

Access to Medicines in the Light of Patent Law Regime in India: A legacy of legislation or Lease of the Judiciary?

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Abstract

This paper aims to trace the development of patent law regime in India, and analyze its evolution in response to globally influential intellectual property framework, such as TRIPS and pressure from developed countries US and Europe to open up her markets to permit cash-rich pharmaceutical companies to sell their drugs and receive patent protection in India.

An observation of the legislative actions and judicial responses reveal that both the parliament and the supreme echelons of the judiciary have been tediously careful in protecting the health care needs of the poor by promoting the generic drug industry through a guarded interpretation of Section 3(d) of Patents Act, 1970. The objective of the paper is to critically analyze the legislative reforms and judicial interpretations of patent law in light of the socio-economic needs of the country.

Keywords: patents, access to medicines, pharmaceuticals, product patents, affordable healthcare

1. INTRODUCTION

Infectious diseases kill over 10 million people each year, more than 90% of whom are in the developing world.¹ The leading causes of illness and death in Africa, Asia, and South America—regions that account for four-fifths of the world's population are HIV/AIDS, respiratory infections, malaria, and tuberculosis.² The magnitude of the disease crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat these diseases or alleviate suffering.³

In India, Hepatitis-B is one of the most common food or water borne disease in India. There are over 40 million infected patients, and India is second only to China in the highest number of Hepatitis-B (HBV) infected patients by country⁴. Every year, nearly 600,000 patients die from

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¹World Health Organization, *The World Health Report 2001*, 310, WHO (2000).

²*Id.*

³UNAIDS, *UNAIDS: Reports on the Global HIV/AIDS Epidemic*, available at www.unaids.org/epidemic_update/report/Epi_report.pdf (last visited: April 5, 2015); F.M't Hoen, Ellen, *TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond*. (2002).

⁴<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244675/> (last visited: April 15, 2015)

HBV infection in the Indian continent. In addition, around 20,000 people die of typhoid fever in the country.⁵

Among vector-borne diseases, malaria is the most common killer in the country, with 40,297 deaths reported per year.⁶ In 2006, India reported 1.39 million cases of Chikungunya with no attributable deaths.⁷ Ahmedabad alone reported around 60,777 cases⁸. Since 1985, India has reported an estimated 25, 000–30, 000 human deaths from rabies annually. The current statistics now stands at 20, 565 deaths per year.⁹

Besides these common infections, India, with 2.1 million patients, has the 3rd highest number of HIV patients in the world, behind only South Africa and Nigeria.¹⁰ On a brighter note, the 2012 UNAIDS Report stated that new HIV cases among adults declined by half in India since 2000, while praising India's contribution to AIDS response through manufacture of generic antiretroviral drugs.¹¹

The reasons for the lack of access to essential medicines are manifold, however, in many cases, the high prices of drugs are a barrier to needed treatments.¹² Such exorbitant, and thus, prohibitive drug prices are often the result of strong intellectual property protection.¹³ Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has ground to a standstill because drug companies in developed and developing nations simply cannot recoup the cost of R&D for products to treat diseases that

⁵ UNAIDS, *Supra* note 3, at 24-25.

⁶ National Center for Biotechnology Information, *Supra* note 4.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *India has 3rd-highest number of HIV-infected people: UN*, available at: <http://www.thehindu.com/sci-tech/health/india-has-3rdhighest-number-of-hivinfected-people-un/article6220483.ece>, (last visited: 20 April, 2015).

¹¹ "With 80 per cent of these drugs being generics purchased in India, several billion dollars have been saved over the past five years. The country is also committed to new forms of partnership with low-income countries through innovative support mechanisms and South-South cooperation," the UNAIDS report says. It also points out that India already provides substantial support to neighbouring countries and other Asian countries – in 2011, it allocated USD 430 million to 68 projects in Bhutan across key socio-economic sectors, including health, education and capacity-building. In 2011 at Addis Ababa, the Government of India further committed to accelerating technology transfer between its pharmaceutical sector and African manufacturers., available at:

http://www.unaids.org/sites/default/files/media_asset/JC2434_WorldAIDSday_results_en_1.pdf, (last visited: April 20, 2015)

¹² See Ellen F.M. T' Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, available at: <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf> (last accessed: July 14, 2015)

¹³ *Ibid.*

abound in developing countries.¹⁴ A number of new medicines vital for the survival of millions are already too costly for the vast majority of the people in poor countries.¹⁵ In addition, the investment in Research and Development (R&D) towards the health needs of people in developing countries has almost come to a standstill.¹⁶ Developing countries, where three-quarters of the world population lives, accounts for less than 10% of the global pharmaceutical market.¹⁷

The TRIPS Agreement, effective from January 1, 1995, is the most comprehensive multilateral treaty on intellectual property rights till date.¹⁸ This Agreement sets out the minimum standards for protection of intellectual property, including provisions to be made for product patents for drugs and pharmaceuticals (Article 27.1), which member states must comply with.¹⁹ The Agreement, keeping in mind the needs of the developing countries, have afforded certain flexibilities, which may be harnessed by developing and under-developed countries, in order to control over-pricing of the drugs, so that medicines are within reach of the economically disadvantaged sections.²⁰

Indian patent regime cleverly employs these flexibilities to curb monopolistic tendencies of the large pharmaceutical industries, the gates for whom were opened post-TRIPS, with the introduction of patent patents.²¹ In addition, the judiciary, with the manner of its legislative interpretation, has also played a key role in access to medicines in India.

This paper seeks to explore the evolution of patent law in India, the socio-economic, political and international undercurrents that sculpted the law over the period of time, from 1911 to 2005 and the kind of role the judiciary has played in access to medicines in India.

