources. This is all the more so considering that attempts to incorporate the disclosure requirement both in the Nagoya Protocol and the TRIPS Agreement were unsuccessful. As already mentioned, international negotiations concerning the legal instruments for the protection of traditional knowledge in the intellectual property sense primarily take place at the WIPO. The next section addresses this final issue.

[2138] Ebermann (n 977) 37.
[2139] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (1912) 35.

6.4.3. Intellectual Property Protection of Traditional Medical Knowledge

The intellectual property protection of traditional medical knowledge can take two forms: positive and defensive protection. Defensive protection aims to prevent third parties outside the community from acquiring intellectual property rights over traditional medical knowledge.[2140] This can be effected by introducing the disclosure requirement into existing patent laws[2141] and through the use of documented traditional medical knowledge to preclude, oppose or invalidate patents that are directly based on or derived from such knowledge.[2142] An example of such documentation is the already mentioned Indian TKDL, which is a searchable database of traditional medicine in five different languages – English, French, German, Japanese and Spanish – that can provide evidence of prior art during the assessment of patent applications by patent examiners.[2143] In the same vein, the research and documentation, development of treatment guidelines, and development of treatment brochures for preparing traditional medicine suggested in Chapter five can serve a similar purpose.

Also, certain defensive measures have been undertaken by WIPO, including changes to the Patent Cooperation Treaty's Minimum Documentation and the International Patent Classification (IPC) in order to enhance prior art searches and prevent the grant of erroneous patents.[2144] The Patent Cooperation Treaty, a 1970 international patent law treaty that provides for a unified procedure for filing patent applications to protect inventions in each of its 152 contracting states,[2145] between 2003-2005 included certain traditional knowledge documentation, such as the Indian Journal of Traditional Knowledge, Korean Journal of Traditional Knowledge, Journal of Chinese Medicine and Journal of Ethnopharmacology (to mention a few) in its Minimum Documentation,[2146] which comprises patent documents of the major industrialised countries, as well as agreed

[2140] WIPO, 'Intellectual Property and Traditional Medical Knowledge: Background Brief - No 6' (2016)
[2141] Ebermann (n 977).
[2142] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[2143] ibid.
[2144] ibid.
[2145] 'Summary of the Patent Cooperation Treaty (PCT) (1970)' (*World Intellectual Property Organization*) <https://www.wipo.int/treaties/en/registration/pct/summary_pct.html> accessed 7 January 2019.
[2146] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721); see also International Patent Cooperation Union, 'Meeting of International Authorities under the Patent Cooperation Treaty (PCT)' (Geneva: World Intellectual Property Organization 2005).

items of non-patent literature, to facilitate proper prior art searches by the International Searching Authority.[2147] In 2006, again there was an amendment to the IPC, established by the 1971 Strasbourg Agreement to 'classify patent and utility models according to different areas of technology to which they pertain',[2148] to include a category on traditional knowledge which covers traditional medicine.[2149]

As regards positive protection, it grants intellectual property rights to communities over traditional medical knowledge which enables them to control its uses and prevent illegitimate access or the use for commercial gains by others without sharing the benefits derived from such utilisation.[2150] Positive protection may also aid indigenous groups to commercially exploit their traditional medical knowledge if they wish to do so.[2151] This may be achieved through the existing intellectual property system.[2152] Nonetheless, its fundamental characteristics are said to be incompatible with that of traditional medical knowledge.[2153] Essentially, the current international intellectual property system was designed during the age of enlightenment and industrialisation and has subsequently developed to 'respond to [the] needs, concerns and local conditions' of technologically advanced societies,[2154] whereas, traditional medical knowledge, as discussed in Chapter three, is a living body of knowledge that has been developed, maintained, and transmitted from generation to generation within a community, and forms an integral part of its cultural and spiritual identity.[2155] For this reason, it does not readily qualify for protection under the current intellectual property system, which usually protects original works or

[2147] The following Offices have been appointed to act as International Searching Authorities: the Australian Patent Office, the Austrian Patent Office, the Chinese Patent Office, the European Patent Office, the Japanese Patent Office, the Russian Patent Office, the Spanish Patent and Trademark Office, the Swedish Patent Office and the United States Patent and Trademark Office; see 'Introduction to Patent Cooperation Treaty' <http://tm.ua/laws/int/Introduction%20to%20the%20Patent%20Cooperation%20Treaty%20PCT.pdf> accessed 19 March 2018.
[2148] 'WIPO International Classifications' (*WIPO*) <http://www.wipo.int/classifications/en/> accessed 19 March 2018.
[2149] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[2150] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143).
[2151] ibid.
[2152] ibid.
[2153] Doris Estelle Long, 'Traditional Knowledge and the Fight for the Public Domain' (2006) 5 *John Marshall Review of Intellectual Property Law*; see also Kuek Chee Ying, 'Protection of Expressions of Folklore/Traditional Cultural Expressions: To What Extent is Copyright the Solution?' (2005) 2 *Journal of Malaysian and Comparative Law*.
[2154] Peter K Yu, 'A Tale of Two Development Agendas' (2009) 35 *Ohio Northern University Law Review* 465-573, 467; see also WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143).
[2155] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143); see also Long (n 2153).

