

THE INDIAN PHARMACEUTICAL PATENT REGIME: PROTECTION OF INNOVATION VIS-À-VIS ACCESS TO MEDICINES

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Abstract: *The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Factors such as protection of intellectual property are increasing in significance due to the growing recognition of the need to ensure protection of valuable investments in research and development (R&D). Efforts are being made to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive to technological advances and is in keeping with its global commitments including the Trade-Related Aspects of Intellectual Property Rights (TRIPS).*

Patents on medicines have been one of the most hotly-debated topics since the adoption of the TRIPS Agreement because patents grant exclusivity for the duration of the patent term and result in patent holders having control over the production, supply, distribution and, by virtue of exclusivity, price which creates monopoly and eliminates competition in the pharmaceutical market. The introduction of product patent thus reduces accessibility and affordability of drugs effectively putting them out of the reach of the majority. Thereby adversely affecting industrially developing and least developed countries, hampering their ability to formulate appropriate public health policies that would enable their ailing citizen to access medicines. Also, Indian companies have some challenges ahead in product patent regime, as multinational Pharmaceutical giants launch products in India from their portfolio of global products, which may have higher prices.

The paper seeks to discuss these issues and challenges in the light of the flexibilities like Compulsory Licensing, Parallel Imports, and Bolar Exemption that can be used judiciously by Indian government to make drugs affordable to masses.

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INTRODUCTION: EVOLUTION OF THE INDIAN PATENT REGIME

The first Indian Patent Act was enacted in 1856.³In 1859, special privilege was established exclusively for the inventor which conferred the sole use and selling of his/her invention for 14 years.⁴ Then it was replaced by a more comprehensive Patents and Design Act in 1911.⁵ The Act of 1911 allowed for *Product patents* for drugs and medicines.⁶ The consequences of having strong intellectual property laws in place were that the foreign companies or the MNCs enjoyed a complete monopoly and charged exorbitant prices, and thus dominated the Indian drug market.⁷ They were engaged mainly in the import of drugs from their country of origin.⁸ During that time the MNCs even after controlling 80% of the market, did not come forward with financial investment and technological help to establish drug production centers in India.⁹ Most life-saving drugs like *insulin*, *streptomycin*, and *penicillin* were wholly imported.¹⁰

The Indian Patents Act, 1970¹¹ was a response to the Patents Act, 1911.¹² According to one commentator, the 1970 Indian Patent Act stemmed from a 1959 Ayyangar Committee¹³ report that examined the reasons for the high cost of drugs in post-independence India and concluded that the high prices resulted from the monopoly control foreign based pharmaceutical companies exercised over the production of drugs, due to the prevailing patent regime. To find a remedy to this issue, the Act of 1970 not only excluded drugs from the product claims category but also redefined the working of a patent and its commercial exploitation within India,¹⁴ and excluded any importation from abroad. This (together with a few other policies¹⁵ and safeguards¹⁶) brought about significant

³ The Act 6 of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.

⁴ Tanuja Garde, *India, in INTELLECTUAL PROPERTY IN ASIA: LAW, ECONOMICS, HISTORY AND POLITICS* 55, 57 (Paul Goldstein & Joseph Straus eds., 2009).

⁵ P. NARAYANAN, *PATENT LAW* 6 (3d ed. 1998).

⁶ Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 284 (2006).

⁷ Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* 128 (2005).

⁸ Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 284 (2006).

⁹ American Senate Committee headed by *Senator Kefauver* stated in 1959 in its report that in drugs, generally, India ranks amongst the highest priced nations of the world.

¹⁰ PLANNING COMMN, GOV'T OF INDIA, 1ST FIVE YEAR PLAN ch. 32 paras. 94-99 (1952), *available at* <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html>.

¹¹ The Patents Act, 1970 (39 of 1970)

¹² The 1970 law repealed and substituted the 1911 Act so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. The provisions of the 1970 Act became effective on April 20, 1972.

¹³ N. RAJAGOPALA AYYANGAR, *REPORT ON THE REVISION OF THE PATENTS LAW* (1959).

¹⁴ The Act of 1970 was hailed by many developing countries and UNCTAD (United Nations Conference on Trade and Development) as one of the most progressive statutes which safeguards the interest of both the inventor and the consumer in a balanced manner. This Act was a product of deep consideration and long deliberation to synchronize with the DIRECTIVE PRINCIPLES OF STATE POLICY contained in the Constitution which provides in ARTICLE 39 that:

"39. The State shall, in particular, direct its policy towards securing (a) .(b) That the ownership and control of the material sources of the community are so distributed as best to sub 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 of the common detriment."