2. EVOLUTION OF INDIA'S PATENT LAW

2.1. PATENTS ACT, 1911: A LEGACY OF THE BRITISH RAJ

¹⁴ Pècoul B. *et. al.*: *Access to Essential Drugs in Poor Countries. A Lost Battle?* JAMA pp. 281-361 (1999); *Id.* At p. 4.

¹⁵ T'Hoën *Supra* Note 12, at 20-25.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M 81 (1994).

¹⁹ See Ellen F.M. T' Hoën, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, available at: <http://www.who.int/intellectualproperty/topics/ip/tHoën.pdf> (last accessed: July 14, 2015).

²⁰ *Id.*

²¹ ELIZABETH VERKEY, *LAW OF PATENTS*, 15 (Abhinandan Malik ed. 2nd Ed. 2012).

The beginnings of the Indian Patent law is traced back to 1856 when the Protection of Inventions Act was enacted based on the British Patent Law of 1852. Under the Act of 1856, exclusive privileges were granted to the inventors of new manufacturers for a period of 14 years.²²

This Act was modified in 1859, under which patent monopolies, called as exclusive privileges were granted for a period of 14 years from the date of filing of the specification.²³ Subsequently, the Patents and Designs Protection Act was adopted in 1872.²⁴ These acts were consolidated as the Inventions and Designs Act.²⁵ In 1911, the Indian Patents and Designs Act was enacted. The 1911 Act had provisions for both product and process patents.²⁶

A need was felt for a comprehensive law on patent when the 1911 Act was found inadequate to respond to the needs of the society and keeping pace with industrial development of the nation.²⁷ At this point of time, foreign firms controlled about 70 percent of the Indian market, and the Indian drug prices were among the highest in the world.²⁸ Foreign firms could use colonial era patent laws to their advantage to suppress competition from local companies.²⁹ It was generally felt that the patent law had done little good to the people of the country. The way the Act was designed benefited foreigners far more than Indians. It did not help at all in the promotion of scientific research and industrialization in the country, and it curbed the innovativeness and inventiveness of Indians.³⁰

Therefore, shortly after independence in 1949, a committee was constituted under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of the Lahore High Court, to undertake a comprehensive review of the working of the 1911 Act.³¹ The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for

²² *Id.* at p. 16.

²³ *Id.*

²⁴ *Id.* at p. 16.

²⁵ *Id.* at p.17.

²⁶ **Section 2(8) “Invention”** means any manner of new manufacture and includes an improvement and an alleged invention

Section 2(10) “Manufacture” includes any art, process or manner of producing, preparing or making an article, *and*

also any article prepared or produced by manufacture.

Section 14- Term of Patent. (1)The term limited in every patent for the duration thereof shall, save as otherwise expressly provided by this Act, be sixteen years from its date.

²⁷ AYYANGAR J., REPORT ON THE REVISION OF PATENT LAW 27 (1959).

²⁸ VERKEY, *See Supra* Note 21, at 17.

²⁹ V.K. AHUJA, INTELLECTUAL PROPERTY RIGHTS IN INDIA 106 (1st Ed. 2009)

³⁰ *Id.* at 120.

³¹ *Id.* at 131.

prevention of misuse or abuse of patent rights in India.³² It also observed that the Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee. Based on the committee's recommendations, the 1911 Act was amended in 1950 (by Act XXXII of 1950) in relation to working of inventions, including compulsory licensing and revocation of patents.³³ In 1952, a further amendment was made (by Act LXX of 1952) to provide for compulsory license in respect of food and medicines, insecticide, germicide or fungicide, and a process for producing substance or any invention relating to surgical or curative devices.³⁴ The committee's recommendation prompted the Government to introduce a bill (Bill no. 59 of 1953) in Parliament, but the bill was not pressed and it was allowed to lapse.³⁵

2.2. JUSTICE AYYANGAR COMMITTEE REPORT AND ITS IMPLICATIONS

In 1957, Justice Rajagopala Ayyangar was appointed by the Government of India to examine afresh and review the patent law in India and advise the Government on the changes required to be made in the law. Justice Ayyangar analyzed and pointed out that during the period 1930-37, the grant of patents to Indians and foreigners was roughly in the ratio of 1:9. Even after Independence, though a number of institutions for post-graduate training were set up and several national laboratories were established to encourage a rapid growth of scientific education, the proportion of Indian and the foreign patents remained substantially the same, at roughly 1:9.³⁶

Justice Ayyangar further pointed out that this ratio does not take into account the economic or industrial or scientific importance of the inventions.³⁷ If these factors are taken into account, Indians would appear to be lagging even further behind. Further, taking into reckoning the number of inventions for which renewal fees were paid beyond the 6th year, which would give a rough idea of the value attached to the invention by the patentee, the patents taken by Indians would appear to be of little worth as compared with patents held by foreign nationals.³⁸

³² *Id.*

³³ VERKEY, *Supra* Note 21, at 32.

³⁴ *Id.*

³⁵ *Id.*

³⁶ AYYANGAR J. REPORT ON THE REVISION OF PATENT LAW 34 (1959).

³⁷ *Id.*

³⁸ *Id.* at 40.