new inventions by individuals or corporate entities for a limited duration.[2156] Thus, some countries have resorted to *sui generis* legislation, but protections afforded in domestic laws do not apply to other countries.[2157]

As previously noted, negotiations are ongoing in the WIPO-IGC to fashion an international legal instrument that would 'provide effective protection of TCEs/folklore, traditional knowledge (including traditional medical knowledge), and address the [intellectual property] aspects of access to and benefit-sharing of genetic resources'.[2158] The IGC was established in 2000 and during its early years, it was more concerned with analysing and exchanging national experiences to better understand the interface between intellectual property, genetic resources, traditional knowledge and TCEs.[2159] In 2007, however, WIPO member states mandated the committee to accelerate its work 'without prejudice to any outcome, including the possible development of international instrument or instruments'.[2160] Since then, delegates have made progress, although at a glacial pace, towards consolidated texts which include draft provisions (albeit very bracketed) relating to issues, such as the scope of protection, the term of protection, beneficiaries, rights granted and exceptions and limitations.[2161] Importantly, the policy objectives of the Protection of Traditional Knowledge: Draft Articles state that the instrument will aim to provide the beneficiaries – whom it recognised as 'the indigenous [peoples] and local communities' [2162] – with the means to 'prevent the [misappropriation/illegal appropriation, misuse, and unauthorized use], of their traditional knowledge' and 'achieve the fair and equitable sharing of benefits arising from the use of their traditional knowledge, with prior informed consent or approval and involvement, and taking

[2156] Paul Kuruk, 'Protecting Folklore Under Modern Intellectual Property Regimes: A Reappraisal of the Tensions between Individual and Communal Rights in Africa and the United States' (1999) 48 *American Law Review* 779; see also Ying (n 2153).
[2157] WIPO, 'Traditional Knowledge and Intellectual Property' (n 1143).
[2158] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[2159] Daniel F Robinson, Pedro Roffe and Ahmed Abdel-Latif, 'Mapping the Evolution, State-of-play and Future of the WIPO IGC' in Robinson et al., *Protecting Traditional Knowledge* (n 720).
[2160] WIPO, 'The 45 Adopted Recommendations under the WIPO Development Agenda' <http://www.wipo.int/export/sites/www/ip-development/en/agenda/recommendations.pdf> accessed 16 March 2018.
[2161] Robinson et al., 'Mapping the Evolution' (n 2159).
[2162] WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, The Protection of Traditional Knowledge: Draft Articles, Geneva: Thirty-Fourth Session 12-16 June 2017, WIPO/GRTKF/IC/34/5, art 4.

customary law into consideration as appropriate',[2163] thereby referencing the language of the Convention on Biological Diversity and its Nagoya Protocol.

One of the ways the instrument will seek to achieve these objectives, according to the Draft Articles, is to require that intellectual property applications that concern an invention that relates to or uses traditional knowledge should include information on the country from which the applicant collected or received the knowledge (the providing country), and the country of origin if the providing country is not the same as the country of origin of the traditional knowledge.[2164] The application will also state whether prior informed consent or approval and involvement for access and use has been obtained.[2165] If the required information is unknown to the applicant, he is nonetheless obligated to provide the immediate source from which he collected or received the traditional knowledge.[2166] An application that does not comply with the disclosure requirement will not be processed, and the intellectual property office is given the discretion to set a time limit to remedy non-compliance, after which time the application would be entirely rejected.[2167] Any rights arising from a grant will be revoked and rendered unenforceable when the applicant has failed to comply with mandatory requirements or provided false or fraudulent information.[2168] Regarding this, an alternative proposal provides that rights arising from a granted patent will not be affected by any later discovery of a failure by the applicant to comply with the disclosure requirement. Instead, other sanctions outside of the patent system, provided for in national law, such as criminal sanctions including fines, may, however, be imposed.[2169]

Another way to achieve the policy objectives will be for member states to facilitate and encourage, in accordance with national and customary law, the development of three types of national traditional knowledge databases to which indigenous peoples and local communities may voluntarily contribute their knowledge for its defensive protection as provided by Article 5*bis* of the Draft Articles:

[2163] ibid, art 1.
[2164] The Protection of Traditional Knowledge: Draft Articles, art 7.
[2165] ibid.
[2166] ibid.
[2167] ibid.
[2168] ibid.
[2169] ibid.

> 5*bis*. 1 Publicly accessible national traditional knowledge databases for the purpose of transparency, certainty, conservation, and transboundary cooperation, and to facilitate and encourage, as appropriate, the creation, exchange and dissemination of, and access to traditional knowledge;
>
> 5*bis*. 2 National traditional knowledge databases accessible only by intellectual property offices for the purpose of prevention of the erroneous grant of intellectual property rights. Intellectual property offices should seek to ensure that such information is maintained in confidence, except where the information is cited during the examination of an application for intellectual property protection; and
>
> 5*bis*. 3 Non-public national traditional knowledge databases for the purpose of codifying and conserving traditional knowledge within indigenous and local communities. Non-public national traditional knowledge databases should only be accessible by beneficiaries in accordance with their respective customary laws and established practices that govern the access or use of such traditional knowledge.[2170]