¹⁵ Drug Price Control Order, 1970, which put a cap on the maximum price that could be charged, ensured that lifesaving drugs are available at reasonable prices.

¹⁶ Automatic Right to License in the case of lifesaving drugs.

structural changes and growth in the pharmaceutical industry in India.¹⁷ India became self-reliant in drugs. From being an import dependent industry in the 1950s, the Indian pharmaceutical sector has today achieved global recognition as a low cost producer of high quality pharmaceutical products¹⁸ and its annual exports turnover is in excess of \$1.5 billion.¹⁹

India also emerged as a major player in the global pharmaceutical industry and received worldwide recognition as a low cost producer of quality drugs.

The array of measures post 1970, the Indian domestic pharmaceutical industry flourished in the absence of product patents.²⁰ The competitive generic market resulted in production of generic versions of blockbuster drugs at very low prices.²¹ These generic drugs cost about 5% of the price of similar drugs sold by US and EU pharmaceutical firms.²² Apart from the large domestic consumption, cheap Indian generic drugs have been favored by many millions of AIDS patients across the Third World.²³ Generic drugs from India played a key role in lowering the price of *antiretroviral treatment* by as much as 98%, making it feasible to scale up treatment more rapidly for 3.7 million Africans with AIDS lacking access to treatment.²⁴ This could be possible only because there was no product patent system for drugs and pharmaceuticals.

AMENDMENTS AFTER THE TRIPS AGREEMENT

The scenario had to undergo major alteration when in 1995, India became a founding member of the World Trade Organization (WTO) and agreed to the requirements of the WTO intellectual property agreement, Trade-Related Aspects of Intellectual Property Rights (TRIPS) which mandates that all WTO members to adopt and enforce certain minimum standards of IPR protection.²⁵ Because India was a developing country²⁶ and did not provide for pharmaceutical product patenting

¹⁷ Santanu Mukherjee, *The Journey of Indian Patent Law Towards TRIPs Compliance*, 35 INT'L REV. INTELL. PROP. & COMPETITION L. 125, 128-29 (2004).

¹⁸ Medecins sans Frontieres, *Untangling the web of Price Reductions: A Pricing Guide for the Purpose of ARV'S for Developing Countries* 3 (8th ed. 2005), available at <http://www.doctorswithoutborders.org/publications/reports/2005/untanglingthewebv8.pdf>.

¹⁹ Over 20,000 registered pharmaceutical manufacturers exist in the country. The market share of multinational companies has fallen from 75% in 1971 to around 35% in the Indian pharmaceuticals market, while the share of Indian companies has increased from 20% in 1971 to nearly 65%. <http://www.indiapharmachem.com>

²⁰ S. Mukherjee, *The Journey of Indian Patent Law Towards TRIPS Compliance*, 35 *IIC* 125 (2004).

²¹ Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* (Natl. Bureau of Econ. Research, Inc. Working Paper No. 6366, 1998).

²² Intl. Ctr. for Trade and Sustainable Dev., *Indian Parliament Approves Controversial Patents Bill* (Mar. 23, 2005). (available at <http://www.ictsd.org/weeklv/05-03-23/storvl.htm>).

²³ World Heal. Org., *India and Pharmaceutical Patents*. Heal. Tech. and Pharm. News 3 (May 2005) (available at <http://www.who.int/medicines/technologies/newsletter/htp2005May.pdf>).

²⁴ Africa Focus Bull. *India/Africa: Threat to Generic Drugs*, (Mar. 7, 2005) (available at <http://www.africafocus.or2/docs05/indO5O3.php>).

²⁵ A brief summary of the TRIPS Agreement is available at *Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement

²⁶ In 1986, when the negotiations for setting up the WTO began, India and other developing countries—including Brazil and Argentina—strongly opposed it on the premise that protection of IPRs fell within the mandate of the World Intellectual Property Organization (“WIPO”) By 1989, other developing countries changed their stance because of various coercive measures taken by the United States, and India was left alone in its opposition. Thus, India—faced with

when TRIPS came into force, it obtained a 10-year transition period, until January 2005, to put in place pharmaceutical patent protections.²⁷

During this transition period, India was required to provide a means for applications to be filed and assigned a filing date, a “mailbox” facility and “exclusive marketing rights”—the sole right to sell an invention for a specified time—be provided for certain mailbox applications filed during the transition period.^{28,29,30}

