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INDIA'S TRIPS COMPLIANT PHARMACEUTICAL PATENT LAWS: WHAT LESSONS FOR INDIA AND OTHER DEVELOPING COUNTRIES?

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Abstract

India's TRIPS compliant Patent (Amendment) Act 2005 saw the transformation of its laws from a process patent regime to a product patent regime. The amendments have had a direct impact on India's generic drugs manufacturing sector, which was developed through the process patent regime introduced under the 1970 Act. The knock-on effect will soon be felt both domestically and globally, as a number of developing countries have come to rely strongly on Indian generics. This article seeks to study the effectiveness of the Act of 2005, and if it can be seen as an instance of success of the TRIPS provisions in Articles 7 and 8 read along with the Doha Declaration. It will be queried if developing countries in the WTO can possibly benefit from the model set-up by India for the issuance of compulsory licenses, and to check the practice of 'evergreening' by pharmaceutical patent holders. Recent decisions from the Indian judiciary and the quasi-judicial authorities, along with the procedures and policies put in place will be used to carry out the study.

Key Words: TRIPS; Indian patent laws, pharmaceutical patents; evergreening; compulsory licensing; generics; parallel imports

I. Introduction

India passed the Patent (Amendment) Act of 2005 to bring its patent laws in line with the TRIPS Agreement's agenda of extending international intellectual property protection to patent right holders, who were mostly from developed countries. India through the implementation of the TRIPS Agreement was constrained to give up on its process patent regime, which was originally introduced in 1970 to develop its generic drug manufacturing market and to create better access to medicines. The introduction of the new patent laws witnesses a radical shift in Indian policies on pharmaceutical and chemical patenting. Taking TRIPS compliance exercise as an opportunity, India has firmed up on its compulsory licensing laws, introduced direct provisions on 'exhaustion of patent rights', 'pre-grant' and 'post-grant' opposition, and has most importantly introduced provisions to check the practice of evergreening. It can be argued that the patent law regime introduced in India demonstrates how developing countries can utilise the TRIPS flexibilities to introduce laws to suit the requirements of its own health care policies.

The decision to change the patent laws gains in importance, as India is one of the fastest growing pharmaceutical markets, with some writers referring to it as the 'pharmacy of the developing world'. The jurisprudence from the courts on the Amended Act of 2005 is still nascent; but one can still infer, from the decisions of Indian courts and quasi-judicial authorities, the strong stance taken by India on patent evergreening, the use of pre-grant and post-grant opposition, and compulsory licensing. Although there is clear judicial precedent, emerging from developed countries like the U.S. and U.K. where evergreening is scorned upon,

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it is India that has taken the first step in introducing legislative measures to check the practice of evergreening. A combined reading of the amended laws, the provisions of the TRIPS Agreement and the recent judicial and quasi-judicial renderings from India present an interesting area for study. They seem to suggest that developing countries can operate the TRIPS flexibility to deal with national emergencies, as access to patented medicines become unaffordable and reliance is more on generic medicines.

II. Indian Patent Laws

Indian patent laws are steeped in its colonial past, as it was under British rule for close to two hundred years, between 1757 and 1947.¹ This period saw the introduction of the common law in India, and importantly the first legislation on patent rights in 1856, which was primarily designed to serve the interest of British patent holders. It is safe to assume that any legislative attempts to codify a practice of granting patents began in India only during the British rule and in particular from the nineteenth century². The Indian patent laws can be broadly categorised under two heads, viz., ‘pre-independent India’ and ‘post-independent India’.³ The legislative history of pre-independent India’s patent laws is well chronicled,⁴ and the current study will focus on patent laws passed in India from the post-independent period, leading up to its amendment in 2005.

A. Post-Independence

At the time of independence from British rule, India was predominantly an agrarian society, with over two thirds of its population living in rural areas. Access to medicines was scarce, and much limited to the affluent, due to a lack of indigenous production of drugs,⁵ and for want of a proper health care system. India’s industry sector was weak, and was only contributing to a mere quarter of the national income.⁶ Post-independent India’s pharmaceutical industry was still largely controlled by multinational pharmaceutical corporations, with eight of the ten pharmaceutical companies controlled by foreign interests and holding nearly all of the pharmaceutical patents.⁷ The indigenous pharmaceutical companies felt the growing need for change, as in their view the patent system in place was not

¹ India was under the British East India Company Rule from 1757 until the transfer of power to the British Crown in 1858, and later Queen Victoria was proclaimed Empress of India in 1876. The British rule, referred to as ‘British Raj’ came to an end in August 1947. The region referred to as ‘British India’ also included the modern day states of India, Pakistan, Nepal, Bangladesh, and other countries.

² Legislative attempts began with the first legislation under British rule on the subject, and the Indian Patent Act was passed in 1856. Roundabout the same time, power was completely transferred to the Crown from the British East India Company.

³ The modern history of Indian patent laws can be brought within three categories, namely, pre-legislation period, the period of exclusive privileges, and the period of patents. See DN Choudhary, *Evolution of Patent Laws: Developing Countries Perspective* (Capital Law House, 2006) 13.

⁴ TV Garde, ‘India’ in P Goldstein and J Strauss (eds), *Intellectual Property in Asia: Law, Economics, History and Politics* (Springer 2009). For a detailed legislative history of the Indian Patent Act, see generally, JM Mueller, ‘The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation’ (2007) 68 U Pitt L Rev 491.

⁵ Choudhary (n 3) 9-10. See also ‘First Five Year Plan’ promulgated by India, where one of the objectives sought to be achieved was identified as improvement of “...standard of living of the people by efficient exploitation of the resources of the country”. Government of India, Planning Commission <<http://planningcommission.nic.in/plans/planrel/fiveyr/default.html>> accessed 5 September 2013.

⁶ Garde (n 4) 55.

⁷ P Wilson & A Rao, ‘India’s Role in Global Health R&D’ Center For Global Health R&D Policy Assessment (2012) 47 <<http://healthresearchpolicy.org/assessments/india%E2%80%99s-role-global-health-rd>> accessed 2 November 2013; T Garde (n 4) 57. See also (n 4), ‘First Five Year Plan’ Chapter 32 entitled ‘Health’, where one of the priorities mentioned was achieving ‘...self sufficiency in drugs and equipment’. The plan clearly identified the need for ‘...a co-ordinated programme of development of the pharmaceutical industry’

capable of ensuring effective patent rights to promote industrial growth and development in India.⁸

In 1948 the government of India appointed the Patent Enquiry Committee, which was tasked with reviewing the Patents and Designs Act 1911, and to advise on any changes.⁹ In 1950, three years after gaining independence, India adopted its first written constitution,¹⁰ and officially became a republic. The policies contained in the constitution were designed to give the State the ownership and control of key community resources.¹¹ It is to be noted here that India's second five-year plan had industrialisation at the heart of the agenda with the objective of achieving self-reliance.¹² In April 1950, the committee headed by Justice Bakshi Tek Chand,¹³ submitted a report, recommending a series of changes, including the introduction of compulsory licensing, and the creation of a more stable legal framework to tackle the abuse of patents.¹⁴ In 1953, based on the recommendations of the committee, a bill was tabled before lower house of the parliament, which was to lapse due to the dissolution of the lower house.¹⁵

B. Justice Ayyangar Committee

In 1957, a decade after independence, the Government of India appointed yet another committee, headed by Justice N Rajagopala Ayyangar, to review the adequacy of the Indian patent system. This committee known as Justice Ayyangar Committee presented its report in September 1959.¹⁶ The report was in two parts, with the first part dealing in general aspects of patent laws and containing recommendations, and the second part presenting comments on the lapsed bill of 1953 and suggesting improvements.¹⁷ Some of the views expressed by this

⁸ Garde (n 4) 59.

⁹ Dr YK Hamied, 'Indian Pharma Industry: Decades of Struggle and Achievements' (2 April 2005) 3 <<http://www.arvindguptatoys.com/arvindgupta/avra-hamied.pdf>> accessed 12 September 2013. The author states that prior to World War II, there was no basic drug manufacturer in India, and that in post-independent India, the key sectors of agriculture, medicine, and education, were prioritised for heavy investment in order to achieve self-reliance and self-sufficiency.

¹⁰ Although India gained independence from British rule on August 15 1947, it had the status of a 'Dominion' until 1950, with George VI as head of state, and Earl Mountbatten as Governor General. The Indian Constitution adopted in 1950, is seen as the longest written constitution of any sovereign nation in the world, containing 444 articles, 22 parts and 12 schedules. See generally G Austin, *The Indian Constitution: Cornerstone of a Nation*, (OUP 1999), where the author observes the Indian Constitution as being a document primarily aimed at furthering the objective of social revolution.

¹¹ The foundations of the policy are to be found in the Directives on State Policy in the Indian Constitution, which states that "the ownership and control of the material resources of the community are so distributed as best to subserve the common good." Constitution of India, Part IV, Art. 39(b). See also Garde (n 4) at 55.

¹² Garde (n 4) at 57. The model presented by Mr Prasanta Chandra Mohalonobis for India's second five year plan had a nationalist approach to industrialization, with an argument for self-reliance over foreign manufactured goods.

¹³ Justice Tek Chand a retired judge from the High Court of Calcutta headed the Patents Enquiry Committee (also known as Tek Chand Committee) between 1948 and 1950.

¹⁴ The committee filed a 216 page report. It recommended that the Patents Act should contain provisions to ensure that food and medicine, surgical and curative devices were made available to the public at the cheapest price possible while giving reasonable compensation to the patentee. See also Choudhary (n 3) 10. The committee relied on some of the findings of the Swan Committee report which was constituted by the Board of Trade in the UK; S Banerji, 'The Indian Intellectual Property Regime and the TRIPs Agreement' in C Long (ed), *Intellectual Property Rights in Emerging Markets* (American Enterprise Institute Press, 2000) 63.

¹⁵ Controller General of Patents, Designs and Trade Marks, India, *Manual of Patent Practice and Procedure* (3rd edn 2008) 8.

¹⁶ A Report on the Revision of the Law in India Relating to Patents for Inventions (September 1959) <http://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf> accessed 13 October 2013. See also AD Damodaran, 'Indian Patent Law in the Post-TRIPs Decade: S&T Policy Appraisal' *Journal of Intellectual Property Rights* Vol. 13 (September 2008) 415; Choudhary (n 3) 13.

¹⁷ Controller General of Patents, Designs and Trade Marks, India (n 15) 10.

committee on how food patenting and pharmaceutical inventions can affect accessibility to medicines, and on compulsory licensing continued to form part of the debates before the WTO in the run up to the signing of the TRIPS Agreement.¹⁸

The Ayyangar Committee's report which is seen as being central to the creation of patent laws in post-independent India, recommended that India should deviate from patent policies of industrialised countries,¹⁹ and proposed radical changes to the then existing Indian patent laws.²⁰ The committee observed that the high cost of drugs in post-independent India resulted directly from the monopoly exercised by foreign based pharmaceutical companies over drug production in India. It was of the view that food and medicines, which are important in daily life and vital for the health and well being of the community, should be made available to the public at a reasonable price, and hence strongly recommended against the granting of product patents in those areas of food and medicines.²¹ The rationale behind the recommendation for a process patent regime stemmed from the premise that the recognition of the 'process of production' would accelerate research in developing alternative processes, leading to increased diversity of products at competitive prices.²² For the purposes of industrial advancement the Ayyangar Committee favoured the 'process' rather than 'product' protection for chemicals in India.²³ The Committee noted that in countries where restrictions were placed on the patents for chemical inventions by confining patentability to the invented processes, there was a similar or even greater restriction on the grant of patents to inventions in relation to articles of food and medicine. This was to be expected, as most of the pharmaceutical preparations were the products of chemical processes.²⁴ Around the same time, the pharmaceutical industry in India was also campaigning for changes to be brought to the patent laws, as it strongly believed that the Patents Act 1911 was not fit for purpose and had to be completely changed.²⁵

C. Indian Patent Act 1970

India's first post-colonial legislation on patents, the Indian Patent Act 1970 came into force on 20 April 1972. The objectives of the Act were, to boost the Indian economic growth through indigenous technology development, to make the fruits of technological innovations to be accessible for public purposes (particularly in public health), to protect domestic enterprise, and to meet the constitutional obligations of the State under the fundamental rights

¹⁸ S Ragavan, 'Of the Inequals of the Uruguay Round' (2006) 10 Marq Intell Prop L Rev 273, 282. The TRIPS Council's task was to enable local industrialization in least developed nations, and the Ayyangar Committee Report which also advocated self-reliance can be seen as a useful resource in that pursuit.

¹⁹ *ibid.*

²⁰ S Narayanan, *Patent Law* (4th edn Eastern Law House, 2006) 6. See also S Ragavan (n 18) 281, where the author observes that the report, as modified by the Report of the Joint Committee of Parliament in 1966, forms the backbone of the Indian patent system.