Two points are crucial to note as regards this provision: first, documentation projects of traditional knowledge, whether through databases, written registries and files, treatment guidelines and brochures, images, videos or audio, should be done with the full participation and prior informed consent of indigenous peoples and local communities.[2171] WIPO observes that participation should be transparent and free, engaging all relevant actors and stakeholders who may have an interest in the project during the planning stage and throughout its lifespan, in accordance with international human rights standards.[2172] This also includes providing indigenous peoples and local communities with timely and adequate information to support decision-making processes by their representatives, as well as the right to reject such project should they decide not

[2170] The Protection of Traditional Knowledge: Draft Articles, art 5*bis.*
[2171] World Intellectual Property Organization, 'Documenting Traditional Knowledge – A Toolkit'' (Geneva: WIPO 2017).
[2172] ibid.

to participate or support it.[2173] Applied to the context of access to quality, safe and effective traditional medicine for sustainable development, this would mean that governments of developing and least-developed countries or their entities should develop treatment guidelines, treatment brochures for traditional medicine preparations and conduct research and documentation of traditional medicine with full participation and prior informed consent of indigenous peoples and local communities within their territories, as demonstrated by the Kirumba Crisis-Management Group case study in Chapter five.[2174]

Secondly and intimately related to this, while documentation may be useful for protecting traditional medicine by providing prior art information to prevent illegitimate patents, as previously noted such protection does not extend to the underlying traditional knowledge.[2175] In other words, documentation can be used to stop third parties from acquiring patents over traditional knowledge but does not stop them from using the knowledge. This could lead to further misappropriation, especially in cases where documentation is publicly available. What is more, and as acknowledged by Article 5*bis*. 2, the burden to prove that a claimed invention is already in the prior art lies with patent examiners.[2176] Therefore, when a patent office denies a patent application on the grounds that the claimed invention is traditional knowledge, it is obligated to disclose the entire gamut of the traditional knowledge related to the claimed invention as a citation of prior art to the applicant.[2177] The danger is that this creates a window for 'fishing expeditions' by third parties, who may file frivolous patents with the aim of seeking out traditional knowledge contained in documentation not accessible to the public for subsequent use.[2178] More so, there is no doubt that any subsequent claim may not indicate the use of such traditional knowledge. Thus, having a complementary measure that requires as part of patent disclosure that an applicant *mandatorily* discloses at the point of processing

[2173] ibid.
[2174] Kasilo and Trapsida (n 887).
[2175] WIPO, 'Intellectual Property and Traditional Medical Knowledge' (n 721).
[2176] The Protection of Traditional Knowledge: Draft Articles, art 5BIS; see also R S Praveen Raj, 'Traditional Knowledge: Beware of Patent Protection' (*The IPKat*, 21 March 2017) <http://ipkitten.blogspot.co.uk/2017/03/traditional-knowledge-beware-of-patent.html> accessed 17 August 2017.
[2177] Raj (n 2176).
[2178] ibid.

applications any use of traditional knowledge in developing the subject matter of its claims seems to be a logical and effective way of preventing further misappropriation.[2179]

Having said that, it has been almost 18 years since the IGC was established; 'no agreement has yet been reached, and perhaps never will be'.[2180] As mentioned in Chapter two, important disagreements regarding some key issues remain,[2181] and it would appear that a few powerful developed countries (Canada, Japan, South Korea, the US and to a limited extent, the EU) are determined to ensure that negotiations will not yield a good outcome. [2182] An academic, Chidi Oguamanam, explains that the 'North-South geopolitical power relations as an obvious and enduring undercurrent' has impugned 'expectations and [chilled] hope by developing countries over the sincerity of their developed-world counterparts in nurturing the development agenda within and outside the WIPO committee process'.[2183] One of the lingering disagreements is as regards the role or modality for developing national traditional knowledge databases [2184] – specifically, whether such databases would be complementary, defensive measures against traditional knowledge abuse through the patent regime, or instead, an independent alternative mechanism to the instrument(s) expected from the IGC.[2185] It is worth noting that delegates still argue over what constitutes misappropriation and what definition should be given to it. [2186] Relating to this, there is an apparent trepidation about legitimising the concept of 'biopiracy' in the text of the instrument(s), as it is perceived as a word 'too-politically-loaded'.[2187] Additionally, there has been a lack of consensus concerning whether to include a requirement of disclosure of information on the

[2179] Aman Gebru, 'The Global Protection of Traditional Knowledge: Searching for the Minimum Consensus' (2017) 17 *Marshall Review of Intellectual Property Law* 42, 78; see also Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (1912) 35-36.
[2180] Dutfield, 'TK Unlimited' (n 727) 144-159, 146.
[2181] Robinson et al., 'Mapping the Evolution' (n 2159) 4.
[2182] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2183] ibid 341.
[2184] Daniel F Robinson and Claudio Chiarolla, 'The Role of Databases, Contracts and Codes of Conduct' in Robinson et al., *Protecting Traditional Knowledge*' (n 720) 108; see also Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2185] Robinson and Chiarolla, 'The Role of Databases, Contracts and Codes of Conduct' (n 2184) 108; see also Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2186] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2187] ibid.