TRIPS accelerated the transformation of India’s patent laws³¹ in a multiphased manner that corresponded to three amendments to the Patents Act, 1970.³² Initially a mailbox facility was established, which allowed applicants to file pharmaceutical product patent applications.³³ Applicants were to be given exclusive marketing rights (“EMRs”), subject to certain conditions, to market the product for a period up to five years from the date of grant.³⁴ The second amendment to the 1970 law was made in 2002³⁵ which brought it into conformity with TRIPS on many issues, as it provided for a twenty year patent term,³⁶ reversal of the burden of proof for process patent infringement³⁷ and modifications to compulsory licensing requirements.³⁸ By virtue of the third amendment in 2005,³⁹ the 1970 law offered patent protection to pharmaceutical products⁴⁰ and in the process became substantially compliant with TRIPS.⁴¹

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced

the unviable alternative of remaining completely outside the WTO system—was forced to sign the TRIPS Agreement and join the WTO in 1995

²⁷ Article 65.2 of TRIPS permits developing countries, a transition period of five years to implement the provisions of TRIPS. In addition, if a country did not provide product patent protection in any field when TRIPS came into force, then under Article 65.4, she gets another five years (in addition to the five years permissible under Article 65.2) to introduce such protection

²⁸ Articles 70.8 and 70.9 of TRIPS put a limitation on the transition periods allowed under Articles 65 for two classes of products - pharmaceuticals and agricultural chemicals.

²⁹For a discussion of these transitional arrangements under TRIPS, see Ganesan 1999 in the Indian context and UNCTAD-ICTSD 2003; 2004 in the general context.

³⁰ after WTO complaint was filed by the United States and resolved against India (WTO 1998)

³¹Shamnad Basheer, India’s Tryst with TRIPS: The Patents (Amendment) Act, 2005, 1 INDIAN J.L. & TECH. 15, 16–17 (2005) [hereinafter India’s Tryst with TRIPS].

³²Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 514 (2007)

³³*Id.*

³⁴ The Patents (Amendment) Act, 1999, No. 17 sec. 24(B)(1)(a)-(b), Acts of Parliament, 1999 (India), available at http://ipindia.nic.in/ipr/patent/patact_99.PDF.

³⁵ The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India), available at <http://www.ipindia.nic.in/ipr/patent/patentg.pdf>.

³⁶ *Id.* at sec. 27(a).

³⁷ *Id.* at sec. 43.

³⁸ *Id.* at sec. 39 (substituting ch. XVI, paras. 84-92).

³⁹ The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India), available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

⁴⁰ The Act repealed the controversial Section 5(1) of the Patents Act, 1970, which provided for process patents in this field, and also removed the definition of food.

⁴¹ D.K. Nauriyal, *TRIPS-Compliant New Patents Act and Indian Pharmaceutical Sector: Directions in Strategy and R & D*, INDIAN J. ECON. & BUS. 189 (2006).

the most advanced medicines through reverse engineering.⁴² Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market.⁴³ Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms. The purpose of the patent is to provide a firm of protection for the technological advances and thereby reward the innovator not only for the innovation but also for the development of an invention up to the point at which it is technologically feasible and marketable.⁴⁴

Indian drug manufacturers believed EMRs would lead to the destruction of the local drug industry and that it was more restrictive than even the product patent regime. They argued that foreign drug companies would get the right for exclusive marketing in India before going through an examination in India. However, the biggest impediment to the implementation of the EMR legislation was the fear that the cost of medicines would increase substantially. It was also feared that the Indian drug companies would be driven out of business.⁴⁵ But TRIPS provides some flexibility to the member countries of WTO to take action to tackle such negative consequences of product patent protection.⁴⁶

THE FLEXIBILITIES BUILT INTO INDIAN PATENT LAW

While India made the necessary adjustments to its laws to satisfy the requirements of TRIPS⁴⁷, criticism and concern about the effect of pharmaceutical patents on domestic drug prices compelled the Indian government to retain legitimate means for balancing innovation incentives against the social costs of pharmaceutical product patents.⁴⁸

I. SECTION 3(D) OF INDIAN PATENTS ACT, 1970

⁴²“Four Opportunities in India’s pharmaceutical market”, The Mckinsey Quarterly, Number 4, 1996.

⁴³ Trade & Development Case Studies, <http://www.itd.org/issues/india5.htm>

⁴⁴Jean O Lanjouw, *The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?*, Center Discussion Paper No. 775.