²¹ Ragavan (n 18) 285.

²² Ragavan (n 18) 285-286.

²³ Under the German Patent Law of 1877, where patentability was restricted to novel chemical processes, a stimulated research with regard to alternative methods for producing the same product was witnessed. The rise of the German chemical industry dated from 1877, and in the course of a period of 30 years, it witnessed tremendous growth and came to occupy the foremost position in Europe. See also Choudhary (n 3) 26-27.

²⁴ Choudhary (n 3) 27.

²⁵ In 1961, the Indian Drug Manufacturers Association (IDMA) was formed for the purpose of boosting the national pharmaceutical industry. The organisation campaigned for the amendment of the patent laws then prevailing in India. See generally, Hamied (n 9).

guaranteed to the citizens of the country.²⁶ The Patent Act 1970 was hailed by the UNCTAD and some developing countries as a progressive statute.²⁷

The Act of 1970 recognized both process and product patents, but the latter was not available for food, medicine, or drugs or substance produced by chemical processes, and also redefined the working of the patents.²⁸ The two key features of the Act were the introduction of 'process patents' for inventions relating to food, medicine and chemical entities, and the shortening of the term of patent protection for pharmaceutical patents.²⁹ Under the Act of 1970 the term of process patent protection over food, drug, and medical inventions was limited to five years. In essence, the process patent regime defined under S 5(1) of the Patent Act 1970 protected the method through which the product was arrived at, *i.e.*, the process of making the product, and excluded the protection of the end-product.³⁰ It was, therefore, perfectly possible for several manufacturers to simultaneously hold a process patent for identical products.

The process patent regime under the Act of 1970 aided the Indian pharmaceutical companies to manufacture generic drugs using expired patents. The Act also introduced an automatic right to license (compulsory license) in the case of life-saving drugs. This safeguard along with the Drug Price Control Order 1970, which put a cap on the maximum price that could be charged, ensured that life-saving drugs were available at a reasonable price in India.³¹ The process patent framework also enabled indigenous pharmaceutical companies to produce drugs at an affordable cost. The growth of the Indian generic pharmaceutical industry is largely attributed to the Indian Patents Act of 1970. It is also to be observed that the number of patent applications filed during the operation of the Act remained stagnant³², and it is arguable that it did not contribute to any major innovation in the pharmaceutical sector.

The Indian drug manufacturers, aided by the 1970 Act, were able to develop alternate processes for production of life-saving drugs. The domestic pharmaceutical industry in India

²⁶ Choudhary (n 3) 37. The objectives of the Act were in line with the State Policy contained in the Constitution of India which provided in Article 39 that '...State shall, in particular, direct its policy towards securing (a)..... (b) that the ownership and control of the material resources of the community are so distributed as best to serve the common good; and (c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment'.

²⁷ *ibid* 40. See also, FM Scherer & J Watal, 'Post-TRIPS Options for Access to Medicines in Developing Countries' (2001) Commission on Macroeconomics and Health Working Paper Series, Paper No. WG4:1, 4 <http://library.cphs.chula.ac.th/Ebooks/HealthCareFinancing/WG4/Paper%20No.%20WG4_1.pdf> accessed 16 September 2013. Many of today's developed countries excluded pharmaceutical products from patent protection until quite recently. Germany excluded pharmaceutical product patents until 1968, Italy until 1978, Spain until 1992, Portugal until 1992, Finland until 1995, Iceland until 1997, Switzerland until 1977, and Norway until 1997.

²⁸ Controller General of Patents, Designs and Trade Marks, India (n 15) 10.

²⁹ *Ibid* 11.

³⁰ The Patents Act of 1970, S 5 (1) reads as follows: In the case of inventions— a. claiming substances intended for use, or capable of being used, as food or as medicine or drug, or, b. relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substance themselves, but claims for the methods or processes of manufacture shall be patentable.

³¹ India introduced drug price control measures during the Chinese conflict in 1962, amidst fears that it could escalate prices of essential drugs. These measures were taken with a view to making access to medicines affordable within the country. The Drug Price Control Order, introduced in 1970, imposed an indirect control on the profitability of pharmaceutical industries. M Das & SK Basu, 'Drug Price Control in India: "The Past and the Present"', NSHM Journal of Pharmacy and Healthcare Management VOL. 03 (February 2012) 41-47, 41. See also, R Govindaraj & G Chellaraj, 'The Indian Pharmaceutical Sector: Issues and Options for Health Sector Reform' (September 2002) World Bank Discussion Paper No.437 <<https://openknowledge.worldbank.org/bitstream/handle/10986/15231/multi0page.pdf?sequence=1>> accessed 18 September 2013. The authors observe that "...the objective of the Indian Government regarding pharmaceuticals have remained the same: promotion of the domestic industry and ensuring adequate access to good quality drugs."

³² Damodaran (n 16) 415.

developed over a relatively short period of time, making India self-sufficient in the production of basic drugs covering major therapeutic groups.³³ As a result, drug prices in India ranged from 5 to 30 times lower than in countries where ‘product patent’ was in place. The next three decades, saw India emerge as a globally recognized producer of low-priced generic drugs.³⁴ India is currently the leading exporter of generic antiretroviral drugs (ARVs) to other developing and least developed countries, which is used in the treatment of HIV/AIDS.³⁵ The Indian Patents Act, 1970 is viewed by some as a landmark in the history of industrial development in India, and by some others as having a negative effect to innovation in the country.³⁶

III. WTO Membership, TRIPS Negotiation and Compliance

The World Trade Organization (WTO), which is a rules-based organization, was established in January 1995. The TRIPS Agreement is one of the covered agreements of the WTO, and along with the agreements on trade in goods, and trade in services, constitutes the three pillars on which the organization operates. The TRIPS Agreement is seen as one of the most controversial components of the WTO system, due to its far-reaching implications on international intellectual property rights protection. It covers a wide range of intellectual property rights protection, from copyrights and trademarks, to patent rights and trade secrets. The Agreement obligates countries to grant product patents for a period of twenty years in all fields of technology, including pharmaceuticals.³⁷ The TRIPS Agreement sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. It requires all Member states to establish legal and administrative procedures at the domestic level to ensure effective protection to patent holders (both domestic and international) for their intellectual property rights, and also the appropriate mechanism for redress in the event that their rights are infringed. Member states failing to embody these standards into their national laws or to give effect to them may be challenged by the trading partners before the WTO following the dispute settlement procedures.

A. India’s Role in the TRIPS Negotiation

The negotiations on the TRIPS Agreement were conducted during the long running Uruguay Round between 1986 and 1994.³⁸ Prior to these negotiations on the TRIPS Agreement, intellectual property rights were principally regulated at the international level by

³³ Choudhary (n 3) 40.

³⁴ Mueller (n 4) 514-516. See also Cherri Grace, ‘Update on China and India, and Access to Medicines’ (2005) DFID Briefing Paper No 8 <<http://www.heart-resources.org/wp-content/uploads/2012/09/Update-on-China-and-India-and-Access-to-Medicines.pdf>> accessed 18 September 2013. By 2004, India was supplying 22 percent of the world’s generic drugs and a significant amount of the vaccines to the developing world.

³⁵ B Waning, E Diedrichsen & S Moon, ‘A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries’ (2010) *Journal of International AIDS Society* <<http://www.biomedcentral.com/content/pdf/1758-2652-13-35.pdf>> accessed 5 September 2013.

³⁶ JO Lanjouw, ‘The Introduction of Pharmaceutical Product Patent in India – Heartless Exploitation of the Poor and Suffering’ (1997) NBER Working Paper No. W6366, 3-4 <<http://www.nber.org/papers/w6366>> accessed 15 September 2013. The author opines that the 1970 legislation weakened intellectual property protection available in India, particularly to pharmaceutical innovations. In the author’s view the pharmaceutical product innovations, as well as those for food and agrochemicals, became un-patentable, allowing innovations patented elsewhere to be freely copied and marketed in India.

³⁷ The TRIPS Agreement also contains flexibilities, including grant of compulsory licenses, and allowance of parallel imports. CM Correa, ‘Intellectual Property Rights and Inequalities in Health Outcomes’ in Ronald Labonté, et al. (eds), *Globalization and Health: Pathways, Evidence and Policy* (Routledge 2009) 265.

³⁸ The Uruguay Round was the eighth round of multilateral trade negotiations, and took over seven years to complete. WTO, ‘The Uruguay Round’ <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> accessed 12 September 2013.

a number of treaties administered by the World Intellectual Property Organization (WIPO), which included the Paris Convention on Industrial Property and the Berne Convention on Literary and Artistic Works.³⁹ The negotiations on TRIPS Agreement came about at a time when there was a deadlock between developed and less developed countries over the revision of the Paris Convention for the Protection of Industrial Property before the WIPO.⁴⁰ Close to fifty developing countries that sought membership at the WTO, were not granting patent monopolies for drugs at the time the Uruguay round of negotiations were taking place.⁴¹

India was a vocal opponent of the initiative to include intellectual property rights in the GATT system, and was seen as the voice of the developing countries at the TRIPS negotiations. In July 1989, it submitted a detailed paper elaborating the developing country perspective on the negotiations.⁴² India, along with Brazil, Argentina and other developing countries, strongly criticised the proposal on the grounds that the GATT mandate did not allow for the discussion of substantive issues on intellectual property, and it was only the World Intellectual Property Organization (WIPO) that had the institutional competence to discuss such issues.⁴³ The Indian position was debated extensively at the negotiations,⁴⁴ but towards the end of 1989 and the beginning of 1990 almost all developing countries had changed their position. The shift came about due to the coercive strategies adopted by the United States, and as a result India found itself isolated in the negotiations.⁴⁵ During the same period, India had sought assistance from the International Monetary Fund (IMF), to address depletion in its foreign currency reserves which had brought it to the brink of an economic crisis. It is worth pointing out that the U.S. was the chief benefactor of the IMF at that time and heavily influenced any outcomes.⁴⁶ Due to a combination of its weak financial position and potential trade losses with the United States, India relaxed its opposition to the TRIPS Agreement at the negotiations.⁴⁷ With India agreeing

³⁹ UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (2005) 3.

⁴⁰ The 1980's and 1990s saw the shift in the administration of international intellectual property rights from the WIPO to the GATT through the lobbying of transnational corporations (TNCs). The TNCs were convinced that renegotiation of the Paris Convention under the aegis of the WIPO will never give them the level of protection they sought. See also, PK Yu, 'Currents and Crosscurrents in the International Intellectual Property Regime' *Loy LA L Rev* 38(1) (2004) 323, 357-58.

⁴¹ CM Correa, 'Patent Rights' in CM Correa and AA Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer 2008) 227, 229.

⁴² UNCTAD-ICTSD (n 39) 6.

⁴³ J Watal, *Intellectual Property Rights in the WTO and Developing Countries*, (Kluwer Law International 2001) 21. See generally P Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (2002) UK IPR Commission Study Paper 8 <http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf> accessed 2 October 2013.

⁴⁴ UNCTAD-ICTSD (n 39) 7. India had all along argued that any principle or standard relating to IPRs should be carefully tested against the needs of developing countries, and that it would be inappropriate to focus the discussions on the protection of the monopoly rights of the owners of intellectual property, when almost 99 percent of the patents were owned by industrialised nations. It also stressed that substantive standards on intellectual property were more in the realm of socio-economic, industrial and technological development, especially in the case of developing countries. It urged that the group focus on restrictive and anti-competitive practices of the owners of IPR and evolve standards and principles for their elimination to avoid distortion of trade.

⁴⁵ RC Bird & DR Cahoy, 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' 5 *NW. J. TECH. & INTELL. PROP.* 1 (2007) 400, 403-04. See also J Watal, (n 43). For a detailed account of the TRIPS negotiations, see DJ Gervais, 'Intellectual Property, Trade & Development: The State of Play' *Fordham L Rev* 74(2) (2005) 505.

⁴⁶ GK Foster, 'Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath' 3 *UCLA J Int'l L & Foreign Aff* (1998) 283, 316. See also generally, P Drahos (n 43). The author argues that developing nations had comparatively far less influence on outcomes in the international intellectual property standard-settings, at both pre-TRIPS and post-TRIPS negotiations. The author attributes the weak position of the developing nations to the use of coercive tactics by the U.S. and EU, who had all along stressed the need for excessively high global standards on intellectual property protection.

⁴⁷ Foster, (n 46) 317.

to accede to the TRIPS Agreement, any opposition from the developing countries on the inclusion of intellectual property rights protection into the WTO's covered agreements came to an end.