utilisation of traditional knowledge and associated genetic resources for patent-protected inventions.[2188] If so, another controversial issue that has arisen is what scope – of the source or the origin – should be afforded to disclosure of information.[2189] Also, the nature of sanctions for non-compliance is a highly contested matter.[2190]

In respect of the disagreement about the scope of the disclosure, the natural and complex migration of genetic resources and associated traditional knowledge shows that a simplistic demarcation between source and origin is problematic[2191] – '[e]ndemicity in biology and culture is less and less common, or at least is much harder to demonstrate'.[2192] Borders are becoming mere 'political constructs' as many indigenous groups straddle one or more, and neither species nor related knowledge – which moreover can be translated into digital codes – can claim national citizenship.[2193] As mentioned in Chapter three, it is possible to find that similar treatments for similar diseases are used by traditional practitioners belonging to indigenous groups in different regions of the world.[2194] Recall the use of *Eriobotrya japonica* (Loquat) as treatment for tuberculosis and cough amongst the Bapedi traditional healers of the Limpopo Province in South Africa, the peoples of Muroto and Susaki in Japan, traditional healers in Korea and traditional Chinese medicine.[2195] In this instance, questions arise as to which indigenous group can make a credible claim to the traditional medical knowledge.[2196]

While Article 10 of the Nagoya Protocol suggests the possibility of a global multilateral benefit-sharing mechanism to deal with cases such as this, developing such a mechanism as already pointed out, is not foreseeable in the near future.[2197] Nevertheless, the Nagoya

[2188] ibid; see also Bagley (n 725) 85.
[2189] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340; see also Bagley (n 725) 85.
[2190] ibid.
[2191] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2192] Dutfield, 'TK Unlimited' (n 727) 144-159, 155.
[2193] ibid.
[2194] Semenya and Maroyi, 'Medicinal Plants Used for the Treatment of Tuberculosis by Bapedi Traditional Healers' (n 832) 316-323; see also Dutfield, 'TK Unlimited' (n 727) 144-159, 152.
[2195] Semenya and Maroyi, 'Medicinal Plants Used for the Treatment of Tuberculosis by Bapedi Traditional Healers' (n 832) 316-323; Nishioka et al. (n 839) 1053-1057; Ito et al. (n 839) 687-693; and Parihar et al. (n 839) 9-18.
[2196] Dutfield, 'TK Unlimited' (n 727) 153.
[2197] ibid 155; see also Dutfield, 'Transboundary Resources, Consent and Customary Law' (n 1971) 259, 260.

Protocol Article 11 calls for cooperation between communities where traditional knowledge is transboundary, and this has been adopted by both the IGC draft text on traditional knowledge and consolidated document on genetic resources.[2198] Also, while recognising disclosure as a crucial strategy against biopiracy, it is equally essential to acknowledge the 'futility of confining the norms of exchange to intellectual property rights, contracts, top-down government regulations…. [those] are the laws of the powerful'. [2199] To effectively protect traditional medical knowledge for sustainable development, it is necessary, and developing, and least-developed countries are well-advised to likewise strengthen the role of customary law concerning the management of resources and the rights and responsibilities relating to associated traditional knowledge in a culturally appropriate manner.[2200]

Thus, at present, intellectual property protection of traditional medical knowledge is a matter for governments of developing and least-developed countries – homes to the majority of the world's indigenous and local communities, and custodians of traditional knowledge.[2201] While no concrete outcome has emanated from the IGC negotiations, the exchanges so far regarding core issues of the legal instrument for the protection of traditional knowledge can be leveraged to form the basis for national legislation or policies.[2202] However, this will depend on the political will of developing and least-developed countries to seize the initiative.[2203] Some countries have taken such steps to protect traditional knowledge by either recalibrating their national patent laws or adopting related legislation to include some of the fiercely contested issues at the IGC. For instance, some developing countries have adopted the disclosure requirement to protect both traditional knowledge and associated genetic resources, including the Andean Community (Bolivia, Colombia, Ecuador, and Peru), Brazil, China, Costa Rica and

[2198] Nagoya Protocol 2010, art 11; see also The Protection of Traditional Knowledge: Draft Articles, art 16; and WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Consolidated Document Relating to Intellectual Property and Genetic Resources, Geneva: Thirty-Fifth Session 19-23 March 2018, art 10.
[2199] Dutfield, 'TK Unlimited' (n 727) 156.
[2200] ibid.
[2201] WIPO, 'Developing a National Strategy on Intellectual Property, Traditional Knowledge and Traditional Cultural Expressions: Background Brief - No 3' (2016).
[2202] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.
[2203] ibid.