Sudip Chaudhari in his book titled, *The WHO and the Indian Pharmaceuticals Industry*³⁹ describes the market shares of multi-national companies and Indian companies in India as under:

Year	MNCs (%)	Indian Companies
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77

The fall and rise of the Indian pharmaceutical industry is explained as the result of certain factors, not the least important of which was the change in the patent law in the country, which made medicines and drugs and chemical substances non-patentable.⁴⁰ Chaudhuri explains that before the introduction of sulfa drugs (1930s) and penicillin (1940) that brought about the therapeutic revolution, drugs of natural origin were more important than synthetic ones.⁴¹

By the time the Second World War started (1939), several indigenous firms were engaged in manufacturing drugs, and indigenous producers met 13 per cent of the medicinal requirements of the country.⁴² Indigenous firms and producers still had a long way to go to attain self-sufficiency but in terms of the range of operations they were already manufacturing all types of drugs.⁴³ By the early 1950s, because of the spread of manufacturing activities, the indigenous sector dominated the pharmaceutical industry in India.⁴⁴ It accounted for about 62 per cent of the market in 1952 (the table above). However, the rise and growth of multinational corporations (MNCs) worldwide in the post-Second World War period, as well as the therapeutic revolution changed these dynamics.⁴⁵ The

³⁹ See SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 1, 29 (2005) (estimating 68 percent); P. K. Ramachandran & B. V. Rangarao, *The Pharmaceutical Industry in India*, 7 *Econ. & Pol. Wkly.* M-27, M-30 (1972) (estimating 75 percent).

⁴⁰ *Id.* at p. 123.

⁴¹ *Id.* at 56-58.

⁴² *Id.* at 34.

⁴³ *Id.* at 45.

⁴⁴ *Id.* at 72.

⁴⁵ *Id.* at 31.

MNCs started research for developing new drugs in the 1930s-40s.⁴⁶ As a result, in the late 1940s and during the 1950s and even after that at a slower rate, new drugs discovered by the MNCs began to be available for medical use. The indigenous sector was not equipped for research for developing new drugs, that is, for developing a new chemical entity.⁴⁷ With the introduction of new drug at a rapid rate by the MNCs, the role of patents became important. Because of the patent regime under the 1911 Act and the unsupportive industrial policy, the indigenous sector lost its status in the 1950s and the 1960s.⁴⁸ In contrast to 62 per cent of the market in the early 1950s, the market share of the indigenous sector declined to 32 per cent by 1970. In contrast, the market share of the MNCs increased from 38 per cent in 1952 to 68 per cent in 1970 (the table above).

However, according to Chaudhuri, the situation changed in the 1970s. Several official initiatives were taken in the 1970s, of which the most important one was the enactment of the Patents Act, 1970, which changed the environment in favour of the indigenous sector.

Observing that industrial countries and under-developed countries had different demand and supply requirements, Justice Ayyangar pointed out that the same patent law would operate differently in two countries at two different levels of technological and economic development, and hence the need to regulate the patent law in accordance with the need of the country.⁴⁹

Justice Ayyangar observed that the provisions of the Patent law have to be designed with special reference to the economic conditions of the country, the state of its scientific and technological advancement, its future needs and other relevant factors, and so as to minimize, if not to eliminate, the abuses to which a system of patent monopoly is capable of being put. Bearing in view the matters set above, he recommended retaining the Indian patent system, but with a number of improvements.⁵⁰

One of the improvements suggested was to define, with precision, those inventions which should be patentable and equally clearly identify certain inventions, the grant of patents to which

⁴⁶ *Id.* at 90.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ AYYANGAR J., *Supra* Note 37, at 265.

⁵⁰ *Id.* at 201.

would retard research, or industrial progress, or be detrimental to the national health or well-being, and to make those inventions non-patentable.⁵¹

In regard to patents for chemical substances, he examined the history of the law in other countries and pointed out that Germany was the first to adopt the system of confining the patentability of inventions relating to chemical products or substances to process claims. The law was then followed in many other countries in the world, for instance Austria, Brazil, Czechoslovakia, Holland, Hungary, Japan, Mexico, Norway, Poland and the U.S.S.R.⁵² Products produced by chemical process were not patentable though processes for making such products were patentable, if they satisfied the other tests of patentability, e.g. novelty, subject matter, etc. In light of the experience of the other countries, Justice Ayyangar recommended that only process claims should be permitted for chemical and pharmaceutical industry.⁵³

Coming to the patents for inventions relating to food and medicine, Justice Ayyangar pointed out that barring the US, there was hardly any country that allowed unrestricted grant of patents in respect of articles of food and medicines, or as to the licensing and working of patents in this class.⁵⁴ In none of the countries of Europe were patents granted for product claims for articles of food or medicine, and in a few (Denmark for articles of food; and Italy, under the law of 1957, for medicinal products) even claims for processes for producing them were non-patentable. He explained that the reason for this state of law is stated to be that the denial of product claims is necessary in order that important articles of daily use such as medicine or food, which are vital to the health of the community, should be made available to everyone at reasonable prices and that no monopoly should be granted in respect of such articles. Refusal of product patents would enlarge the area of competition and thus result in the production of these articles in sufficient quantity and at the lowest possible cost to the public.⁵⁵

Ayyangar Committee Report⁵⁶ advised against patenting of products in the case of food, medicines, drugs and chemical substances, as the Committee found that foreigners held between eighty and ninety patents in India, and more than 90 percent of the these patents were not

⁵¹ *Id.* at 405.

⁵² *Id.* at 550.

⁵³ *Id.* at 407.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

commercially worked in India. In light of its conclusions, the Committee concluded that the system was exploited by multinationals to achieve monopolistic control over the market. This recommendation of the Committee saw its light of the day in the Patents Act, 1970, which came into force on 20 April, 1972.