Following Concerns raised by African groups and supported by other developing countries, the Council for TRIPS⁴⁸ agreed to deal specifically with the relationship between the TRIPS Agreement and public health. Developing countries had argued that the TRIPS Agreement did not limit their sovereign powers when addressing health crises such as HIV/AIDS, but on the other hand the U.S. and Switzerland argued that the only flexibility afforded by the Agreement was its staggered implementation in some cases. There was a growing concern amongst the developing countries that patent rules might restrict access to affordable medicines for their citizens, and also impede their efforts to control diseases of public health importance, including HIV/AIDS, tuberculosis and malaria. In June 2001, for the first time, the Council for TRIPS systematically considered the relationship between public health and TRIPS.⁴⁹

The Doha Declaration on TRIPS and Public Health (the Doha Declaration) made on November 2001, helped in resolving the above concerns and other divergent perspectives and views held by the member states on the application and ambit of the TRIPS Agreement.⁵⁰ The concerns raised by India and other developing countries⁵¹ regarding the implications of the TRIPS Agreement on public health were reflected in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health. WTO Members also adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). One of the key issues emphasized in the Doha Declaration was that the provisions of the TRIPS Agreement should "be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles".⁵² The Doha Declaration proclaimed that each Member had the right to grant compulsory licenses, and to determine the grounds for the grant and also what constituted a national emergency.

To some degree the economic liberalisation policy introduced in the early 1990s can be seen as one of the factors in India relaxing its robust opposition to the inclusion of intellectual property rights within the ambit of the WTO.⁵³ India's accession to the TRIPS Agreement, and its move from being a process patent regime to a product patent regime was viewed by some⁵⁴

⁴⁸ The Council for TRIPS is charged with the monitoring of WTO Members' compliance with their obligations under TRIPS. The legal basis for the establishment of the Council is found in Article IV.5 of the WTO Agreement, which stipulates that the Council "shall oversee the functioning" of TRIPS Agreement. See also UNCTAD-ICTSD (n 39) 739.

⁴⁹ The World Health Assembly had in 1996 examined the relationship between public health and the TRIPS Agreement, as it was mandated to report on the impact of the work of the WTO with respect to national drug policies and essential drugs. This was addressed in a resolution on the Revised Drug Strategy, Resolution WHA49.14 (25 May 1996).

⁵⁰ JT Gathii, 'The Legal Status of Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties' Harv JL & Tech (Spring 2002) 292, 293.

⁵¹ The developing countries were well supported by the NGOs during the negotiations. Drahos (n 43) 26-28.

⁵² Doha Declaration on The TRIPS Agreement and Public Health <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf> accessed 12 October 2013.

⁵³ VK Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework' Global Business & Development Law Journal Vol. 25 (2011) 323, 330.

⁵⁴ One of the strong critics of the TRIPS Agreement was Justice VR Krishna Iyer, a former judge of the Supreme Court of India and a panel member of the People's Commission on GATT, which filed its report in 1996. He was of the strong view that the act of signing the TRIPS Agreement would be *ultra vires* the Constitution of India. BK Keayla, 'TRIPS Patent System and Doha Declaration: Implementation Process by India' (2004) RGICS Working Paper Series No. 45, 3 <<http://www.rgics.org/pdf1/wpn-45.pdf>> accessed 10 October 2013.

in India as a clear departure from the vision the founders had of a free India. The action was strongly criticised, as it was firstly viewed as being in violation of the fundamental rights guaranteed under Constitution of India, and secondly, the TRIPS Agreement valued and prioritised the economic gains of patent holders living in faraway countries, ahead of the millions who would suffer from non-availability of affordable medicines.⁵⁵ This was not just about India, but also about other developing and least developed countries that relied strongly on the generic drugs produced by Indian drugs manufacturers.

B. TRIPS Compliance

The accession to TRIPS Agreement mandated India to carry out fundamental changes to its existing intellectual property laws, especially in relation to patents.⁵⁶ India was to change its patent laws to recognise product patents and move away from process patents. Following the transitional arrangement provisions in the TRIPS Agreement, India was not required to comply with the product patent requirements of TRIPS until 2005,⁵⁷ while least developed countries were given an extension up to 1 January 2016 by the TRIPS Council which met in 2002. Nevertheless, India as per Art 70.8(a) was mandated to create a 'mailbox' for the filing of patent applications that would be examined when changes to the law were made and came into effect in 2005.⁵⁸ The mailbox facility set up by India following the Appellate Body's report,⁵⁹ allowed for the filing of pharmaceutical product patent applications pending the introduction of changes to the Patent Act of 1970.

The TRIPS Agreement also required the grant of EMRs, or exclusive marketing rights, for mailbox applications⁶⁰ that met specific conditions during the transitional period. Under Article 70.9, if the products featured in the mailbox applications were granted patent, and had also obtained marketing approval in any of the WTO member countries, then India was obligated to grant a five year exclusive marketing rights (EMRs) before the patent on the product was either granted or rejected in India.⁶¹ In March 1999, India passed the Patents

⁵⁵Justice VR Krishna Iyer, 'Human Health and Patent Law' (*Frontline*, Vol. 17 - Issue 21, 14-27 October 2000) <<http://www.frontline.in/static/html/fl1721/17210790.htm>> accessed 15 October 2013.

⁵⁶ The TRIPS Agreement obligates all WTO members to make available a 20-year patent protection for novel, non-obvious and useful inventions, whether products or processes. Although the obligations under the TRIPS Agreement relate to all the areas of intellectual properties identified by the Agreement, it was the obligation relating to patents that required the most changes as far as India was concerned. S Raghavan, 'Patent Amendments in India in the Wake of TRIPS' CASRIP Newsletter (Winter 2001) 1 <<http://www.law.ou.edu/faculty/facfiles/CASRIP.pdf>> accessed 18 September 2013.

⁵⁷ TRIPS Agreement, Articles 65(2) and 65(4), in certain cases, allows delaying the application of the provisions on product patents to such areas of technology for an additional period of five years. See also L Chung, 'Use of Paragraph 6 System for Access to Medicines' 36 *NCJ Int'l L & Com Reg* (2010) 137, 174.

⁵⁸ TRIPS Agreement, Art 70.8(a), requires developing countries to set up a 'mailbox' system during the transitional period.

⁵⁹ As India failed to formally enact the 'mailbox' regime into law, the US resorted to the WTO's dispute resolution mechanism. WTO, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products –Report of the Appellate Body* (19 December 1997) WT/DS50/AB/R, where India was directed to set up the 'mailbox'. Following the report of the Appellate Body, the 'mailbox' was implemented by the Patents (Amendment) Act, 1999, No. 17, Acts of Parliament, 1999, ss 2 and 3. India also took other steps towards complying with TRIPS requirements in 2002, when it extended a twenty-year term to all patents, reversed the burden of proof in process infringement cases, and introduced for the first time a definition of "inventive step." The Patents (Amendment) Act, 2003, No. 38, Acts of Parliament, 2003, ss 27 and 43, 3(f).

⁶⁰ K.G. Narendranath, 'Patent Mailbox Opens, Pfizer is Top Applicant' (*The Financial Express*, 21 March 2005) <http://www.financialexpress.com/old/fe_full_story.php?content_id=8578> accessed 14 October 2013. Around 9000 mailbox applications were filed during the transition period, of which 84 per cent originated from multinational corporations, with Pfizer coming first. Indian submissions totalled for 1,406, including 1,300 in the pharmaceutical sector. Applications from the U.S. topped the list, followed by India, Germany and the UK.

⁶¹ TRIPS Agreement, Art 70.(9) requires the grant of exclusive marketing rights (EMRs) in certain cases following the setting up of the 'mailbox' provision under Art 70(8). See also B Dhar and KM Gopakumar, 'Effect of Product

(Amendment) Act 1999,⁶² to implement the mailbox procedure as per Article 65(4) of the TRIPS Agreement. The 1999 Act was given retroactive effect from 1 January 1995 to facilitate receipt of patent applications for pharmaceutical and agro-chemical products under the mailbox procedure.

A second amendment to the 1970 Act was made in 2002, which introduced a twenty year patent term,⁶³ reversed the burden of proof for process patent infringement, and also modified the compulsory licensing requirements.⁶⁴ The passing of the 2002 Amendment Act also concluded India's accession to the Paris Convention for the Protection of Industrial Property 1883, and the Patent Co-operation Treaty 1970. The combined effect meant that the India had to follow the national treatment principles laid down in the Paris Convention and also grant a twelve month priority period for foreign applicants who had previously filed a patent application in their home countries.⁶⁵ One of the notable changes brought about by the 2002 amendment was the grounds for seeking a compulsory license on pharmaceutical patents. Broadly, a compulsory license can be sought in the case of non-working of the patented work after three years of sealing of the patent, in the event of a national emergency (through a government notification), or in certain cases where patents are essential for the efficient working of other patented inventions.⁶⁶ In conclusion it can be stated that the 2002 Amendment laid the groundwork for the passing of the Patent (Amendment) Act 2005.

IV. The Amendment Act 2005

The membership of the WTO was expected to spur the economic growth of a nation, and India was doing as much as possible to create an environment to achieve this goal and bring in foreign investment. To this end, and to meet the obligation as a WTO member, India was to pass the Patent (Amendment) Act 2005.⁶⁷ This amendment Act was preceded by a presidential ordinance in 2004.⁶⁸ The efforts to make changes to the patent laws generated much controversy even in the discussion stages,⁶⁹ both in India and abroad, as the action of the Indian government was seen as overzealous in some quarters.⁷⁰ The NGOs and the World Health Organisation (WHO) in particular, were concerned about the plight of the HIV/AIDS sufferers in the least developed countries and who were strongly reliant on Indian generic

Patents on the Indian Pharmaceutical Industry' Centre for WTO Studies, Indian Institute of Foreign Trade (2008) 6, <<http://wtocentre.iift.ac.in/Papers/3.pdf>> accessed 19 October 2013.

⁶² The Patents (Amendment) Act 1999, No. 17, Acts of Parliament, India, 1999 <<http://www.wipo.int/edocs/lexdocs/laws/en/in/in030en.pdf>> accessed 14 October 2013.

⁶³ Prior to the 2002 Amendment, pharmaceutical process patents issued under the 1970 Act lasted for a period of five years from sealing, or seven years from the date of the patent, whichever was less.

⁶⁴ The Patents (Amendment) Act 2002, No. 38, Acts of Parliament, India, 2002 <http://www.wipo.int/wipolex/en/text.jsp?file_id=207496> accessed 14 October 2013.

⁶⁵ Article 2, and Article 4(C)(1), Paris Convention for the Protection of Industrial Property 1883 (as Amended on 28 September 1979) <http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf> accessed 15 October 2013.

⁶⁶ Sections, 84, 92, and 91 respectively of The Patents (Amendment) Act 2002, No. 38, Acts of Parliament, India, 2002 <http://www.wipo.int/wipolex/en/text.jsp?file_id=207496> accessed 14 October 2013.

⁶⁷ See statement of Kamal Nath, the then India Union Minister of Commerce & Industry, on the Ordinance Relating to Patens (Third) Amendment, Press Information Bureau, Government of India (27 December 2004) <<http://pib.nic.in/newsite/erelease.aspx?relid=6074>> accessed 15 October 2013.

⁶⁸ The Patents (Amendment) Ordinance, 2004, Ordinance No. 7, India <<http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf>> accessed 15 October 2013.

⁶⁹ R Ramesh, 'Cheap AIDS Drugs Under Threat' *The Guardian UK* (London, 23 March 2005) <<http://www.theguardian.com/world/2005/mar/23/india.aids1?INTCMP=SRCH>> accessed on 13 October 2013.

⁷⁰ See, letter from Achmat Dangor, Director of Advocacy, Communication and Leadership for UNAIDS, to Kamal Nath, the then Minister of Commerce and Industry of India on the Amendments to the Patents Act under Debate (23 February 2005) <<http://www.cptech.org/ip/health/c/india/unaid02232005.html>> accessed 15 October 2013.

drugs.⁷¹ On the one hand India was bound by its obligations to WTO, the international body facilitating negotiations in world trade, and on the other hand it was strongly urged by a UN Special Envoy to ensure that India's new patent laws did not harm the supply of generic drugs to the developing countries.⁷²

The picture that emerged at that time was a collage of worry, expectation, and disbelief, as it was generally perceived that any action taken to change the patent regime other than a process patent will have a long lasting impact on India and its generic drug producers, on pharmaceutical patents around the world, and most importantly on millions of sufferers of HIV/AIDS living in the least developed countries,⁷³ who were strongly reliant on India's generic ARVs. There was also a growing feeling that the Indian government was working on a TRIPS compliant patent legislation that could potentially jeopardise access to medicines for many poor patients in the developing world. Against this backdrop, India passed the Patent (Amendment) Act 2005, to bring its patent laws in line with the TRIPS Agreement, while bearing in mind its unwritten commitment to the developing countries and least developed countries that strongly relied on its generic drugs to do battle with the scourge of HIV/AIDS. The 2005 Amendment Act, contains a wider framework for compulsory licensing, incorporates procedures governing both 'pre-grant' and 'post-grant' opposition to patent applications, contains provisions on 'patentable subject matter' and 'exhaustion of patent rights', and most importantly witnesses the setting up of an 'inventive step' for patentability into the patent regime.