India.[2204] Interestingly, some developed countries have equally provided for disclosure of the use of traditional knowledge and genetic resources, namely Belgium, Denmark, France, Germany, Italy, and in more recent times, the EU has submitted proposals advocating the adoption of the disclosure requirement.[2205] That said, this development is with the notable exception of the US.[2206]

Besides the Indian TKDL, there has been other documentation, such as the writing down of the medicinal preparations by the Shipibo communities (Peru), the Maori (New Zealand), and the Maasai (Kenya and Tanzania); and the photographing of medicinal practices of the Shuar (Ecuador).[2207] Additionally, Panama established a *sui generis* regime for the protection of the traditional knowledge of its indigenous peoples through a system of registration in 2000.[2208] The law recognises prior informed consent as a precondition for accessing and using traditional knowledge and envisages negotiation between users and the Traditional Indigenous Authority which is vested with the exclusive collective rights of the registered elements of traditional knowledge.[2209] Reference must also be made to the Thai Traditional Medicinal Intelligence Act 1999, a *sui generis* legislation that rewards traditional healers for their contribution to health care by vesting in them the rights to control and regulate access to traditional medicinal knowledge through a public registry.[2210] Similarly, Peru has adopted a *sui generis* system which declares that the rights of indigenous peoples in their collective knowledge are inalienable and indefeasible.[2211] The law recognises the rights of the indigenous peoples to preserve, develop and dispose of their collective knowledge as they see fit.[2212] Also, tribal representatives are appointed under the law to negotiate with third parties seeking

[2204] 'Disclosure Requirement Table October 2017' (*WIPO*) <http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf> accessed 17 March 2018.
[2205] 'Disclosure Requirement Table October 2017' (n 2204); see also Gebru (n 2179) 42, 78.
[2206] ibid.
[2207] WIPO, 'Documenting Traditional Knowledge – A Toolkit' (n 2171) 9.
[2208] Law No 20 of June 26, 2000, on Special System for the Collective Intellectual Property Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge.
[2209] ibid.
[2210] Protection and Promotion of Traditional Thai Medicinal Intelligence Act, B.E. 2542 (1999); see also Timmermans (n 869).
[2211] Law No 28216 of April 30, 2004, on the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, art 12.
[2212] ibid, art 1, art 32.

access, and the law establishes a negotiated percentage of gross sales from commercial efforts for the welfare of indigenous peoples.[2213] In other words, the law subjects access to traditional knowledge to community prior informed consent, as well as benefit-sharing. The indigenous representative organisation, whose prior informed consent is sought, is required by the law to inform the widest possible number of communities holding the same knowledge that it is entering into negotiations and take into account their various interests.[2214]

Although these are laudable initiatives, it is recognised that national strategies do not adequately cover the international dimension of misappropriation. Nonetheless, it is a positive sign that developed countries have begun to incorporate the disclosure requirements in their laws to require at the time of processing patent applications that applicants indicate any use of traditional knowledge or genetic resources in developing the claimed invention. What is more, countries – developing or developed – need not alter their intellectual property laws to achieve this measure. Adopting administrative rules, which require patent applicants to verify whether or not their invention was based on or derived from traditional knowledge and genetic resources by merely marking a box in a questionnaire, would suffice.[2215] In addition, whereas it is admitted that pre- and post-grant challenges are not sustainable options, they still provide an opportunity for developing and least-developed countries to be proactive in preventing acts of misappropriation, especially in the US. This is worth some consideration because of the change in the position of the law that undocumented foreign knowledge is not admissible as novelty-destroying prior art (as previously mentioned).[2216] In essence, oral evidence of prior art may now be admissible in the United States. Finally, it is hoped that by the end of 2018, consensus will be reached at the IGC on the core provisions of the international legal instrument for the effective protection of traditional knowledge, or perhaps one should begin to consider that its 'potential for shaping policy, and advancing the development imperative, may not be necessarily a function of the ultimate outcome'.[2217]

[2213] ibid, art 14, art 8.
[2214] ibid, art 6.
[2215] Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources' (1912), 36.
[2216] Leahy-Smith America Invents Act 2011, s 3; see Summary of the America Invents Act (n 755).
[2217] Oguamanam, 'Ramifications of the WIPO IGC for Intellectual Property and Development' (n 727) 339-346, 340.

Providing a basis upon which progress can be made in other fora and regimes, national and international, to combat the scourge of biopiracy may be all that it is destined to be.[2218]

In conclusion, in spite of its deficiencies, the Convention on Biological Diversity is a useful framework that provides general principles to guide its contracting parties in making decisions regarding biodiversity management. As established, conservation and sustainable use are critical for minimising the loss of biodiversity in order to ensure sustained access to traditional medicine. Its Nagoya Protocol, notwithstanding the lack of strong enforcement provisions, comprises significant legally binding provisions to prevent misappropriation of genetic resources and associated traditional knowledge, including access and benefit-sharing requirements. Given that nothing concrete has resulted from the IGC negotiations, intellectual property protection of traditional medical knowledge is an issue for national legislation. Thus, in order to ensure access to quality, safe and effective traditional medicine for sustainable development, the effective conservation of biodiversity and sustainable use of its components, implementation of access and benefit-sharing requirements, and protection of traditional medical knowledge will primarily depend on the political will of governments of developing and least-developed countries to take the necessary legislative, administrative or policy measures. These measures should be adopted with the full participation of indigenous and local communities within their territories, and in conformity with international human rights obligations and customary laws pertaining to the management of resources and traditional knowledge. Accompanying this, the willing cooperation of other stakeholders – developed countries and the biotechnology and pharmaceutical industries – that have significant interests in the utilisation of genetic resources and associated traditional knowledge is equally important, but certainly beyond the control of developing and least-developed countries.

[2218] ibid.