2.3. PATENTS ACT, 1970

The 1970 Act introduced the definition of “patent”⁵⁷ as a right granted for an invention as a new product or a process involving an inventive step and capable of industrial application. The Act further defines an invention as a new product or a process involving an inventive step and capable of industrial application. On combined reading of Section 2 (j), (ac) and (ja), in order to qualify as an invention, a product should satisfy the following tests:

1. It should be novel, or “new”
2. It should be an outcome of inventive activity,
3. It should have utility, or “capable of being used in an industry”
4. It should not be contrary to law and morality,
5. It must come into being as a result of an invention which has feature that:
 - (a) Entails technical advance over existing knowledge;
 - (b) Or has an economic significance
6. Makes the invention not obvious to a person skilled in the art

The 1970 Act served as a substantial driver of three decades of growth in the domestic pharmaceutical industry.⁵⁸ One of the significant changes made by the 1970 Act was prohibiting product patents on medicines. In the years that followed the enactment of the Act, the number of patents granted in India dropped significantly.⁵⁹ Although the law permitted process patents related to medicines, they were very limited in scope and rarely sought. The law thus, created significant space for the entry of local pharmaceutical firms, and they rapidly, increased their share of the Indian market.⁶⁰ Indian companies became skilled in reverse engineering and developing new

⁵⁷ Section 2(j), (m), Patents Act, 1970.

⁵⁸ Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CLR 1571, 1577 (2009) (discussing the importance of Patents Act, 1970 in Indian patent law regime).

⁵⁹ *Id.* at 1578.

⁶⁰ See, e.g., Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: “Heartless Exploitation of the Poor and Suffering”?* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 6366, 1998), available at www.oiprc.ox.ac.uk/EJWP0799.pdf (last visited: April 20, 2015).

processes for drug production. In the mid-1970s, Indian firms became more technically sophisticated, producing active pharmaceutical ingredients (APIs), with production steadily increasing over the next three decades.⁶¹ Over time, the Indian industry also evolved to become extraordinarily competitive and diverse. Numerous surveys indicate that Indian drug prices by the 1990s were among the lowest in the world.⁶²

In regard to the Patents Act, 1970, Chaudhuri maintains that Patent “reforms” contributed directly to the transformation of the pharmaceutical industry. He points out that under the Patents Act, 1970, articles of food, medicines and drugs and chemical substances could be patented only for a new method or process of manufacture, not for the products as such (section 5 of the 1970 Act). Further, unlike in the previous patent regime, for each particular drug only one method or process – the best known to the applicant - could be patented (sections 5 and 10 of the 1970 Act).⁶³ Also, even in case of a process patent for an article of food, medicine or drug, the term of the patent was brought down from fourteen (14) years to five (5) years from the date of sealing of the patent, or seven (7) years from the date of patent whichever was earlier. Till the early 1970s the industry was dominated by MNCs who commanded 68% of the market share. India was dependent on imports for many essential bulk drugs.⁶⁴ This import dependence constricted consumption in a country deficient in foreign exchange, and inhibited the growth of the industry. Drug prices in India were very high. In the late 1970s and 1980s, Indian companies started large-scale production of bulk drugs.⁶⁵ The development of the bulk drugs sector is actually the most important achievement of the pharmaceutical industry in India. This led to the transformation of the industry.

The most rapid growth of the Indian pharmaceutical industry took place from the 1990s onwards. Both production and exports grew remarkably fast. The production of both bulk drugs and formulations started increasing sharply and steadily.⁶⁶ From Rs.6, 400 million in 1989-90, bulk drugs production increased to Rs.77, 790 million in 2003-04; and from Rs.34, 200 million in 1989-90, formulation productions increased to Rs.276, 920 million in 2003-04.⁶⁷ The growth was most

⁶¹ Aradhna Aggarwal, *Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry* 16 (Research & Info. Sys. for Dev. Countries, Discussion Paper No. 80, 2004), available at http://www.ris.org.in/Dp80_pap.pdf. (last visited: April 21, 2015).

⁶² CHAUDHARI, *Supra* Note 39, at 345-346.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

remarkable from 2000 to 2005, when production increased much more than it had in the last two decades.⁶⁸ Indian companies further consolidated their domination in the domestic market. Their market share increased from 60 per cent in 1991 to 68 per cent in 1998 and 77 per cent in 2003.⁶⁹

The growth was also very fast in the export markets. India became a net exporter by 1988-89, and since then there has only been an increase in the Indian exports.⁷⁰ As a result, net exports as a percentage of exports have increased from 4.4 per cent in 1988-9 to about 50 per cent in the early 1990s and more than 75 per cent in the early 2000s. More than three-fourths of bulk drug production and almost one-fourth of the formulations production are exported.⁷¹ The USA, which has the toughest regulatory requirements, has emerged as India's largest export partner in pharmaceuticals.

Dealing with the growth of the Indian pharmaceutical industry after the change in the patent law, Chaudhuri⁷² writes:

" Because of the rapid growth and structural transformation in the last three decades or so, India now occupies an important position in the international pharmaceutical industry... India has received worldwide recognition as a low cost producer of high quality bulk drugs and formulations. India produces about 350 bulk drugs ranging from simple pain killers to sophisticated antibiotics and complex cardiac products. Most of the bulk drugs are produced from basic stages, involving complex multi-stage synthesis, fermentation and extractions. For more than 25 bulk drugs, India accounts for more than 50 per cent of the international trade. India is a major force to reckon with in the western markets for such drugs as ibuprofen, sulphamethoxazole... "

2.4. WTO AND TRIPS: THE TWIST IN TALE

In 1995, India joined the WTO and with it had to join the TRIPS Agreement.⁷³ TRIPS had the effect of altering the terrain of international law.⁷⁴ The treaty was product of intensive lobbying and concerted efforts by the multinational firms in information-intensive industries that persuaded United States, Europe, and Japan that their national trade supremacy depended on stronger

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ See Kapczynski, *Supra* Note 58, at 1611.