A. Compulsory Licensing

The discussion on the issue of compulsory license became more intense in the 1990s with the HIV/AIDS crisis. Currently, the population that is most affected from the crises live in developing and least developed countries, where generic ARVs are seen as the only answer, as patented drugs for the treatment of the disease are absolutely unaffordable. India is currently the leading exporter of generic antiretroviral drugs (ARVs) in the world.⁷⁴ Patent protection is cited as one of the reasons for the limited availability and affordability of medication for the treatment of HIV/AIDS.⁷⁵ Compulsory licensing of patented drugs is said to be one of the essential pillars of the patent system, and found in international conventions,⁷⁶ enables the access to essential medicines in times of need. It is well recognised that compulsory licences

⁷¹ See Letter from U.N. Special Envoys for HIV/AIDS to the then Prime Minister and President of India on the Amendments to the Patents Act Under Debate (11 March 2005), where India's efforts and role in promoting access to essential medicines is referred to as being crucial <<http://www.cptech.org/ip/health/c/india/unaid03112005.html>> accessed 15 October 2013.

⁷² *ibid.*

⁷³ See Letter from Jim Yong Kim, HIV/AIDS Director of the World Health Organization to Dr A Ramadoss, the then Minister of Health and Family Welfare of India (17 December 2004) <<http://www.cptech.org/ip/health/c/india/who12172004.html>> accessed 15 October 2013.

⁷⁴ Waning, et al., (n 35).

⁷⁵ *ibid.*

⁷⁶ Article 5A of the Paris Convention for the Protection of Industrial Property, provides for the signatories to the Convention to have the right 'to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.' Under Art 5A 'failure to work', or 'insufficient working' of a patent would tantamount to abuse of the patent rights, and can be seen as giving rise to grounds for the grant of compulsory license. GHC Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (WIPO Publication 2007) 67-73. See also Article 31, TRIPS Agreement ("Other Use Without Authorization of Rights of Holder"), and Article 30, TRIPS Agreement ("Exceptions to Rights Conferred"). The Doha Declaration, seen as a corollary to the TRIPS Agreement, proclaims that each Member had the right to grant compulsory licenses.

play an important role in preventing abuse of patent rights that may arise when a patent holder tries to pre-empt entry of competitors using its statutory rights.⁷⁷

The Doha Declaration states that every WTO Member has “the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”.⁷⁸ As mentioned earlier, the Amendment Act 2005 contains a much liberal framework for the grant of compulsory license, and the Indian government preserved the original provisions of the 1970 Patents Act regarding compulsory licensing for use within India.⁷⁹ Similar provisions on compulsory licensing have also been introduced into Brazilian legislation.⁸⁰ Under section 84 of the Act, an application for compulsory license is sustainable three years from the grant of a patent, upon successfully satisfying the condition that the “reasonable requirements of the public with respect to the patented invention have not been satisfied”, that “the patented invention is not available to the public at a reasonable price,” and lastly the patented invention is not worked in the territory of India.⁸¹ The circumstances for “reasonable requirements of the public” would arise if the patent holder refuses to grant a licence on reasonable terms. This refusal, in turn, can affect the development of new trade or industry in the country, the establishment or development of commercial activities in India, and the development of the export market for a patented article manufactured in India.⁸²

Some NGOs have raised concerns about the three-year lock-in period prescribed under section 86(6) for lodging an application for the grant of compulsory license. Their concerns relate to the plight of HIV/AIDS sufferers living in developing and least developed countries, and fast developing resistance to first-generation ARV Drugs, and who therefore will be in need of second and third-generation drugs in a short time. These second and third-generation drugs are mostly under patent, and going by section 84(6) will not be available for compulsory licensing for three years.⁸³ The Indian government in its Amendment Act 2005 expanded the opportunities to obtain compulsory licences for export of patented pharmaceuticals to least developed countries. The new Act confers on the government the powers to grant a compulsory license in circumstances involving national health emergencies,⁸⁴ and it also provides the mechanisms to manufacture and export patented medicines to other countries that do not have the necessary infrastructure to manufacture drugs.⁸⁵

⁷⁷ Dhar and Gopakumar (n 61) 15. See also S Barnes, Note, ‘Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa’ 91 Ky LJ (2003) 911, 922.

⁷⁸ Doha Declaration on the TRIPS Agreement and Public Health (n 52).

⁷⁹ See Indian Patents (Amendment) Act 1999. Sections 84, 86, 89, 92, and 93 of the Patents Act govern domestic compulsory licenses, which remains largely unchanged by the Amendment Act of 2005. See also B Waning, et al., (n 35).

⁸⁰ See generally Article 68 - 74, Chapter VIII, Section III, Law No. 9.279 of May 14, 1996, to Regulate Rights and Obligations Relating to Industrial Property (Brazilian Laws), which provides for the grant of compulsory licences under various circumstances. It is worth mentioning that Brazil used the threat of compulsory licenses on the patent for Glivec (marketed in the US as Gleevec) to obtain a price discount of more than 65 percent.

⁸¹ The Act contains a list of instances where the reasonable requirements of the public shall be deemed to be unsatisfied. See sections 84(1)-(6) of The Patents Act, No. 39 of 1970, India Code (1995) <http://www.wipo.int/wipolex/en/text.jsp?file_id=128092> accessed 1 November 2013.

⁸² Dhar and Gopakumar (n 61) 16.

⁸³ D Jain and JJ Darrow, ‘An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India’ Health Matrix, Journal of Law-Medicine, Vol. 23, Issue 2 (2013) 438-439 <<http://law.case.edu/journals/HealthMatrix/Documents/23HealthMatrix2.Darrow.pdf>> accessed 2 November 2013.

⁸⁴ The Patents (Amendment) Act, 2005 sec. 55 (updating s 92A).

⁸⁵ Ibid. The new section 92A titled “Compulsory License for Export of Patented Pharmaceutical Products in Certain Exceptional Circumstances” expressly provides for the manufacture of essential medicines in response to public health crises. Section 92A(1) enjoins that the importing country must have “insufficient” or “no manufacturing” capacity, and allows for the importation of patented pharmaceutical products from India.

From a reading of the relevant provisions on compulsory licensing, it is clear that the Indian government and the Controller of Patents are vested with sweeping powers to grant compulsory licenses in suitable cases. Before the grant of any compulsory license the concerned authority is required to take into account additional factors such as, the nature of the invention and the measures already taken by the patentee or licensee to make full use of the invention, the ability of the applicant to work the invention to the public advantage, the capacity of the applicant to undertake the risk in providing capital and working the invention, and the efforts made by the applicant to obtain a licence from patentee on reasonable terms and conditions and that such efforts were not successful within a reasonable period.⁸⁶

Some commentators are sceptical about these provisions. In their view the procedural requirements are too onerous and could result in delays, as it is not clear if the grant of a compulsory license would be automatic if a patentee refuses to issue a voluntary license on reasonable terms, as the grounds for determination of anti-competitive practices in India have not been spelt out clearly either in the Patents Act, or in the Indian Competition Act 2002.⁸⁷ It can be said that the Amendment Act 2005, through its provisions, protects India's existing generics drugs industry, as a patentee cannot possibly bring a patent infringement action against a generic manufacturer who has been producing a patented product prior to 2005, and who also continues to manufacture the product on the date of the patent grant. Some writers have criticised this as essentially being a 'compulsory license' granted to the generics producers.⁸⁸ Since the introduction of the new laws in 2005, the offices of the Controller of Patents, having offices in the four major cities in India, have been inundated with applications from overseas corporations. During the same period there had been a number of applications received from Indian generic drugs manufacturers for grant of compulsory license. In this regard, a couple of decisions made by the authorities in India in recent months are taken up for study as they present contrasting pictures.

a. Natco v Bayer

Sorafenib Tosylate is a drug used in the treatment of liver and kidney cancer. The patent holder, Bayer Corporation was marketing the drug under the trade name of Nexavar. Bayer Corporation, extended its patent application for Sorafenib Tosylate to India in 2001, and the registration was granted in March 2008. Further, the Indian authorities granted Bayer regulatory approval for marketing the drug under the trade name Nexavar in India in 2008. In July 2011, Natco Pharmaceuticals Ltd., an Indian generics manufacturer lodged its application for the grant of compulsory license to manufacture Nexavar.⁸⁹ This was seen by some industry experts as a strategic move by Natco, as there were pending infringement actions against Natco, brought by Bayer. Natco argued that Bayer's patented drug, Nexavar, had not been made available to the public at a reasonably affordable price, and that the reasonable requirements of the public had not been met. It was also Natco's case that Bayer failed to work the patent in

⁸⁶ Dhar and Gopakumar (n 61) 16-17.

⁸⁷ Dhar and Gopakumar (n 61) 17; Jain and Darrow (n 83) 439; see also KM Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' *The Law and Development Review* Vol. 3, No. 2, Article 11 (2010) 325, 340-341.

⁸⁸ R Chodock, 'TRIPS: Transformation of the Indian Patent System and Its Effect on the Indian Pharmaceutical Sector' No 2 ABA, The Scitech Letter 4 (Fall 2005) 4, 6 <<http://www.paulweiss.com/media/1825664/00000001.pdf>> accessed 2 November 2013; AK Hason and JE Shimotake, 'Recent Developments in Patent Rights for Pharmaceuticals in China and India' 18 *Pace Int'l L Rev* (2006) 303, 313-314.

⁸⁹ Prior to lodging the above application, Natco Pharmaceuticals had filed applications for grant of compulsory license under section 92A of the Indian Patent Act for two cancer drugs, namely, Suninat and Tarceva as early as 2007. Suninat and Tarceva are patented to Pfizer and Roche, respectively. Natco intended to manufacture and export them to Nepal, but later withdrew its application for issue of compulsory license.

India within the specified three-year period, as it was still importing the drug into the country although it had a manufacturing unit in India, which in turn resulted in an unaffordable price being charged for the drug in India.

It was Bayer's case that a 'reasonably affordable price' should be calculated with reference to the public as well as the patentee and the price of the patented drugs has to be sufficient to support future drug development. Further, 'working' in relation to patents in India meant supplying the drug to the Indian market on a commercial scale, that the relatively small market demand for Nexavar did not justify the manufacture of the product in India, and that Bayer was providing the drug only to 2 percent of the estimated number of patients in India. The Controller of Patents considered the fact that Bayer had not at all sold the medicine Nexavar in India in 2008, and only sold very small quantities in 2009 and 2010. The Controller of Patents found that all the necessary grounds prescribed under section 84 of the Indian Patents Act for the issuance of a compulsory licence were met, as Bayer did not meet the reasonable requirements of the public with respect to the patented drug Nexavar, that Bayer's pricing of the drug was exorbitant and did not constitute a 'reasonably affordable' price, and that Bayer could not be said to have complied with the 'working' requirements under the Indian Patent Act, as it did not manufacture the drug Nexavar in India.⁹⁰

On March 9 2012, the first compulsory licence was granted by the Indian Controller of Patents at Mumbai, on the application taken out by Natco to manufacture and sell a generic version of the drug Nexavar. The drug manufactured under the compulsory license by Natco, was to cost nearly 30 times lower than that was being charged by the patent holder Bayer Corporation, and Natco was to pay Bayer a quarterly royalty at 6 per cent of the net sales of the drug. Bayer Corporation challenged the decision of the Controller of Patents before the IPAB (Intellectual Property Appeal Board), Chennai. The IPAB in its judgment dated 14 Sep 2012 confirming the order of the Controller of Patents, held that Bayer did not satisfy the reasonable requirement of the public and that the drug was not made available at a reasonably affordable price. Bayer has since challenged the decision of the IPAB before the High Court in Mumbai. The Controller's observations on 'local working' by Bayer on the drug Nexavar will prove controversial, as almost 90 percent of the drugs patented in India to multinationals are not manufactured in India, and could be susceptible to compulsory license.⁹¹ Worthy of noting is the fact that compulsory license was granted on an application taken out by a third party and not by the government, and all parties concerned were heard following the principles and procedures set out under the TRIPS compliant Indian patent legislation.⁹²

Some have expressed the view it is possible that India might be in violation of the non-discrimination principle mandated under Article 27(1) TRIPS,⁹³ and others have opined that going by WTO decision in the *Canada – Patent Protection of Pharmaceutical Products*⁹⁴ the

⁹⁰ In the proceedings Bayer argued that Cipla, another Indian generic drugs manufacturer, had been marketing a generic version of Nexavar in India at a much lower price since April-May 2010, such that no objection regarding the medicine's availability could be legitimately raised. However, the Controller noted that Bayer had commenced infringement proceedings against Cipla, and thus the sales carried out by an alleged infringer should not be taken into account to support Bayer's position.