CONCLUSION

The overall objective of this research was to consider how developing, and least-developed countries can make progress towards achieving the United Nations (UN) 2030 Agenda for Sustainable Development. The research recognised the realisation of Goal 3, which aims to ensure healthy lives and promote well-being for all at all ages, as central to the successful collective action for progress towards the Agenda. As explained by the research in Chapter one, this is because of the mutually dependent relationship that exists between the concepts of sustainable development and health. Whereas health is determined by social, economic and environmental dynamics (the sustainable development triad), and so, a product and indicator of sustainable development, health is pivotal to the realisation of *all* sustainable development goals because individuals and populations require some level of good health to participate in, contribute to and enjoy sustainable development.

The research noted that to maintain a reasonable measure of health and well-being to achieve sustainable development, access to essential medicines is indispensable for preventing and treating diseases. Nonetheless, the reality in developing and least-developed countries is the prevalence of malaria, tuberculosis, HIV/AIDS, communicable and non-communicable diseases and the lack of access to essential medicines for treatment. While this situation of lack of access to medicines is the result of multiple barriers, the research observed that the policy incoherence between the patent rights of inventors provided by the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, international human rights law, trade rules and public health in the context of health technologies presents a more complex problem and has occupied discussions within the international community. Thus, this research addresses only this barrier to access to medicines in developing and least-developed countries and is limited in this respect.

Recognising the potential impact of poor health and lack of access to medicines on progress towards sustainable development in developing and least-developed countries, Goal 3 aims to achieve health and well-being for all particularly those in developing and least-developed countries by eradicating malaria, tuberculosis, HIV/AIDS,

communicable and non-communicable diseases by 2030 by promoting universal health coverage and access to essential medicines through the full use of the TRIPS flexibilities by developing and least-developed countries and the negotiation of a binding convention on drug research and development (R&D) that delinks the costs of R&D from end prices of health technologies and redirects R&D to pressing public health needs. On this note, this research investigated four main questions:

(a) Can the strategy of utilising the TRIPS flexibilities and the negotiation of a binding convention on drug R&D promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030?

(b) Can traditional medicine contribute to achieving sustainable development by 2030 through providing treatment for malaria, tuberculosis and HIV/AIDS?

(c) Are there challenges confronting the use of traditional medicine for health care?

(d) How can traditional medicine be integrated into the national health systems of developing and least-developed countries?

(a) Can the strategy of utilising the TRIPS flexibilities and the negotiation of a convention on drug R&D promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030?

The research makes an original contribution to literature by assessing the functionality of this strategy. While there is considerable literature on TRIPS flexibilities and access to medicines, none has critically assessed the full use of the flexibilities, as well as the proposed binding convention on drug R&D for promoting universal health coverage and access to medicines in developing and least-developed countries to achieve the 2030 Agenda for Sustainable Development. In this regard, the research in Chapter two considered the incoherence between the justifiable rights of inventors, trade rules, international human rights and public health and examined how this interaction impacts on access to medicines in developing and least-developed countries. It found that while

the justification for awarding patent rights is to incentivise innovation by allowing inventors to exercise monopoly rights over their inventions in return for sharing technology with society, the inefficiencies and abuse resulting from monopoly market power have outweighed social gains, in the context of access to affordable life-saving medicines in developing and least-developed countries.

Chapter two further considered the Doha Declaration which first confirmed the right of member states of the World Trade Organization (WTO) to use the TRIPS flexibilities to address public health concerns and analysed how the flexibilities can be leveraged to enhance access to medicines. Notwithstanding that a few developing and least-developed countries have used the TRIPS flexibilities to enhance access to medicines, the research discovered that there are impediments to their utilisation. Notably, the implementation of higher intellectual property standards for economic and political gains, pressures and threats to enforce these high standards from developed countries, particularly the US, to protect the interest of the pharmaceutical industry, and TRIPS-plus obligations in free trade agreements prevent developing and least-developed countries from using the TRIPS flexibilities. The research concluded that these would equally impede the use of the flexibilities to promote universal health coverage and access to medicines to attain Goal 3; more so, given the proliferation of free trade agreements comprised of TRIPS-plus provisions, such as the Trans-Pacific Partnership (TPP) Agreement which would induce developing and least-developed countries with promises of access to foreign markets.

Furthermore, drawing from the negotiation history of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity 2010, which took almost 10 years to conclude, and the ongoing process within the World Intellectual Property Organization's Intergovernmental Committee (WIPO-IGC) relating to the intellectual property protection of genetic resources, traditional knowledge and traditional cultural expressions/folklore which has lasted nearly 18years with no concrete agreement, the research envisaged a parallel situation with the negotiation of the binding convention on drug R&D. It suggested that the process would be complex and long-winded owing to the presence of multiple stakeholders with competing interests, as well as highly controversial issues which must be agreed upon for the outcome to be workable. In

relation to the latter, the research foresees a conflict between the objectives of the TRIPS Agreement and the United States Bayh-Dole Act 1980 on the one hand, and the proposed convention on drug R&D on the other hand.