⁷⁴ *Id.* at 1600.

protection for IP abroad, especially in the developing countries.⁷⁵ The “single undertaking” nature of the WTO ensured that countries would have to accept TRIPS if they wanted to be part of the WTO.⁷⁶

TRIPS has caused the most controversy in the domain of access to medicines because it requires patents on pharmaceutical products.⁷⁷ India opposed TRIPS, and particularly its patent provisions, as did the bulk of the Indian pharmaceutical industry.⁷⁸ Faced with the alternative of remaining entirely outside the WTO framework, India nonetheless acceded to the Agreement, negotiating in the process for certain flexibilities that would limit the effects of the changes it required.⁷⁹

The TRIPS Agreement also provides for a built-in mechanism for review through the biennial Ministerial Conference (vide Article 71). The Ministerial Conference is the highest decision-making body of the WTO and it can make decisions on all matters under any of the WTO agreements, including the TRIPS Agreement.⁸⁰ The fourth WTO Ministerial Conference in Doha on November 14, 2001, adopted the Doha Declaration on the TRIPS and Public Health.⁸¹

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at 1579.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 1601.

⁸¹ “1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

2.5. TRIPS AND ITS CONSEQUENCES ON INDIAN PATENT LAW

Under the TRIPS Agreement, developing countries that did not provide patent protection for pharmaceutical and agricultural chemical products were given 10-year transition period to establish such protection.⁸² In the interim, however, these countries were required to establish a “mail box system” to receive and date patent applications.⁸³ In addition to the grant of mail applications, as designed to preserve the novelty of the inventions and priority of the applications during the transition period, the TRIPS Agreement also required the countries to grant Exclusive Marketing Rights (EMRs) to certain products that are subject to mail box applications.⁸⁴

India was required to comply with the product patent requirements of TRIPS until 2005, although it did have to create a “mailbox” for filing of patent applications that would be examined when the 2005 changes came into effect.⁸⁵ While the full legal effects on India were nonetheless substantial, because of its impact on the behavior and thinking of industry and health advocates. In order to meet the December 31, 2004 deadline for the introduction of product patents, India passed an ordinance that temporarily brought its law into compliance.⁸⁶ The Ordinance, set to expire in approximately three months, set the stage for intense debating and protests from several advocacy groups.⁸⁷ The exceptionally globalized advocacy efforts around the bill resulted in several consequential changes in the new law: The Patents (Amendment) Act, 2005.

d. The effect of the provisions in the 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 provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.”

⁸² VERKEY, *Supra* Note 21, at 390-394.

⁸³ Art. 70(8), TRIPS.

⁸⁴ VERKEY, *Supra* Note 21, at 435.

⁸⁵ *Id.* at 436.

⁸⁶ *Id.*

⁸⁷ *Id.*

2.6. PATENTS (AMENDMENT) ACT, 2005: SALIENT FEATURES AND RESULTANT CHANGES IN THE LAW

The changes brought about by the 2005 Amendment, included most insignificantly, new subject matter exclusions, and the resurrection of full pre-grant opposition system.⁸⁸ One of the most significant amendments was the deletion of Section 5 of the Act, which prohibited patenting of products in case of food, drugs, medicines, chemical substances. With the amendment, it is now possible to obtain product patents in the case of drugs, food, medicines, and chemical substances.⁸⁹ This was, without hesitation, the single most important change brought about by the Amendment of 2005, as it opened doors for product patents in areas of food, medicines, and agro-chemicals in India.⁹⁰ The removal of Section 5 was also accompanied by amendments in clauses (j) and (ja) of Section 2(1), apart from some other ancillary clauses of Section 2(1), as well as amendments in Section 3, which redefined the concepts of invention and patentability.⁹¹

The reintroduction of the product patents was a cause of concern not only for the country, but also for other developing countries and international agencies, as the earlier patent system which had barred patent products for pharmaceuticals, food and agro-chemicals, had led to exponential growth of the indigenous drug industry, which scaled great heights and became a major supplier of affordable medicines to a number of developed and other developing countries.⁹²

Another cardinal amendment was the inclusion of Section 3(d), which states that “mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is *not* (emphasis added) an invention, and therefore not patentable. Therefore, under this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers,

⁸⁸ *Id.* at 550.

⁸⁹ See Kapczynski, *Supra* Note 58, at 1580-81.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Letter of the HIV/AIDS Director of the WHO, dated December 17, 2004, to the Minister of Health and Family Welfare, Government of India, “We would like to bring to your attention that several of our Member States have expressed their concern that in the future, generic antiretroviral drugs from India may no longer be available to them. Among other places, these concerns were expressed by the delegations of Ghana, Lesotho, Malawi, and Namibia at our recent Procurement & Supply Management (PSM) Workshop in Nairobi, Kenya (2-9 December, 2004), and by Bangladesh, Cambodia, China, Indonesia, Korea, Laos, Thailand, Papua New Guinea, and Vietnam at the Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines held in Kuala Lumpur, Malaysia (28-30 November 2004)... As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to antiretrovirals, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines.”

mixtures of isomers, complexes, combinations and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.⁹³ Further, Section 21 of the 2005 Amendment⁹⁴ removed Chapter IV A of the 1970 Act, dealing with provisions related to Exclusive Marketing Rights (EMRs). Since the grant of pharmaceutical patents was a particularly controversial issue, developing and Least Developed Countries (LDCs) were required to grant EMRs to certain products that are subject to mail box applications under the TRIPS Agreement.⁹⁵ According to Article 70 (9) of the TRIPS Agreement, a grant of EMRs is contingent on two pre-conditions:

1. The issuance of a patent to another WTO member state for the product that is subject of mail box application;
2. The securing of marketing approval for the product in the country where the mail box application is filed.