⁹¹ S Basheer, 'India's First Compulsory License: Patents vs. Public Health?' IP Osgoode (2 April 2012) <<http://www.iposgoode.ca/2012/04/india%E2%80%99s-first-compulsory-license-patents-vs-public-health/>> accessed 23 October 2013.

⁹² The decision was welcomed by Médecins Sans Frontières (MSF), as it demonstrated that new patented drugs can be produced by generic makers at a fraction of the price. MSF Press Release <http://www.doctorswithoutborders.org/press/release_print.cfm?id=5816> accessed 5 November 2013.

⁹³ E Bonadio, 'Compulsory Licensing of Patents: The Bayer/Natco Case' Eur IP Rev, Issue 10 (2012) 719, 720.

⁹⁴ WTO, *Canada – Patent Protection of Pharmaceutical Products* – Report of the Panel (17 March 2000) WT/DS114/R.

action is unlikely to constitute any violation.⁹⁵ In the aftermath of the IPAB decision in the above case, there are signs that patent holding multinationals are forging alliances with local manufacturers in India, as they view voluntary licensing to local partners under mutually agreeable terms as an effective way to avoid compulsory licensing and also at the same time expand their market presence in the region.⁹⁶ The swiftness with which the multinational pharmaceutical corporations are reacting to the decision to avoid any further losses to their patent rights and market share is striking.

b. BDR v Bristol-Myers Squibb

Dasatinib which is used in the treatment of Chronic Myeloid Leukemia (CML) is marketed by the patent holder Bristol-Myers Squibb (hereafter Bristol-Myers) under the brand name Sprycel. In March 2013, the Mumbai based BDR Pharmaceuticals filed an application under section 84 of the Indian Patent Act before the Controller of Patents, Mumbai for the grant of compulsory license to manufacture a generic version of the drug Dasatinib. BDR Pharmaceuticals (hereafter BDR) argued that the drug had received ‘orphan drug designation’⁹⁷ in the US, Europe and Switzerland, and that it had the capacity to manufacture and supply the drugs in India. It was also contended by BDR that its efforts to engage the patentee in a dialogue for the purposes of securing a grant of a voluntary license were fruitless, and hence it was constrained to approach the Controller of Patents with an application for grant of compulsory license for the drug Dasatinib. The patentee Bristol-Myers, in contrast, was able to demonstrate that it did respond in time to the applicant’s request for voluntary license and sought additional information regarding BDR’s capabilities, intent, etc., but did not receive any response from the applicant.

The Controller of Patents concluded that the applicant BDR Pharmaceuticals failed to satisfy the requirements for grant of a compulsory license under section 84 of the Indian Patent Act. The Controller of Patents observed that the stage to make a decision on the merits of the case presented under section 84 had not arrived yet, as the applicant deliberately refrained from engaging in any kind of dialogue with the patentee for the purposes of securing the grant of a voluntary license, and also the applicant did not follow the scheme of law and the procedure mandated for the grant of a compulsory license under section 84 of the Indian Patent Act.

To the patentee Bristol-Myers, the decision is a relief, as it did not lose any revenue on its patent, but is a big disappointment to millions of patients suffering from Chronic Myeloid Leukemia (CML), as the drug will not be accessible due its very high price. In India, a month’s dose of the drug costs about Rs 100,000, and BDR’s application for compulsory license was based on the premise that it will be able to sell a month’s dose of the drug for a mere Rs 8,100. In sharp contrast to the response to the decision made in the *Natco v Bayer* case, which was received with shock by multinational drug manufacturers operating in India, the decision in the *BDR v Bristol-Myers* case was received in muted silence. The above two applications for grant of compulsory licenses were made under section 84 of the Indian Patent Act. The above

⁹⁵ S Basheer (n 91). The author also argues that TRIPS is premised on the promise of technology transfer to developing countries, and that a local working provision is geared towards encouraging such technology transfer.

⁹⁶ Some of the alliances referred to here are marketing arrangements and does not include technology transfer to local manufacturing units. See CH Unnikrishnan, ‘Compulsory License May Spur More Voluntary Licensing Deals’ *Livemint* (24 January 2013). <<http://www.livemint.com/Home-Page/f0R9060osU7bENFNwlnx5O/Compulsory-licences-may-spur-more-voluntary-licensing-deals.html>> accessed 23 Oct 2013.

⁹⁷ Orphan drugs are used in the treatment of patients with rare diseases. The term orphan drug is used both in US and EU legislations to describe a drug that is indicated for a rare disease, or ‘orphan disease’. Under the US Orphan Drug Act, ‘orphan drug’ designation is accorded if the drug is intended to treat a condition affecting fewer than 200,000 of the population in the US, or which will not be profitable within 7 years following approval by the FDA. In the EU it is intended to treat a disease affecting fewer than 5 per 10,000 of the population.

decision demonstrates that Indian authorities are keen to interpret the law in the light of its true purport, and compulsory licence will not be granted on all applications.

c. Other Developments:

In Feb 2013, while the above applications for the grant of compulsory licenses were pending, the Department of Industrial Policy and Promotion (DIPP) sought details from the Indian Health Ministry regarding three medicines sold by Roche and Bristol-Myers Squibb. The drugs in question were Trastuzumab, Ixabepilone, and Dasatinib, which are expensive and unaffordable, and used in the treatment of cancer.⁹⁸ As a follow up, in August 2013, the DIPP has had further discussions with the Drug Controller General of India (DCGI) on whether marketing approval had been sought for the above drugs by generic drug makers, as it was considering a health ministry proposal for issuing a compulsory license for Trastuzumab under section 92 of the Indian Patent Act.⁹⁹ Section 92(1) of the Patent Act vests discretionary powers on the Indian government to issue a compulsory licence in circumstances of national emergency, extreme urgency, or in case of public non-commercial use. Any decisions taken by the DIPP in this regard will have a major impact on the generics pharmaceutical industry in India and the accessibility to medicines for cancer treatment.

The requirement of the statute is that the grant of the compulsory licence must be "necessary" for such purposes mentioned, and the same is to be followed by a declaration by notification in the Official Gazette.¹⁰⁰ According to Section 117A of the Patents Act, the notification under Section 92 may be challenged at the Intellectual Property Appellate Board (IPAB), and in addition, it may also be challenged at the High Court. The grant of a compulsory license by the government under section 92 of the Act differs from a grant under section 84 of the Act by the Controller of Patents, as the government can under section 92, issue a compulsory license if in its view there existed a national emergency. Proceedings falling under section 92 do not follow the same procedural rigours of Section 84, and is less time consuming.

In a separate development, the Swiss drug manufacturer Roche decided not to seek extension of its patent for the cancer drug Herceptin in India, which expired in May 2013, thereby paving the way for generic drug makers to manufacture the drug.¹⁰¹ Roche had come under severe pressure from the Indian government to cut the prices of key anti-cancer drugs as it is beyond the reach of a large number of cancer patients. It is pertinent to mention that Biocon-Mylan, Reliance Life Sciences and BDR Pharmaceuticals are some of the companies who are currently working on a copy of the cancer drug Herceptin in India.¹⁰²

Criticism:

The procedure laid down for the grant of compulsory license under the new laws is cumbersome and long drawn, with no time limit specified in the Act or the Rules for the disposal of an application. Lack of clarity in this regard could see the compulsory provision becoming redundant and unusable for the purposes for which it was incorporated into the Act.

⁹⁸ Press Trust of India, 'DIPP Seeks Details of 3 Cancer Drugs for Compulsory Licensing' *The Economic Times* (21 February 2013) <http://articles.economictimes.indiatimes.com/2013-02-21/news/37221846_1_nexavar-drug-dasatinib-trastuzumab> accessed 14 October 2013.

⁹⁹ S Das, 'DIPP May Seek Information from DCGI to Manufacture Generic Version of Roche's Anti-Cancer Drug' *The Economic Times* (6 August 2013) <http://articles.economictimes.indiatimes.com/2013-08-06/news/41131672_1_compulsory-licence-trastuzumab-leena-menghaney> accessed 14 October 2013.

¹⁰⁰ Sections, 84, 92, and 91 respectively of The Patents (Amendment) Act 2002, No. 38, Acts of Parliament, India, 2002 <http://www.wipo.int/wipolex/en/text.jsp?file_id=207496> accessed 14 October 2013.

¹⁰¹ D Rajagopal, 'Swiss Drug Major Roche to Drop Anti-Cancer Drug Herceptin Patent in India' *The Economic Times* (16 August 2013) <http://articles.economictimes.indiatimes.com/2013-08-16/news/41417840_1_major-roche-herceptin-patent-office> accessed 14 October 2013.

¹⁰² *ibid.*

Further, the Act does not fully utilise the TRIPS flexibilities, as any final decision regarding the use of a patented invention under compulsory license can be challenged in a court of law and an injunction sought to prevent the use of a patented invention.¹⁰³ Under Article 44 of the TRIPS Agreement there is no obligation on the part of a Member State to provide for the remedy of injunction against government use. The practices in the U.S. and U.K., in this regard are different and less cumbersome, as the governments in both countries can take over the patent invention without seeking a license or engage in lengthy negotiations with the patent holder. The only remedy available is for the patent holder to sue the government for compensation, and not for an injunction.¹⁰⁴ Some commentators opine that India, with public sector pharmaceutical industry, should strengthen the government use provisions in its patent Act¹⁰⁵ and remove any uncertainties.

Question:

The question that comes to haunt us is, if such grant of compulsory licenses will in any way fail to provide incentives to innovate in India, and drive away international corporations from India. Critics of the compulsory license regime have always argued that grant of compulsory license discourages innovation. Issuing of patent is strongly predicated on the premise that it encourages innovation by offering a limited monopoly to the patentee, which presents the argument that compulsory licenses will kill off innovation. There is no strong empirical evidence to suggest that compulsory licences do have a negative effect on innovation.¹⁰⁶ In contrast, the studies available only indicate that licenses do not have any significant demonstrable effects on the rate and pace of innovation.¹⁰⁷ There are also others who seriously question the efficacy of the compulsory licensing system under the TRIPS Agreement, which they think has not helped in achieving the goal of access to affordable medicines.¹⁰⁸ For now, the evidence seems to suggest that grant of compulsory license does not affect innovation in the Indian pharmaceutical sector which is dominated by generic manufacturers.

B. Pre-Grant and Post-Grant Opposition

Section 25 of the Patent (Amendment) Act 2005 provides for pre-grant opposition¹⁰⁹ of patents in India. Under this provision any third party can challenge the application for grant of patent. Section 25(1) lists eleven grounds for lodging a pre-grant opposition and challenge the grant of a frivolous or invalid patent. The introduction of pre-grant and post-grant opposition under the amended patent laws is viewed by some developed countries as a controversial step, as it slows down the grant of patents.

The Patent (Amendment) Act 2005 also provides for taking out a post-grant opposition within one year from the date of publication of the grant of patent, and the same can be viewed

¹⁰³ Gopakumar (n 87) 341.

¹⁰⁴ CM Correa, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (1999) Trade-Related Agenda, Development & Equity, South Centre, Working Paper No 5, 14 <http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf> accessed 15 October 2013.

¹⁰⁵ Basheer (n 95).

¹⁰⁶ Ibid.

¹⁰⁷ C Chien, 'Cheap Drugs at What Price to Innovation: Does Compulsory Licensing of Pharmaceuticals Hurt Innovation?' Berkeley Tech LJ Vol.18 (2003) 853, 896-907.

¹⁰⁸ K Paas, 'Compulsory Licensing Under the TRIPS Agreement - A Cruel Taunt for Developing Countries?' Eur IP Rev Vol. 31, Issue 12 (2009) 609-613.

¹⁰⁹ See generally, S Tripathi, 'Pre-Grant Oppositions and Refusal of Grant'(1 June 2013) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2273074> accessed 22 October 2013.

as a second-window of opportunity for lodging any opposition.¹¹⁰ Under this provision any ‘interested person’ may give notice of opposition to the Controller in the prescribed manner on any of the grounds mentioned in section 25 of the Patent (Amendment) Act 2005. The grounds for both pre-grant and post-grant opposition are identical, and there is nothing in the Act to preclude a pre-grant opponent from subsequently filing a post-grant opposition on the same patent.