On this basis, the research found that the effectiveness of the strategy of the full use of TRIPS flexibilities and the negotiation of a binding convention on drug R&D to promote universal health coverage and timely access to medicines in developing and least-developed countries by 2030 is marred by economic and political realities of these countries, as well as great complexity and uncertainty. Because of this, the research considered the potential for traditional medicine to contribute to sustainable development so that if it were found that it could provide treatment for malaria, tuberculosis and HIV/AIDS, then it would propose its integration into the national health systems of developing and least-developed countries as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D. In this respect, the research makes a novel contribution to knowledge in that it adopts an interdisciplinary approach – drawing knowledge from four disciplines, i.e. ethnopharmacology, health policy, law and medical anthropology – to propose how developing and least-developed countries can make progress towards achieving the 2030 Agenda for Sustainable Development.

(b) Can traditional medicine contribute to achieving sustainable development by 2030 through providing treatment for malaria, tuberculosis and HIV/AIDS?

To answer this question, Chapter three of this research explored various traditional remedies for malaria, tuberculosis and HIV/AIDS; traditional approaches to sickness, causation and healing in the traditional medicine cosmology; preparation and administration of traditional medicine; and the reason some patients find traditional medicine more appealing than conventional medicine. The research found that the traditional medicine system embodies curative and palliative treatments for malaria, tuberculosis and HIV/AIDS. These remedies have for many centuries been a source of primary health care for the populations of developing and least-developed countries. Significant international organisations including the UN, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have recognised this fact, as well as the potential for traditional medicine to contribute to realising sustainable

development. According to WHO, when compared with conventional medicine, traditional medicine is care that is close to homes, accessible and affordable.[2219] Also, the traditional medical approach to treatment in terms of causation of sickness and healing practices makes it more appealing to some patients than conventional treatments, as traditional healing methodologies are directed towards achieving whole-person-care.

Thus, this research concluded that traditional medicine could promote universal health coverage and access to medicines and proposed its integration into the healthcare systems of developing and least-developed countries as a complementary tool to the use of TRIPS flexibilities and (probably) a convention on drug R&D for progress towards sustainable development by 2030. Regarding this conclusion, it must be noted that the research investigated only the potential for traditional medicine to provide treatments for malaria, tuberculosis and HIV/AIDS notwithstanding that Goal 3 of the 2030 Agenda for Sustainable Development also aims to reduce global maternal mortality, end preventable deaths of newborns and children under five years, eradicate neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable and noncommunicable diseases by 2030.[2220] This was aimed at achieving clarity of purpose and analysis, and because malaria, tuberculosis and HIV/AIDS are listed among the top 10 causes of death in developing and least-developed countries.[2221]

(c) Are there challenges confronting the use of traditional medicine for health care?

The traditional medicine system is not perfect, and Chapter four of this research evaluated the challenges to its proper use and integration into national health systems. It found that there have been negative reports concerning dishonest and unsafe practices by traditional practitioners and manufacturers of herbal medicines, which have had immediate and harmful effects on the health of patients. This 'bad press' has not only resulted in a section of society regarding traditional remedies as 'fake' but also its practitioners as 'quacks'. There has also been a considerable level of marginalisation and discrimination against

[2219] Chan, 'Opening Remarks at the International Forum on Traditional Medicine' (n 10).
[2220] United Nations, 'Transforming Our World: the 2030 Agenda for Sustainable Development' (n 3) Goal 3.
[2221] 'WHO Updates Fact Sheet on Top 10 Causes of Date (27 January 2017)' (n 21).

traditional practitioners by their conventional medicine counterparts, despite global recognition of traditional medicine and its practitioners as a source of primary health care. Besides ideological differences, this is perhaps due to the negativity surrounding traditional medicine and its practices. Moreover, there has been an increase in the global call for the generation of more evidence regarding the safety and efficacy of traditional medicine, irrespective of the statistics that almost 80 per cent of the populations of developing and least-developed countries rely on it for treatment. Thus far, various attempts at ascertaining the pharmacological effects of herbal medicines are unconvincing due to the adoption of inadequate research methodologies. Hence, these calls have suggested the adoption of rigorous clinical trials.

Additionally, there is a lack of quantitative research to determine the levels of existing access to traditional medicine – relating to both cost and geographic accessibility, as well as a lack of qualitative research to establish the factors that could potentially constrain such access. One of such factors is the environmental concern of the loss of biological diversity, as traditional medicine depends on genetic resources and other forms of biodiversity as its main ingredients. The loss of biodiversity could undermine access to traditional medicine as it could mean not only the loss of existing traditional remedies but also of potential treatments. Also, the traditional medical knowledge implicated in the use of biodiversity is of substantial benefit to the biotechnology and pharmaceutical industries as it is increasingly appropriated sometimes for research and potential drug discovery, other times, adapted and patented without compensation to the indigenous and local communities. While research and documentation, development of treatment guidelines, and development of treatment brochures for preparing traditional medicine, which are to be made publicly available, are essential to the quality, safety and efficacy of traditional medicine, these measures will effectively make traditional medical knowledge readily accessible for further exploitation by third parties.

Chapter four found that these challenges stem from the inadequacy of existing national policy and regulatory frameworks on the traditional medicine system, its practices, products and practitioners, and observed that for traditional medicine to contribute to realising sustainable development by 2030, there would be a need for developing and least-developed countries to take appropriate national policy and regulatory actions to

address these challenges, otherwise, the challenges could undermine the use of traditional medicine in the national health systems of these countries to promote universal health coverage and access to medicines.