In order to bring India in line with the obligations of Article 70(8) and (9), the President of India promulgated an amendment to the Indian Patents Act, 1994.⁹⁶ However, the ordinance failed to receive endorsement from the Parliament when it resumed session. As a result, India had no explicit, published legal basis for receiving mail box applications or for granting of EMRs for pharmaceutical and agricultural chemical products.⁹⁷ On request filed by US, the WTO established a panel to hear a dispute filed USA regarding India's non-compliance of Article 70 (8) and (9) of the TRIPS Agreement. The Panel found that India had violated Article 70(8) and (9) of TRIPS.⁹⁸ India's appeal was rejected by the appellate body on the grounds that its administrative mechanisms for accepting "mail box applications" were insufficient to establish legally tenable provisions.⁹⁹ In addition, India had also failed to institute a legal mechanism for granting of EMRs by January 1, 1995.

2.7. PATENTS (AMENDMENT) ACT, 1999

Subjected to intense international pressure, India introduced the first amendment to Patents Act, 1970 in 1999.¹⁰⁰ Two key aspects of this amendment were: "provision for mailbox", and the

⁹³ Explanation to Section 3(d), Patents Act, 1970.

⁹⁴ Patents (Amendment) Act, 2005.

⁹⁵ Article 70(8), TRIPS.

⁹⁶ See Kapczynski, *Supra* Note 58, at 1582.

⁹⁷ VERKEY, *Supra* Note 21, at 456.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

“provision for EMR” for products related to drugs, pharmaceuticals and agrochemicals, effective from January 1, 1995.

Under the Patents (Amendment) Act, 1999 which established EMRs for mailbox applications in India, the following conditions were laid down:

1. The product must be patentable, that is, it must be an invention as per the Patents Act 1970.
2. The invention must have been made in India or in a WTO Convention country. If made in a convention country, the invention must have been:
3. (i) Filed on or after January 1, 1995, and
(ii) Before getting a patent in India, the applicant must have obtained such a patent in the Convention country.
4. If the invention has been made in India,
5. (i) The application for patent for the method or process of production of such a substance should have been filed on or after January 1, 1995, and
(ii) The patent must have been granted on or after the date of filing of such EMR.¹⁰¹

The Patents (Amendment) act, 2005 removed this provision for EMRs, after the patent law of India was brought fully in line with TRIPS, at the end of the 10-year transition period.¹⁰²

2.8. THE PATENTS (AMENDMENT) ACT, 2002

The 2002 Amendment to Patents Act, 1970 was particularly significant because it inserted Section 104A, dealing with burden of proof in case of infringement.¹⁰³ In the case of *Glenmark*

¹⁰¹ Patents (Amendment) Act, 1999.

¹⁰² Patents (Amendment) Act, 2005.

¹⁰³The Section states that, “(1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process if,-
(a) the subject matter of the patent is a process for obtaining a new product; or
(b) there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used: Provided that the patentee or a person deriving title or interest in the patent from him, first proves that the product is identical to the product directly obtained by the patented process.
(2) In considering whether a party has discharged the burden imposed upon him by sub-section (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so.”

*Pharmaceuticals Ltd. v. Symead Labs Limited*¹⁰⁴, a single judge of the High Court of Delhi had granted an interim injunction in favour of Symead, which had filed this application on the alleged infringement of two of its patents, API linezolid, a synthetic compound used to treat infections of the skin and blood, and also pneumonia. Thus, Glenmark was restrained from manufacturing Linezolid using the process patented by Symead. Thus, on January 19, 2015, Glenmark appealed before the Division Bench of the High Court, requesting the vacation of the interim injunction. The Court set aside the single judge's order because the Division Bench found that the Single Judge had failed to come to the conclusion that Linezolid API manufactured by the Plaintiff using its patented process was identical to the Linezolid API manufactured by the defendants/appellants. This judgment is particularly significant because the Division Bench of the High Court set aside the erroneous application of Section 104A, which states that in case of alleged infringement of process patent, the Burden of Proof lies upon the Defendant to prove that process used for obtaining the product, identical to the product of the patented process, is different from the patented process.

2.9. IMPLEMENTING TRIPS: INDIA'S RESPONSE TO TRIPS AND ITS FLEXIBILITIES

Patent granted to Roche India, the Indian branch of the Swiss Hoffman La Roche, for Pegasys, or pegylated interferon alfa-2-a, a drug used for treatment of Hepatitis-C¹⁰⁵, was the first product patent for medicines in India. Roche, thus, earned for itself the distinction of being the first MNC to be granted a product patent for a medicine in India, under the TRIPS mandated product patent for medicines in India. However, in 2007, concerned with the impact of this patent on public health and accessibility of the medicine in the country, as patients with Chronic Hepatitis-C, who need a six-month course, have to purchase it at a discounted price of Rs. 3, 14, 496, Wockhardt, Indian generic major, and Sankalp, an organisation that provides treatment and rehabilitation support for injecting drug users, filed post-grant opposition, which was invalidated by the Patent Office. Generic versions of another drug, interferon (alpha 2b) are also available in India. The cost of this treatment regimen varies from Rs 1.5 to 2.5 lakh, for the same period. Sankalp, appealed

¹⁰⁴ I.A. No. 5908/ 2013 (Order XXXIX Rules 1 and 2 CPC) and I.A. No. 5417/ 2013 (Order VII Rules 10 and 11 CPC) in CS (OS) No. 678/ 2013.

¹⁰⁵ Lynn Taylor, *India Revokes Roche's Patent on Pegasys*, Nov. 5, 2012, available at: http://www.pharmatimes.com/article/12-11-05/India_revokes_Roche_s_patent_on_Pegasys.aspx (last visited: May 20, 2015); P.T. Jyothi Dutta, *Hepatitis C drug may turn cheaper as Roche loses Pegasys patent*, Nov. 2, 2012, available at: <http://www.thehindubusinessline.com/companies/hepatitis-c-drug-may-turn-cheaper-as-roche-loses-pegasys-patent/article4057999.ece> (last visited: May 20, 2015).

against the order before the IPAB. The IPAB revoked the patent, more than six years after it was granted.