Criticism:

The opposition at the pre-grant stage is more by way of representation as opposed to notice of opposition, and further, there is no scope for an appeal against the decision of the Controller on any pre-grant opposition.¹¹¹ The only remedy that is open to the aggrieved party in such circumstances is to seek judicial review under the Constitution of India,¹¹² which can be a lengthy procedure allowing the patent holder to enjoy a wrongful monopoly during the pendency of such proceedings before the court. Some generic drugs manufacturers and public interest groups have utilised the pre-grant provisions to prevent frivolous patents, but the provision still remains under utilised due to barriers in accessing information.¹¹³ Denial of access to, or non-disclosure of information on pending applications pose serious threat as the Indian Patent Office does not publish full details of pending applications. It is important to clarify this provision, especially when India has introduced measures to check the practice of patent evergreening. The Novartis case which is discussed in the next section of this article arose out of pre-grant oppositions lodged by generic drugs manufacturers and NGOs.

C. Patentability & Patent Evergreening

The Justice Ayyangar Committee report had recommended¹¹⁴ the introduction of process patents into the patent laws in India. The recommendations were based on a detailed, in-depth study of post-independent India’s economic and social conditions, and the need to develop a self-reliant and self-sufficient nation. After close to thirty five years,¹¹⁵ India has moved towards a product patent system, which embraces the opposite of what was recommended by Justice Ayyangar Committee in 1959. One of the important changes made to the laws is the introduction of ‘patent eligibility’ under section 3(d). This provision prohibits the grant of patents on derivatives of known substances, unless such derivatives display significantly enhanced efficacy. Section 3(d) spells out such instances which will not be seen as an ‘inventions’ under the Act. The text of section 3(d) reads as follows:

d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property

¹¹⁰ Article 99 of the European Patent Convention (EPC) allows for an opposition to be filed by any person within nine months of the publication of the grant of the European Patent (EP) in the European Patent Bulletin (EPB). Any opposition lodged applies to the EP patent in all contracting States where the EP patent has effect. The U.S. has a provision for re-examination to challenge the validity of a granted patent. Here again, the re-examination procedure can be invoked by any person at any time during the period of enforceability of a patent. The U.S. re-examination procedures are detailed and fall under two categories, namely, *ex-parte* re-examination and *inter partes* re-examination.

¹¹¹ Gopakumar, (n 87) 345. However, it is to be pointed that the Madras High Court allowed *Novartis* to challenge the order passed by the Controller under the pre-grant procedure before the Intellectual Property Appellate Board (IPAB).

¹¹² Judicial review is available under Article 226 before the High Court under its ‘extraordinary original jurisdiction’ in individual states, and under Article 32 before the Supreme Court of India.

¹¹³ Gopakumar, (n 87) 346.

¹¹⁴ A Report on the Revision of the Law in India Relating to Patents for Inventions (n 16).

¹¹⁵ The Patent Act 1970 came into force on 20 April 1972.

or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combicountries and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3(d) is aimed at denying patent for trivial modifications on existing patents and preventing the practice of ‘ever-greening’. The expression evergreening¹¹⁶ is used to identify the practice of obtaining multiple patents that cover different aspects of the same product, and is also known variously as ‘stockpiling,’ ‘life-cycle management,’ ‘patent-layering,’ and ‘line-extension’. Evergreening in effect, refers to the attempts by pharmaceutical patent owners to extend the term of patents they already hold through modified forms of the same drug, new delivery systems and new uses for the drug,¹¹⁷ and scholars have expressed serious concerns about the practice.¹¹⁸ Pharmaceutical companies resort to the practice with a view to maximising on the monopoly period enjoyed by the patented drug.¹¹⁹ Multiple patenting of known substances, or evergreening, considerably delays and poses a threat for the legal entry of generics into the market, and can successfully prevent competition in the pharmaceutical market. Some from the pharmaceutical industry believe that the term ‘evergreening’ is pejorative and is misleading.¹²⁰ When India set up the ‘mailbox’ under the transitional arrangements,¹²¹ it received close to 9000 applications, and a number of the overseas applications lodged by multinational corporations through the system could be said to fall under the above category of ‘evergreening’.¹²²

India’s pharmaceutical industry, being strongly driven by generic drugs manufacturers, required a strict patentability criterion to ensure the early entry of generics into the market. The introduction of section 3(d) was seen as the answer, as it aims to both increase the threshold limit of patentability criteria and also exclude certain types of inventions from the ambit of the Patent Act. This section seeks to disallow the patenting of a known substance unless it results in an enhancement of the efficacy of that substance, and can be seen as a bold legislative step to curb the practice of ‘evergreening’.¹²³ Importantly, section 3(d) applies to both pharmaceutical patents and chemical patents.

The section encourages sequential developments of existing products or technologies that help bring in improved products to the market, as opposed to evergreening which can be

¹¹⁶ LJ Glasgow, ‘Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?’ 41 IDEA (2001) 227. The author analyses how pharmaceutical companies are able to lengthen the patent life of drugs to obtain an exclusive market share.

¹¹⁷ JM Mueller & DS Chisum, ‘Enabling Patent Law’s Inherent Anticipation Doctrine’ 45, No 4, Hous L Rev (2008) 1101, 1106-7; R Feldman, ‘Rethinking Rights in Biospace’ 79 S Cal L Rev (2006) 1, 30.

¹¹⁸ JO Lanjouq, ‘A New Global Patent Regime for Diseases: US and International Legal Issues’ 16 Harv JL & Tech (2002) 85, 94-95. Here, the author defines the practise of ‘evergreening’ by pharmaceutical corporations.

¹¹⁹ ME Furrow, ‘Pharmaceutical Patent Life-Cycle Management after KSR v. Teleflex’ 63 Food & Drug LJ (2008) 274.

¹²⁰ GlaxoSmithKline, ‘Evergreening’ (August 2011) <<http://www.gsk.com/content/dam/gsk/globals/documents/pdf/GSK-and-evergreening.pdf>> accessed 15 November 2013.

¹²¹ The Patents (Amendment) Act 1999 (n 62).

¹²² Dhar and Gopakumar (n 61) 8-9. The authors refer to the practice of granting patents to IMDs (Incrementally Modified Drugs) in the US, and how an overwhelming majority of the applications received through the ‘mailbox’ set up by India would be falling under IMDs category.

¹²³ R Sen and A Ramanujan, ‘Pruning the Evergreen Tree or Tripping up Over TRIPS? Section 3(d) of the Indian Patents Act 1970’ 41 Int’l Rev of Intell Prop & Competition L (2010) 170, 186.

seen as the improper extension of patent monopoly of a pharmaceutical product.¹²⁴ It is the first step in bringing about a fundamental shift in the way pharmaceutical patent applications are to be scrutinised henceforth, in India. Judicial precedent has been set in the U.S.¹²⁵ and the U.K.,¹²⁶ both common law countries and holding a number of pharmaceutical patents, to discourage the practice of evergreening. Introduction of section 3(d) into the patent laws can be viewed as a definitive legislative measure taken by India to tackle “evergreening”. Interestingly, the U.S. topped the list of pharmaceutical patent applications lodged when India set up the ‘mailbox’ under the transitional arrangement, with the U.K. coming fourth in the list behind Germany.¹²⁷ It is worth mentioning here that a number of applications received from multinationals through the ‘mailbox’ can be seen as attempts at ‘evergreening’ of existing patents.¹²⁸

a. Novartis – Glivec Saga:

In 1993, Novartis AG (hereinafter Novartis) filed a patent in the U.S. covering the free base¹²⁹ Imatinib and other pharmaceutically acceptable salts. Later, Novartis derived the drug Glivec, which is the beta-crystalline form of imatinib mesylate. This drug is known to make chronic myeloid leukaemia a manageable disease by controlling cellular action that allows the cancer to grow. Although it does not cure the disease, it is seen as a step forward in the treatment of cancer. Novartis also marketed Glivec in the U.S. under the trade name Gleevec.

Novartis lodged its application for a patent in India through the ‘mailbox’ on 17 July 1998, and also applied for an exclusive marketing right (EMR).¹³⁰ With the grant the EMR in 2003, the consumers in India saw a ten-fold increase in the price of Glivec. Novartis’ patent application for Glivec faced severe opposition from Indian generic manufacturers (against whom Novartis had filed infringement suits) and the NGO, Cancer Patients Aid Association (CPAA). The main grounds for opposition were that the application lacked novelty, it did not demonstrate any significant ‘efficacy’ under section 3(d), it did not have any obviousness, and it also had a wrongful priority. The opposition could be heard at a stage prior to the grant of patent, as the 2005 Amendment Act had provided for a ‘pre-grant’ opposition¹³¹ on any application for the issue of a patent. On 8 March 2006, agreeing with the arguments of the opposition to the patent, the Assistant Controller of Patents rejected the application taken out

¹²⁴ Incremental innovations are not the same as evergreening, and section 3(d) draws a distinction between the two. S Basheer, ‘Limiting the Scope of Pharmaceutical Patents and Micro-organisms: A TRIPS Compatibility Review’ Intellectual Property Institute (2005) 47-49.

¹²⁵ The courts in the United States rely on the doctrine of inherent anticipation to deal with instances of ‘patent evergreening’, which was demonstrated in the judgement handed down by the Court of Appeals for the Federal Circuit (CAFC) in *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373 (Fed Cir 2003). Also, the U.S. Hatch-Waxman Act 1984 provides for financial incentives, and encourages generic firms to identify and challenge improperly issued secondary patents. That said, the provisions of the Hatch-Waxman Act, cannot be equated to the Indian Patent Act, which also provides for pre-grant opposition under the 2005 amendment.

¹²⁶ The courts in the United Kingdom follow similar principles to discourage patent ‘evergreening’. See the Court of Appeal decision in *Les Laboratoires Servier v Apotex Inc* [2008] EWCA Civ 445. The court while dismissing the appeal held that Servier’s patent was invalid for lack of novelty and obviousness, and Lord Justice Jacob observed that “It is the sort of patent which can give the patent system a bad name.... The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest.”

¹²⁷ Narendranath (n 60).

¹²⁸ Dhar and Gopakumar (n 61) 8-9.

¹²⁹ The expression ‘free base’ is commonly used in organic chemistry and pharmaceutical research to describe the ‘deprotonated’ amine form of a chemical compound. It refers to the pure basic form of an amine, as opposed to the salt form.

¹³⁰ Narendranath (n 60).

¹³¹ The Patents (Amendment) Act 2005, section 23, which replaced the old sections 25(1) and 25(2). India is one of the few countries which provide for a pre-grant as well as post-grant opposition proceedings.

by Novartis holding that the new version of Glivec was not sufficiently different from the old unprotected version to warrant a patent. Novartis filed two petitions before the Madras High Court, seeking to reverse the decision of the Assistant Controller of Patent and to declare that section 3(d) of the Amendment Act was unconstitutional and in violation of India's obligation under the TRIPS Agreement. Pending proceedings the Government constituted the Intellectual Property Appellate Board (IPAB),¹³² and the first of the petitions mentioned above was transferred to the IPAB.

Novartis also argued that section 3(d) violated Article 14¹³³ of the Constitution of India as it vested unbridled powers on the patent controller, leading to discriminatory results. The second of the petition mentioned above, challenging the TRIPS compliance and the constitutional validity of Section 3(d) was heard by the Madras High Court. The court by judgment dated 6 August 2007 held that the provision in question was not in violation of article 14 of the Constitution of India¹³⁴ and did not confer the Controller of Patents with uncontrolled powers. The court held that it did not have the jurisdiction to decide on the compliance of a domestic Indian law to that of an International treaty, and refused to grant a declaratory relief to Novartis. Accordingly, the court declined to deal with the issue if section 3(d) of the Indian Patent Act was consistent with Article 27 of the TRIPS Agreement. The court also observed that the government had a constitutional duty to provide good health care to its citizens through access to medicines, and for that purpose there should be suitable legislative measures in place to prevent the practice of 'evergreening', which has a negative impact on the availability of affordable medicines. The petition challenging the decision of the Controller of patents dealing with patentability of Glivec was heard by the IPAB, at Chennai, which also ruled against Novartis.¹³⁵

Novartis was granted special leave to appeal against the above decisions to the Supreme Court of India. A total of five appeals were lodged before the Supreme Court, and on 1 April 2013, the Supreme Court of India delivered its detailed judgment on the matter.¹³⁶ The Supreme Court ruled that imatinib mesylate was a known substance since 1994 and does not qualify as an 'invention' in terms of clause (j) and (ja) of section 2(1).¹³⁷ Further, it also held that the beta crystalline form does not satisfy the requirements of the criterion set under section 3(d). The court concluded that Section 3(d) was meant to create a "second tier of qualifying standards" for chemical substances to combat "any attempt at repetitive patenting or extension of the patent term on spurious grounds." Most importantly the Supreme Court interpreted efficacy to mean therapeutic efficacy.¹³⁸ Here, the Supreme Court was linking patenting to therapeutic benefit, or more precisely net benefits to society, thereby highlighting the relevance

¹³² Notification No.12/15/2006-IPR-III, dated 3 April 2007, issued by the Ministry of Commerce & Industry, under the Patents (Amendment) Act (section 117G), which authorised for all pending appeals before the High Courts to be transferred to the Appellate Board (IPAB) <http://ipindia.nic.in/ipr/patent/gazetteofindia_apr2007.pdf> accessed 4 November 2013.