⁴⁵Damanjeet Ghai, PATENT PROTECTION AND INDIAN PHARMACEUTICAL INDUSTRY, *International Journal of Pharmaceutical Sciences Review and Research*, Volume 3, Issue 2, July – August 2010; Article 008 ISSN 0976 – 044X, Available online at www.globalresearchonline.net

⁴⁶In order to address the concerns of developing countries of possible misuse and prevent IPR holders from charging exorbitant and commercially unviable prices for transfer or dissemination of technologies, TRIPS Agreement incorporated particularly Articles 7 and 8. Article 7 identifies that there is need for ‘.....transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge ... conducive to social and economic welfare, and ... balance of rights and obligations’³ while Article 8 identifies that adoption of ‘...measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance.....’, and ‘prevent the abuse of intellectual property rights by right holders ...’⁴. Moreover, The TRIPS Agreement left certain room for the member nations to modify national legislations to their particular needs and policy objectives and yet broadly conform to the global TRIPS framework.

⁴⁷ Ryan Cardwell and Pascal L. Ghazalian, *The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights*, INTERNATIONAL TRADE JOURNAL (2011).

⁴⁸Antara Dutta, From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry, 93 REV. ECON. & STAT. 160, 162 (2011).

A significant means by which the Indian government can “limit the reach of product patent protection” is section 3(d) of the Patents (Amendment) Act of 2005.⁴⁹ Section 3(d) essentially provides for a tougher standard for securing patents.⁵⁰ Companies that introduce new versions of their pharmaceutical products must demonstrate that the new versions are “therapeutically more beneficial than earlier versions on which patents had expired.”⁵¹ Through Section 3(d), India is able to prevent “evergreening,” which critics characterize as a “common abusive patenting practice”⁵² where pharmaceutical companies attempt to extend patent protection by making minor changes to existing drugs.⁵³ Predictably, India’s strict patent regime has spawned discontent among large multinational pharmaceutical corporations interested in tapping into India’s growing market.⁵⁴ Despite concerns on the limiting scope of Section 3(d) in the context of future drug discovery trends, what can be established with certainty is that in the nine years since its inception, Section 3(d) has not resulted in discrimination against western manufacturers as is often claimed.⁵⁵ India’s novel approach to patent law has allowed it to successfully strike a balance between its obligations to TRIPS and its desire to discourage patent evergreening in the best interests of its citizens.⁵⁶

⁴⁹Linda Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 299 (2008). at 294. Section 3(d) states:

[T]he 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 or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known 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, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The Patents (Amendment) Act, 2005, No. 15 of 2005, § 3(d), Gazette of India, section I(2) (Apr. 4, 2005), available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf

⁵⁰Rumman Ahmed & Amol Sharma, *Novartis Fights India for Cancer Pill Patent*, WALL ST. J., <http://online.wsj.com/article/SB10000872396390444233104577594973786074692.html>. According to PricewaterhouseCoopers LLP, India’s pharmaceutical industry amounted to \$11 billion in 2011. Id.

⁵¹Id. The underlying assumption behind section 3(d) is that derivatives, such as salt forms, polymorphs, isomers etc.] that are structurally similar to known pharmaceutical substances are likely to be functionally equivalent as well, and if this is not the case and the new form of an existing substance works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim to a patent.

Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing Out the Creases in Section 3(d)*, 5 SCRIPTED 232, 239 (2008) [hereinafter *The “Efficacy” of Indian Patent Law*].

⁵²Leena Menghaney, *India’s Patent Law on Trial*, BMJ GROUP BLOGS (Sept. 27, 2012), <http://blogs.bmj.com/bmj/2012/09/27/leena-menghaney-indias-patent-law-on-trial/>.

⁵³Helen Pidd, *Indian Court to Hear Crucial Novartis Patent Case on Cut-Price Generic Drugs*, GUARDIAN (Aug. 21, 2012), <http://www.guardian.co.uk/business/2012/aug/21/novartiscourt-battle-glivec-patent>.

⁵⁴Taking Pains: Indian Patent Rules Infuriate Big Pharma, ECONOMIST (Sept. 8, 2012), <http://www.economist.com/node/21562226> [hereinafter *Taking Pains*].

⁵⁵In the three fiscal years between April 2010 and March 2013 alone, India’s Controller General of Patents, Designs and Trade Marks awarded as many as 1001 pharmaceutical patents, of which 771 (a staggering 77 per cent) were granted to foreign firms from the US and Europe. The two greatest beneficiaries during this period were US-based pharma giants Eli Lilly and Pfizer, who between them secured a total of 68 patents [Hemant Krishna Singh & Aman Raj Khanna, “*India’s IPR regime-Moving beyond the myth of US pharma*”, Business Standard, October 2013.