The IPAB revoked the patent on the grounds that a “person” skilled in the art could have easily predicted the claims made by the patent, since, the pegylated form of interferon to improve the activity of protein-based drugs had been recognized since the 1970s. Impliedly, the respondent could not show “increased efficacy over known substances” as required under Section 3(d). More importantly, the Court said that appellant has valid locus standi because patient groups working for persons who are in dire need of the medicine, are definitely “persons interested” under Section 64 of the Act.

The IPAB decision spelled a major victory for public health activists and interest groups. The decision was an epitome of the IPAB recognizing the interests of the patients, which outweighed the private monopolistic interests of the pharmaceutical giant. The decision also implied the efforts of the judicial bodies to make essential drugs more affordable and easily accessible in the country.¹⁰⁶ The order also implies that the generic version of Pegasys may become available in the near future. However, that depends upon whether Roche India decides to appeal the ruling. Furthermore, the decision specified that a patient group is considered to be an interested party in patent opposition cases, raising the possibility of additional patent challenges in future.

While TRIPS includes many relatively clear obligations, such that the duration of protection for patents should be minimum twenty years, it also includes many vague and undefined commitments, such as the requirement to engage in “reasonable” efforts to negotiate with the patent holders before overriding a patent.¹⁰⁷

In the process of interpreting the TRIPS Agreement, and exploiting sustainably its flexibilities, in response to the intervention of local industry and health advocates, India introduced robust versions of the compulsory licensing mechanism, one of the most significantly utilized flexibilities to TRIPS till date, but also some entirely new flexibilities.¹⁰⁸ Among those flexibilities are novel limitations on subject matter, and exceptionally high inventive step standard, procedural

¹⁰⁶ *Id.*

¹⁰⁷ *See* Kapczynski, *Supra* Note 58, at 1589.

¹⁰⁸ *Id.* at 1590.

requirements that could decrease the patent grant rate, and limitations on injunctive remedies.¹⁰⁹ Therefore, India was able to fully embrace TRIPS, instead of rejecting its terms.¹¹⁰

2.9.1. Compulsory Licensing

The provision for compulsory licensing is reflected under Section 84(1) of the Act. The Patents (Amendment) Act, 1999 added a full chapter for the grant of compulsory licenses and the revocation of licenses. After the 1999 amendment, the grounds on which a compulsory license could be granted were:

- a) Reasonable requirements of the public with respect to the patented invention have not been satisfied; or,
- b) The patented invention is not available to the public at a reasonably affordable price; or,
- c) The patented invention is not worked (i.e. not used or performed) in the territory of India.

The Amendment of 2005 added an Explanation to Section 84 (6), which states that the Controller, while examining the application for the grant of compulsory license, “shall take into consideration that the Applicant has made efforts to obtain a license from the patentee... and such efforts have not been successful within a reasonable period of time.” The Explanation states that “reasonable period” shall be construed as a period not ordinarily exceeding six months. The Explanation also added under what conditions “reasonable requirements of the public shall not be deemed to have been satisfied”.

In addition, Section 90 (1) (vii) was added to the Act, which states that in settling the terms and conditions of the compulsory license as required under Section 84 of the Act, the Controller shall “secure that the license is granted with the primary purpose of supply in the Indian market, and the licensee may also export the patented product, if need be”.

Another significant insertion to the Act by the 2005 Amendment was the inclusion of Section 92A, which states that “Compulsory license shall be available for the manufacture and export of patented pharmaceutical products to any country having insufficient or manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided such a country permits importation of pharmaceutical products from India.” This

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

provision is particularly significant because India is one of the most important exporters of generic, low-cost medicines to African and other low-income countries. For instance, in an order¹¹¹ dated December 5, 2014, the AP/Telangana High Court denied the appeal of Bristol Myers Squibb (BMS) against Mylan Laboratories, in a patent infringement suit and allowed Mylan to export its generic anti-retroviral drug "Atazanavir" in pursuance of its agreement with the Pan American Health Organization (PAHO) to sell and distribute "Atazanavir" to Venezuela, a WHO recommended, essential drug for treatment of HIV. BMS is actively engaged in the research, formulation and the development of "Atazanavir", sold under the brand name of Reyataz. Atazanavir is used for the treatment of HIV and has been approved by 57 countries throughout the world and is included in WHO's List of Essential Medicines. It is interesting to note that the trial court had denied the interim injunction to BMS because Mylan had raised the defense of "public interest" in its arguments.¹¹² Mylan had argued that the export of a drug to a sovereign government in pursuance of a WHO order does not strictly constitute "sale for commercial purpose" due to the larger interests at stake. Against the rejection of their injunction application by the local Hyderabad trial court, BMS filed an appeal before the AP/Telangana High Court.

The case set itself out as an example of series of cases of voluntary license agreements between branded and generic drug companies in an attempt to promote access to medicines.¹¹³ Voluntary licenses may limit the scope of sale, use and distribution of the essential drug to certain territories, while excluding those where patent application is pending or denied. The judgment in the above case shows that Courts across the country are keen to protecting the interests of the domestic generic drug manufacturing industry.

For the first time, the Indian Patent Office granted compulsory license to Indian generic major, NATCO for the drug Nexavar, used for treating kidney and liver cancer in March, 2012¹¹⁴. Nexavar was manufactured and sold by the Germany-based pharmaceutical company, Bayer, which had received regulatory approval for importing and manufacturing the drug in India. In July 2011, the applicant, NATCO had filed for a compulsory license, after a voluntary license request was

¹¹¹C.M.A. No. 879 of 2014.