¹³³ Article 14, of the Constitution of India deals with the principles of equality before law, and postulates that the State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.

¹³⁴ *Novartis Ag v Union of India and Others* (2007) 4 MLJ 1153.

¹³⁵ Judgment of the IPAB in *Novartis Ag v Union of India & Others* (26 June 2009) <<http://www.ipab.tn.nic.in/Orders/100-2009.htm>> accessed 5 November 2013.

¹³⁶ Judgment of the Indian Supreme Court *Novartis Ag v Union of India & Others* (1 April 2013) <<http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>> accessed 5 November 2013).

¹³⁷ The Patents (Amendment) Act 2005, section 2(1)(ja) defines inventive step as "...a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."

¹³⁸ A Grover, 'Analysing the Supreme Court Judgment' *Economic & Political Weekly*, Vol. XLVIII, No. 32 (10 August 2013) 46, 48.

of specific conditions of a country for deciding the appropriate patent regime.¹³⁹ The court rejected the appeal, as in its view Novartis could not demonstrate that the new form of the known substance was capable of enhancing the therapeutic efficacy of the drug. When Novartis made its application through the ‘mailbox’, it was not required to make out a case for therapeutic benefit as section 3(d) was non-existent, and was only to be introduced later in 2005. Nevertheless, when Novartis was given the opportunity to produce evidence to demonstrate the therapeutic efficacy of beta crystalline at the ‘pre-grant opposition’ stage, it did not do so as there was no study available to that effect.¹⁴⁰ Novartis also argued that its research and development had to be recouped and hence the high price for the drug.¹⁴¹ What is interesting is the patent that was at issue before the Indian Supreme Court was also the target of a Hatch-Waxman challenge in the U.S. in 2007,¹⁴² and Novartis did not appear to be litigating in response to this challenge, suggesting that it accepted the patent as questionable even in the U.S.¹⁴³

The Supreme Court’s rejection of Novartis’ application means that generic drug makers can continue to sell copies of the drug at an affordable price in India. While Novartis has, naturally, not welcomed the decision, the Indian public, the health economists, and other interest groups have all welcomed the decision and view it as a landmark judgment. The Novartis case, through its legal debate on section 3(d) has brought into sharp focus the rights of a sovereign country to build safeguards into its patent laws for protecting public interest, and also on the issue of access to affordable medicines, which is vital for the realization of health as a human right.¹⁴⁴ The judgment links the key question of patenting with net benefits to society, thereby highlighting the relevance of specific conditions prevailing in a country for deciding the appropriate patent regime to adopt.¹⁴⁵ The Supreme Court was unequivocal in stating that the purpose of section 3(d) was to prevent the practice of evergreening.¹⁴⁶ The case will also be seen as a legacy of the TRIPS Agreement and its flawed vision for the creation of a globally harmonised intellectual property protection.¹⁴⁷ Some writers opine that the Novartis case will reach the WTO’s dispute settlement system in some form,¹⁴⁸ although Switzerland, Novartis’s home country seems not so keen in raising a dispute.¹⁴⁹

Criticism:

¹³⁹ S Chaudhuri, ‘The Larger Implications of the Novartis-Glivec Judgment’ *Economic & Political Weekly*, Vol. XLVIII, No. 17 (April 2013) 10, 11.

¹⁴⁰ Novartis opted to file a number of affidavits before the Intellectual Property Appellate Board (IPAB), Chennai, to prove the efficacy of beta crystalline, instead of presenting any clinical studies to that effect.

¹⁴¹ J Love, ‘R&D Costs for Gleevec’ *Knowledge Ecology International* (3 April 2013) <<http://www.keionline.org/node/1697>> accessed 18 November 2013. The author argues that Novartis was ably supported by significant contributions from philanthropic sources in the US, while only spending a fraction on the R&D for the development of ‘Gleevec,’ or Glivec.

¹⁴² B Sampath et al, ‘Challenges to India’s Pharmaceutical Patent Laws’ *Science* Vol. 337 No. 6093 (July 30 2012) 414-415 <<http://personal.lse.ac.uk/shadlen/Science,%20July2012.pdf>> accessed 3 November 2013. See also ParagraphFour.com, Gleevec (Imatinib) tablets <<http://www.paragraphfour.com>> accessed on 4 October 2013.

¹⁴³ Ibid at 142.

¹⁴⁴ R Chandra, ‘The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Case in India’ in Thomas Pogge, et al *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press 2010) 381, 389.

¹⁴⁵ Chaudhuri (n 139) 12.

¹⁴⁶ Judgment of the Indian Supreme Court *Novartis Ag v Union of India & Others* (n 136) paragraphs 100-102.

¹⁴⁷ D Rangnekar, ‘The Supreme Court Judgment: Lawmaking in the South’ *Economic & Political Weekly*, Vol XLVIII, No 32 (10 August 2013) 39.

¹⁴⁸ ZL Turrill, ‘Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India’s Section 3(d) Efficacy Standard’ *Geo J Int’l L* Vol. 44 (2013) 1555, 1566.

¹⁴⁹ E Silverman, ‘Swiss Government Won’t Go to Bat for Novartis’ *Pharmalive* (7 August 2007) <<http://www.pharmalive.com/swiss-govt-wont-go-bat-novartis>> accessed 19 October 2013.

Although section 3(d) is aimed at preventing the practice of evergreening, the scheme of the Act does not completely rule out the possibility of evergreening of patents.¹⁵⁰ The definitions on the criteria of patentability and exclusions of patentability provide scope for pharmaceutical companies to work their way around section 3(d) and obtain patents for known substances.¹⁵¹ Empirical evidence also suggests that the Indian Patent Office may have failed to carry out strict scrutiny of patent applications and unwittingly granted patents to known substance,¹⁵² which demonstrates a weakness on the procedural side. The U.S.-India Business Chamber has criticised section 3(d) as capable of barring inventions that may otherwise meet the requirement of patentability and considered truly inventive. It has further stated that the removal of section 3(d) from the Amended Act would allow all incremental innovations to undergo examination and be treated in the same manner regardless of industry or field of technology.¹⁵³ Much criticism had also flown from the U.S. on India's new patent laws, especially aimed at section 3(d),¹⁵⁴ whereas, there are others who recognise India's new patent laws as a model for developing countries to embrace on the use of the TRIPS flexibilities.¹⁵⁵ In summary the introduction of section 3(d) is a positive step taken by the Indian law makers to tackle the menace of 'evergreening' practiced by pharmaceutical patent holders.¹⁵⁶

Questions:

The Indian Supreme Court in the course of delivering the judgment in the Novartis case observed that it did not wish the Indian patent laws to "...develop on lines where the scope of the patent is determined not on intrinsic worth of the invention but by the artful drafting of its claims, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent." This observation was obviously aimed at the modern day practices of multinational pharmaceutical corporations. The questions that need answering are, not only about the Indian patent laws, but also about the actions of multinational corporations who, well supported by their national governments (through lobbying), have sought to exploit new and emerging patent legislations in the post-TRIPS era to their advantage, and also the actions of developed countries in exerting pressure on developing countries to change their laws and policies on intellectual property rights,¹⁵⁷ which continues to have a devastating impact on access to

¹⁵⁰ KM Gopakumar, 'The Need to Curb Patents of Known Substances' *Economic & Political Weekly*, Vol XLVIII, No 32 (10 August 2013) 56. In the author's estimation close to 3500 product patents have been granted by the Indian Patent Office between 2007 and 2010, and in the author's view many of these patents are likely to have been granted in violation of section 3(d). The author also advocates a review of all these patents in the light of the Supreme Court judgment in the Novartis case.

¹⁵¹ Gopakumar (n 103) 335.

¹⁵² Ibid at 338; see also Gopakumar (n 150).

¹⁵³ White & Case and DUA Consulting, 'The Value of Incremental Pharmaceutical Innovations - Benefits for Indian Patients and Indian Business' Report prepared for US-India Business Council (June 2009) 17 <<http://www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReportFinal.pdf>> accessed 19 October 2013.

¹⁵⁴ The U.S. Trade Representative cites section 3(d) of the Indian Patent Act as one of the reasons to keep India on its 'priority watch list' of countries whose intellectual property regimes are of concern. See Office of the U.S. Trade Representative, *Special 301 Reports 2010-2012* (USTR, Washington DC, 2012) <<http://www.keionline.org/ustr/special301>> accessed 15 November 2013.

¹⁵⁵ UNAIDS, 'DOHA+10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future' UNAIDS Technical Brief, Geneva (2011) <http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf> accessed 3 November 2013.

¹⁵⁶ Sampath, et al., (n 142).

¹⁵⁷ C Grace, 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines' Report for DFID Health Systems Resource Centre (2004) 35 <<http://www.who.int/hiv/amds/Grace2China.pdf>> accessed 2 October 2013.

affordable medicines. This leads us to the next, inevitable question, for how long will WTO permit developed countries to negotiate on access to medicines with intellectual property rights?

D. Exhaustion of Patent Rights & Parallel Imports

India took advantage of the TRIPS flexibility to introduce a few key provisions into its patent laws which included, amongst others, the exhaustion of patent rights and parallel importation. India viewed this as an important step as it had emerged as a key player in producing and exporting generic drugs with the introduction of process patents under the 1970 Act. The TRIPS Agreement allows member states to determine the scope and extent of exhaustion of patent rights. Article 28 (6) of the TRIPS Agreement states that “This right [*i.e.*, the right of importation], like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.” In turn, Article 6 of the TRIPS Agreement postulates that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” Article 5(d) of the Doha declaration provides that “the effect of the provisions of TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment...” In other words the TRIPS Agreement does not pose any restrictions on the application of the doctrine of exhaustion in domestic patent laws, despite dissenting views.¹⁵⁸

The Indian Patent Amendment Act recognises and implements the principle of international exhaustion of patent rights. This principle imposes certain limits on the patentee’s exclusive rights, in that the patentee cannot control the resale or redistribution of the particular product that had already been sold.¹⁵⁹ Under this provision, once a patented product has been sold with the patentee’s approval outside India, the subsequent importation of that same patented item into India will not amount to infringement of the Indian patent.¹⁶⁰ This principle is recognised in countries like, India, Japan, Taiwan, Kenya, Andean Group Countries, Australia and New Zealand, but not recognised in a number of other jurisdictions like the U.S., E.U., Brazil and China.¹⁶¹ The provision was first introduced under section 107(A)(b) of the Patents (Amendment) Act 2002, which provided that the “...importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.’ It was considered restrictive in scope, and was amended by the Patents (Amendment) Act 2005, which states that “importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.”¹⁶²

¹⁵⁸ The U.S. delegation to the Council for TRIPS, which met in June 2001, was of the firm view that Article 6 neither allowed WTO Members to avail themselves of dispute settlement in relation to questions involving parallel imports, nor authorise parallel imports (Delegation of the United States, Council for TRIPS Meeting of June 1822, 2001, JOB(01)/97/Add.5, Council for TRIPS, June 28, 2001). See also CM Correa, ‘The TRIPS Agreement and Developing Countries’ in PJ Macrory, et al (eds), *The World Trade Organisation: Legal, Economic and Political Analysis* Vol. II (Springer 2005) 447.

¹⁵⁹ The doctrine of exhaustion is also referred to as the first sale doctrine.

¹⁶⁰ S Basheer and M Kochupillai, ‘Exhausting Patent Rights in India: Parallel Imports and TRIPS Compliance’ *Journal of Intellectual Property Rights*, Vol. 13 (2008) 486, 487-488.

¹⁶¹ In the absence of any legislation on the subject, all imports are likely to be subject to the patent owner’s exclusive rights.

¹⁶² The Patents (Amendment) Act 2005, No. 15 section 58, Acts of Parliament 2005 (India) <http://ipindia.nic.in/ipr/patent/patent_2005.pdf> accessed 13 October 2013.