(d) How can traditional medicine be integrated into the national health systems of developing and least-developed countries?

This research in Chapter five explained that addressing these challenges is key to appropriately integrating traditional medicine into the national health systems of developing and least-developed countries. Integration entails the official recognition and inclusion of traditional medicine in all areas of health care delivery; utilising research, conventional medicine, and traditional medicine to diagnose, treat and prevent diseases; registration and licencing of traditional medicine practitioners; registration of traditional medicine products and regulation of traditional medicine practices; establishment of national traditional medicine hospitals and inclusion of traditional medicine in national insurance schemes; establishment of research institutions on traditional medicine, and training traditional medicine practitioners at all levels of education, including universities; and inclusion of traditional medicine in national health programmes, and national planning and budgeting.[2222]

Thus, to address the challenges confronting the proper use and integration of traditional medicine into the national health systems of developing and least-developed countries, this research advanced strategic actions targeted at appropriate and effective regulation of traditional medicine, its practices, products and practitioners. These actions include the formulation of adequate national policy and regulatory frameworks on traditional medicine which should: recognise its role in health care delivery and provide the necessary basis for its use as an affordable health care option; provide for the training, qualification and licencing of traditional practitioners; promote collaboration between conventional and traditional medicine practitioners; provide consumer information on proper use; ensure quality, safety and efficacy of traditional medicine therapies; and provide for the regulation and registration of traditional medicine products. Furthermore, to ensure *access* to quality, safe and effective traditional medicine for sustainable

[2222] Cooper et al., *Africa's Health Challenges* (n 1112).

development, the research also suggested the adoption of necessary legislative, administrative or policy measures for the effective conservation of biodiversity and sustainable use of its components, implementation of access and benefit-sharing requirements, and protection of traditional medical knowledge and discussed how these can be implemented in practice. It noted that these measures should be adopted with the full participation of the indigenous and local communities within the territories of developing and least-developed countries, and in conformity with international human rights obligations and customary laws relating to the management of resources and traditional knowledge.

The research equally suggested that unlike the negotiation of the convention on drug R&D, addressing these issues through domestic policies and regulations in time to pursue the 2030 target for achieving sustainable development is straightforward and uncomplicated. The technical guidelines developed by the WHO, and the good practices that can be gleaned from other jurisdictions, particularly China and India, who have fully integrated traditional medicine into their national health systems, can serve as templates for other developing and least-developed countries to fashion their regulations in a manner that best suits their circumstances.

Research Implications

As noted in Chapter one, the goals of the 2030 Agenda for Sustainable Development are merely global developmental aspirations aimed at guiding policy formulation and decision-making with the aim of achieving sustainable development by 2030.[2223] Thus, governments are expected to take ownership and establish national frameworks for the achievement of the 17 goals.[2224] In this connection, this research could occasion the inclusion of the integration of traditional medicine into the national health system as a complementary measure to the use of TRIPS flexibilities and a binding convention on drug R&D (to promote universal health coverage and access to medicines) in the national frameworks of developing and least-developed countries to operationalise the goals of the 2030 Agenda for Sustainable Development.

[2223] United Nations, 'Transforming Our World: the 2030 Agenda for Sustainable Development' (n 3).
[2224] 'United Nations Sustainable Development Agenda' (n 150).

Again, the research could lead to further consideration of issues, such as the exact extent and contours of 'apprenticeship' in the context of qualification and licencing of traditional practitioners; the suitability of clinical trials for evaluating traditional medicine steeped in magico-religious practices and beliefs; and the effect of standardisation on the cost of traditional medicine by the WHO, non-governmental organisations and other stakeholders interested in or that encourage the utilisation of traditional medicine for promoting public health, as these issues could potentially render any policy or regulation on traditional medicine defective. This research provided some suggestions regarding these issues in Chapter five based on which such further investigation may proceed.

The research could also lead to further research on herb-drug and herb-herb interactions (discussed in Chapters four and five). This is important because of the concurrent use of traditional and conventional medicine by consumers, many times without consulting either a conventional or traditional medicine practitioner. Notwithstanding that the simultaneous use of both therapies may produce good results, it may also counter and amplify the effects of treatments.[2225] Closely related to this, this research could lead to further consideration of the relevant measures to ensure that retailers of traditional medicine are licenced persons, possessed of sufficient traditional medical knowledge. As explained in Chapter five, this is crucial as they are expected at the point of purchase to provide consumers with information on the proper use of specific traditional therapies.

Finally, the former WHO Director-General, Dr Margaret Chan remarked that:

> [Conventional] medicine and traditional medicine make unique contributions to health, but both also have their limits and shortcomings. Countries, especially in the developing world, [should be] wise to use the best of these two approaches in a carefully integrated and regulated way.[2226]

[2225] *Guidelines for Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine* (n 981).
[2226] Chan, 'Opening Remarks at the International Forum on Traditional Medicine' (n 10).

On this note, the hope is that this research will be valuable to the governments of developing and least-developed countries when establishing national frameworks for operationalising the sustainable development goals, as well as a veritable guide for harnessing the full potential of traditional medicine for realising sustainable development. Beyond that, it is hoped that this research contributes to improving the lives of the millions who lack access to health care without *truly* leaving anyone behind.

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