⁵⁶Aman Raj Khanna & Hemant Krishna Singh, *India’s IPR Regime: Reconciling Affordable Access with Patent Protection India’s IPR Regime: Reconciling Affordable Access with Patent Protection*, Indian Council for Research and International Economic Relations (August, 2013)

II. COMPULSORY LICENSING

In addition to India's higher standards of patentability, another contentious aspect of India's patent regime is its purported propensity to employ the compulsory licensing provision against (usually foreign) innovators in the Pharma sector.⁵⁷ It is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs. Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person the right to make a patented product, or use a patented process under license, without the consent of the original patent holder.⁵⁸ Under section 84(1) of the amended Act, an application can be made for compulsory license three years after the grant of a patent.⁵⁹ In the context of India's IPR regime, this issue came into the global spotlight in March 2012, when India's Controller General of Patents awarded Indian generic manufacturer NATCO a compulsory license for producing Bayer's blockbuster kidney cancer treatment *Sorafenibtosylate*, widely marketed under the name *Nexavar*.⁶⁰ The proceedings were initiated by NATCO's application for a compulsory license under the provisions of Section 84 of the Indian patent law, after it unsuccessfully approached the patentee for a voluntary license of the product.

III. BOLAR PROVISION

The "Bolar" provision is the best known of the many limited exceptions to the patentee's exclusive rights under Article 30 of the TRIPS.⁶¹ It is very important for generic entry. The amended Patent Act provides for Bolar exception.⁶² This would allow a generic drug manufacturer to produce or import patented drugs for the purpose of development and submission of information for regulatory trials before patents expire. In other words, but for the "Bolar" exception in Indian patent law, generic manufacturers would be forced to wait for the patent to expire before embarking on the mandatory tests necessary for regulatory approvals. This would allow Indian generic manufacturers

⁵⁷ As Y K Hamied, the chief of Cipla, the reputed generic company from India has pointed out, they are not against product patents. They are against monopolies in vital areas of food and medicine and hence wants an easy to use compulsory licensing system. (Interview with Y K Hamied, Mumbai, 22 August, 2002; see also his interview published in *Pharma Bioworld*, February-April, 2004, reproduced in *IDMA Bulletin*, 30 April, 2004).

⁵⁸ World Trade Org., *FAQ on Compulsory licensing of pharmaceuticals and TRIPS*, (available at <http://www.wto.org/lish/tratop e/trips e/public health faqe.htm>).

⁵⁹ With respect to exporting drugs to a country which makes a request for a generic drug, the Act has simplified the compulsory licensing procedure; countries that put in a request for generic drugs do not have to issue a compulsory license:

SECTION 92A. (1) OF THE PATENTS ACT: "*Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of patented pharmaceutical products from India*"

⁶⁰ Maulik Vyas, *Bayer challenges IPAB's compulsory license order to Natco Pharma on cancer drug Nexavar*, *Economic Times*, October 12, 2013.

⁶¹ It is known as 'Bolar' provision after the court case involving Roche, an MNC and Bolar Pharmaceuticals, a generic company. The US court denied Bolar the right to develop and submit a generic product for regulatory approval before the expiry of the patent. The Hatch-Waxman Act basically overrules this court ruling .

⁶² SECTION 107A(A) OF THE PATENTS (AMENDMENT) ACT, 2005, :"*any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.*"

to compete among themselves, ensuring the continued availability of medicines at low costs for domestic, as well as international consumers.⁶³

IV. PARALLEL IMPORTS

Another important flexibility has been provided under Article 6 of TRIPS as Parallel imports. It occurs when patented medicines produced or sold abroad with the consent of the patent owner are subsequently imported into the domestic market at cheaper prices without the consent of the owner. In the Patent Act, 1970, Section 107A (b) contained a provision regarding parallel imports. This has since been streamlined further to avoid unnecessary delays.⁶⁴

CONCLUSION

The concern for securing access to affordable drugs is also a real one and there are strong moral arguments for why increasing patent protection for the products of powerful MNCs works only to hurt the common man. However, in reality, the protection of intellectual property rights provides the corporations with the much needed incentive to invent and manufacture the drugs on which patients around the world rely, whether branded or generic. Patent is an essential component of the framework for developing countries like India to magnetize foreign investment and faster technology transfer. In theory, India could continue down its current path where its generics industry simply reverse-engineers the pharmaceuticals that are researched and developed elsewhere. But if India desires to grow into its role as a major scientific and technological powerhouse, then it must work to protect intellectual property rights, as opposed to doing the bare minimum to ensure compliance with TRIPS. To strike a fine balance between both is the need of the hour which would benefit the domestic industry and the patients.

⁶³Prabhu Ram, *India's New "Trips-compliant" Patent Regime between Drug Patents and the Right to Health*, Chicago-Kent Journal of Intellectual Property (2006)

⁶⁴SECTION 107A(B) of the amended Act reads as follows: *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.*