Parallel imports, which are but a natural corollary of the doctrine of exhaustion, helps in the increased allocation of products at the lowest possible price. It is likened to compulsory licenses and can act as an important device to discipline the markets and to induce suppliers to commercialise their pharmaceutical products on reasonable conditions.¹⁶³ Some writers even opine that parallel imports through compulsory licenses may in some cases be the only way to gain access to affordable medicine, especially when the TRIPS agreement is fully implemented.¹⁶⁴ Recognition of parallel imports can be seen as an emerging trend amongst developing countries that have proceeded to introduce an express statutory provision incorporating international exhaustion of patent rights into their national laws with the aim of ensuring their citizens' access to lower-cost medicines.¹⁶⁵

Pitfalls:

The new patent regime introduced under the Amendment Act 2005 gives India the necessary legal framework to protect its patent system from practice of patent "evergreening", and also expands the scope of granting compulsory licenses in the event of any emergencies. Before the introduction of the TRIPS compliant patent laws into its legislation, there were intense debates in the Indian parliament and in other forums across the country, which demonstrated the elaborate democratic process the proposals went through. If the new patent laws are to work to India's benefit, it will have to address a few shortcomings in the new legislation, the accompanying procedures, and in the national drugs policy.

In 2002, in anticipation of the new patent laws, India introduced a Pharmaceutical Policy¹⁶⁶ aimed at improvement of incentives for research and development within the Indian pharmaceutical industry to achieve sustainable growth.¹⁶⁷ This policy proposed the reduction of the number of drugs under price control, but came to be stayed through a Supreme Court order.¹⁶⁸ The price control mechanism is one of the flexibilities available under the TRIPS Agreement to ensure access to medicines,¹⁶⁹ and every developing country should make use of it to make access to medicines affordable. India announced a revised National Pharmaceutical Pricing Policy (NPPP) in November 2012, which sought to cap the price of 348 drugs.¹⁷⁰ The NPPP and the Drugs (Prices Control) Order 2013 have now come to be challenged before the Supreme Court by the All India Drug Action Network (AIDAN).¹⁷¹ This drug price control policy could see yet another revision in the months to come. India cannot afford to indulge in

¹⁶³ Correa (n 158) 449.

¹⁶⁴ *ibid.*

¹⁶⁵ J Wise, 'Access to AIDS Medicines Stumbles on Trade Rules' 84 *World Health Organization Bulletin* (2006) 342-344 <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627352/pdf/16710536.pdf>> accessed 15 October 2013.

¹⁶⁶ Section 11 of the Indian Pharmaceutical Policy 2002 states clearly that the span of price control over drugs and pharmaceuticals would be reduced substantially <<http://nppaindia.nic.in/may-2002/policy-02.html>> accessed 22 October 2013.

¹⁶⁷ See generally, M Das and SK Basu, 'Drug Price Control in India: "The Past and the Present"' *NSHM Journal of Pharmacy and Healthcare Management* Vol. 03 (February 2012) 41-47. The authors chart the pricing policy trend in the Indian pharmaceutical sector since the early 1960s up to the introduction of the National Pharmaceutical Price Policy in 2011.

¹⁶⁸ The Supreme Court of India, by Order dated 2 May 2003, stayed the policy from being implemented. The Supreme Court also directed the Indian Government "...to consider and formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of price control."

¹⁶⁹ Gopakumar (n 103) 352.

¹⁷⁰ N Prusty, 'India Approves to Cap Prices of 348 Drugs' *Reuters India* (23 November 2012) <<http://in.reuters.com/article/2012/11/22/india-drugs-pharma-policy-idINDEE8AL09T20121122>> accessed 2 November 2013.

¹⁷¹ PTI, 'SC to Examine Pharma Pricing Policy, Order on Drug Control' *Indian Express* (7 Aug 2013) <<http://www.indianexpress.com/news/sc-to-examine-pharma-pricing-policy-order-on-drug-control/1152032/0>> accessed 12 November 2013.

arbitrary drug price policies if it were to take full advantage of the TRIPS flexibilities and implement the new patent laws. Since the passing of the new patent laws in 2005, India has witnessed the acquisition of a number of generic pharmaceutical companies by multinational corporations. These acquisitions do not bode well for India and other developing countries, as they undermine the future availability of affordable medicines and as well as the effective use of the WTO TRIPS flexibilities including pre-grant opposition and compulsory license under the new Act. A study carried out by the India's Parliamentary Standing Committee on Commerce recommended a blanket ban¹⁷² on the acquisition¹⁷³ of Indian pharmaceutical companies by multinational corporations. The Committee noted that the multinational corporations have encroached upon the Indian generic industry base, and was unanimous in its view in seeking a ban on FDI in the existing pharmaceutical sector.

A number of external factors too can be identified as posing threats to the full implementation of the new patent laws. The U.S., in particular, is critical of the new patent laws introduced in India. The U.S. Trade Representative (USTR) has repeatedly identified India's introduction of section 3(d) as the reason for putting it on the priority watch list,¹⁷⁴ which can be viewed as a tactic adopted by the U.S. to exert pressure on India to change its patent laws. It is interesting, as the U.S. has the Hatch-Waxman Act within its patent legislation, which aims to produce a similar result as section 3(d), but albeit at a later stage. The U.S. and EU have through the incorporation of TRIPS plus provisions in Regional Trade Agreements (RTAs)¹⁷⁵ preserved the practice of evergreening for their multinationals in other jurisdictions. India is party to over 25 FTAs, and currently engaged in negotiating FTAs with Japan and the EU. It is understood that the EU has demanded extended terms of patent protection from India, which could potentially undermine India's efforts in putting an end to the practice of evergreening. It is abundantly clear that TRIPS plus provisions in RTAs and FTAs can pose a major challenge to India in the full realisation of its TRIPS compliant patent laws, and India may be pressurised through negotiation to let evergreening through its backdoor.¹⁷⁶ The U.S. with other key trading partners have negotiated the 'secretive' Anti-

¹⁷² Rajya Sabha, Parliament of India, 'One Hundred and Tenth Report on FDI in Pharmaceutical Sector' (August 2011)

<<http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/110.pdf>> accessed 4 January 2014.

¹⁷³ India introduced changes to its FDI policy relating to the pharmaceutical sector in 2011, which allowed 100% FDI in both new and existing pharmaceutical business.

¹⁷⁴ Office of the U.S. Trade Representative, *Special 301 Reports 2010–2012* (n 154).

¹⁷⁵ RTAs and FTAs have facilitated international trade prior to the advent of the WTO, and to some degree also facilitated regional integration. Although RTAs and FTAs potentially undermine the principles of the WTO, it is not prohibited under the rules. As of 31 July 2013, some 575 notifications of RTAs have been received by the WTO, of which, 379 were in force. See 'Regional Trade Agreements' World Trade Organization <http://www.wto.org/english/tratop_e/region_e/region_e.htm> accessed 22 January 2014.

¹⁷⁶ Gopakumar (n 150) 59. The author is of the view that Bilateral Investment Treaties (BITs) may prevent India from the taking effective measures to curb patents on known substances, and advocates the removal of intellectual property rights from the definition of investments.

Counterfeiting Trade Agreement (ACTA),¹⁷⁷ which, if ratified can undermine India's new patent laws besides seriously harming India's position as a generic manufacturer of drugs.¹⁷⁸

V. Conclusion

Through the new patent law framework, India has once again demonstrated it can take the lead role in presenting a patent law regime which can serve as a useful model for other developing countries to emulate.¹⁷⁹ Since its introduction in 2005, the patent law provisions have been frequently invoked by multinational pharmaceutical companies seeking the grant of patents, and on such other occasions by generic drugs manufacturers and NGOs seeking the pre-grant and post-grant opposition, and for grant of compulsory licenses. The decisions taken serve a stark warning on the bumpy road ahead for the multinationals seeking to extend the life span of patents through evergreening, and also to the Indian generic pharmaceutical industry seeking grant of compulsory licenses. It also serves as a reminder to the other developing countries that are heavily reliant on the Indian generic ARVs for the treatment of HIV/AIDS, on the difficulties of obtaining a compulsory license. The interpretation of section 3(d) of the Patent Act by the Indian Supreme Court in the Novartis case demonstrates the unequivocal position taken by India to protect its own patent jurisdiction from being subjected to abuse by multinational pharmaceutical companies through the practice of evergreening. The Supreme Court judgment sets the boundaries on granting patents and on the practice of patent evergreening, and is to be viewed as a benchmark.

Some writers have expressed the view that the patenting trend prevalent in developed countries is not in the interest of the consumers,¹⁸⁰ which makes medicines unaffordable, and have suggested developing countries to follow in the footsteps of India by introducing similar provisions as section 3 (d) into their patent legislations to make medicines more affordable.¹⁸¹ The provision as incorporated by the Indian legislation may suit India's requirements, as it has a robust judiciary to interpret the provisions justly in the light of the objectives of the amendment, and it also boasts of a good infrastructure for manufacturing generics drugs. Besides, India does not face the same problems as other developing countries and least developed countries in the knowledge economy. At this point, the judgment of the Indian Supreme Court can only be seen as a result of the first of the few battles to come on Indian patent laws, and the Indian court rooms will not be the only domain where they will be played out.

India's decision to introduce a product patent regime into its laws in 1970, on the back of the Justice Ayyangar Committee Report,¹⁸² was a reformative measure, as it was in response

¹⁷⁷ The Anti-Counterfeiting Trade Agreement (ACTA) is a plurilateral agreement, initiated by the U.S. and Japan in 2006. The agreement signed in October 2011, seeks to establish an international standard for intellectual property rights enforcement through an international legal framework targeting counterfeit goods, and most importantly generic medicines. If ratified, this agreement will see the creation of a separate governing body outside the WTO, WIPO and UN for the purposes of enforcement. Most strikingly, developing nations, LDCs, civil society groups and the general public were clearly excluded from the negotiation process. See generally, PK Yu, 'Six Secret (and Now Open) Fears of ACTA' SMU L Rev (2011) 975. The author is critical of the ACTA and expresses the view that the agreement militates against domestic legislative reforms.

¹⁷⁸ See generally, Médecins Sans Frontières, 'A Blank Cheque for Abuse: The Anti-Counterfeiting Trade Agreement (ACTA) and Its Impact on Access to Medicines' MSF Briefing Document (February 2012) <http://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_ACTABlackCheque_ENG_2012.pdf> accessed 10 October 2013.

¹⁷⁹ UNAIDS (n 155).

¹⁸⁰ Chaudhuri (n 139). The author is critical of the trend prevalent in developed nations like the U.S. where in the name of innovation 'mindless patenting' takes place much against the interest of the consumer. This model in his view is followed by a number of developing countries either willingly or unwillingly.

¹⁸¹ Ibid.

¹⁸² A Report on the Revision of the Law in India Relating to Patents for Inventions (n 16).

to internal factors, *i.e.*, the socio-economic conditions then prevailing in the country. This measure not only helped India in achieving a greater degree of self-sufficiency in access to medicines through generics drug manufacturing, but also was to help other developing countries in the fight against HIV/AIDS in the years to follow. In sharp contrast, the introduction of the product patent system in 2005 can only be seen as a response to external factors, *i.e.*, TRIPS compliance, and can become counterproductive to India's interests and that of other developing countries who rely on it for generic drugs supply, if not administered properly. The problems identified in the Justice Ayyangar Committee report, especially on access to medicines, have not been fully addressed and the reasons for the introduction of process patent in the 1970s have not been fully realised, but India, nevertheless has moved towards a new patent law regime. This transformation in India will be felt around the globe,¹⁸³ and it will have to be seen how India endeavours to maintain its stance in the face of stiff challenges from developed countries and multinational pharmaceutical patent holders.

¹⁸³ Mueller (n 4).

Email Acceptance Article 1

From: INDIRA CARR <imcarr@btinternet.com>
Reply to: INDIRA CARR <imcarr@btinternet.com>
Date: Friday, 24 January 2014 at 03:30
To: Jae Sundaram <jae.sundaram@buckingham.ac.uk>
Subject: Re: Article Submission

Dear Jae,

I learnt a lot from the article about the current state of play in respect of patent law in India. I am happy to publish the article in ICTL. I enclose the ICTL stylesheet so please make sure they follow the stylesheet. It is based on OSCOLA. Also please remove the Contents, include an abstract and keywords. Under the title your name and affiliation and contact details.

Could I have the amended version by 30th January so that I can include it in the first issue?

best wishes,
Indira

From: Jae Sundaram <jae.sundaram@buckingham.ac.uk>
To: 'INDIRA CARR' <imcarr@btinternet.com>
Sent: Wednesday, 22 January 2014, 12:59
Subject: RE: Article Submission

Dear Indira

Being the first week of term I had a bit more on my plate than usual and couldn't forward you the draft yesterday, my apologies.

Please find attached a draft for your kind consideration, and I hope it meets your expectations. Please let me know of any decisions at your earliest.

Best regards

Jae

From: INDIRA CARR [mailto:imcarr@btinternet.com]
Sent: 20 January 2014 18:31
To: Jae Sundaram
Subject: Re: Article Submission

Dear Jae,

How is the article coming along?

Look forward to hearing from you.

Best wishes,
Indira