¹¹² *Id.*

¹¹³ Rupali Samuel, *Mylan Gets Green Light to Export HIV Drugs to Venezuela*, available at: <http://spicyip.com/2014/12/mylan-gets-green-light-to-export-hiv-drugs-to-venezuela.html> (last visited: April 25, 2015).

¹¹⁴ *Natco Pharma Ltd. v. Bayer Corp.*, C.L.A.No.1 of 2011 (ICPD 2012), available at http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf (last visited: May 22, 2015).

rejected by Bayer. NATCO proposed to sell the drug at Rs. 8800/- for a month's treatment, as compared to Rs. 2, 40, 425 charged by Bayer. The Patent Office granted compulsory license to NATCO for selling the generic version of Nexavar in India, on condition that NATCO shall pay royalty to Bayer at rate of 6% for selling generic versions of Nexavar. On appeal before the IPAB, the Board increased the royalty rate from 6% to 7%. On appeal to the Supreme Court, the decision of the IPAB was upheld. One of the grounds for granting of compulsory license is that requirements of the public should be satisfied. Bayer was able to meet the requirements of only 2% of the 8,842 patients of kidney and liver cancer. Hence, the reasonable requirements of the public were not being met to an "adequate extent" as laid down under Section 84(7) of the Act. The decision reflected that the needs of the public were the driving force for the Supreme Court's decision. The Supreme Court decision implied the desire of the Court to make the anti-cancer drug easily accessible and affordable to the patients. The Order also marked a watershed in the development of jurisprudence of compulsory licensing in India.

In the case of second compulsory license application¹¹⁵ in the country, the Applicant, BDR Pharmaceuticals International Pvt. Ltd., had requested the patentee, Bristol Myers Squibb Co.(BMS), for a voluntary license to manufacture and market its anti-cancer active pharmaceutical compound, Dastanib, sold under the trade name, Sprycel and used for treatment of myeloid leukemia, vide letter dated 2nd February, 2012. On 13th March, 2012, the patentee replied to the voluntary license request with a number of queries that impliedly spelled rejection of the request. On 4th March, 2013, in response to this letter, BDR filed an application for compulsory license under Section 84(1) of the Act. On 16th September, 2013, the application for compulsory license was heard. The Controller of Patents, Mumbai rejected the application for compulsory license on the grounds that the applicant did not try to obtain a voluntary license from the patentee on reasonable terms and conditions.

In addition, the Court said that a compulsory license cannot be granted as a matter of right, but it a remedy to be resorted to only when all attempts to secure a voluntary license from the patentee have failed. In addition, the Court ruled that the objections raised by the patentee were reasonable, and the applicant failed to adequately answer its queries. Further, the applicant failed to make any communication after the initial request failed to bear fruit. The Applicant deliberately waited for time to pass by in order to invoke Section 84. Thus, the applicant did not follow the

¹¹⁵*M/s. BDR Pharmaceuticals International Pvt. Ltd. v. M/s. Bristol Myers Squibb Co.*, CLA No. 1 of 2013.

scheme of the law, and make a *prima facie* case for making an order under Section 84 of the Act. Thus, the application for compulsory license was rejected.

2.9.2. Section 3(d): Restriction of Patentability for “new forms of known substances”

The most important subject-matter exclusion under Section 3(d), has significant implications in the area of pharmaceuticals. This section forbids patents on both new uses of known substances and on new forms of known substances that do not enhance the “efficacy”. The *Explanation* to the Section makes it clear that salts, esters, ethers, polymorphs, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly with regard to efficacy. This is in stark contrast with United States and Europe, where patents for a new form of a known substance are fairly common, and do not cover a compound, but rather a compound’s use in a particular way.¹¹⁶ New forms of known substances that have pharmaceutical applications are also commonly patented.¹¹⁷ These “new forms” could be structural forms of a compound with different properties, such as polymorphs.¹¹⁸

Pharmaceuticals are typically administered in the salt form, as salt forms dissolve more easily into the blood stream.¹¹⁹ Salts are formed with the by adding different acids to bases to produce different forms with different properties.¹²⁰ Patents for pharmaceutical salts have been granted for decades in the United States, upon showing that the salt differed from the previously disclosed compound in an unexpectedly beneficial way.¹²¹

Section 3(d) imposes substantial limits on these claims, limiting the claims on new forms of known substances to those that have “increased efficacy”. The section aims to prevent “ever-greening” of patents, by providing only those pharmaceutical derivatives that demonstrate significantly enhanced efficacy are patentable. The underlying assumption behind section 3(d) is that derivatives such as salt forms, polymorphs, isomers, that are structurally similar to known pharmaceutical substances are likely to be functionally equivalent as well, and if that is not the case

¹¹⁶ Kapczynski, *Supra* Note 58, at 1612.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 1613.

¹¹⁹ *Id.* at 1614.

¹²⁰ *Id.* at 1585.

¹²¹ *Id.* at 1586.

and the new form works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim to a patent.¹²²

To this extent, Section 3(d) draws a distinction between “ever-greening” and incremental innovation. Here, S. 3(d) draws a distinction between “ever-greening” and incremental innovation. By supporting incremental innovation wherein the improved products help achieve better results, S. 3(d) is actually trying to address unmet health needs.¹²³

The definition, meaning and scope of the term “increased efficacy” has enormous implications on the pharmaceutical industry in the country, as is demonstrated in the *Novartis*¹²⁴ judgment. Novartis, the Swiss pharmaceutical giant, developed beta-crystalline form of Imatinib mesylate, an anti-cancer drug used for the treatment of Chronic Myelogenous Leukemia (CML), a debilitating form of cancer. To date, 40 patents covering this polymorph have been granted to Novartis in various countries. Owing to the unavailability of drug patents in India until 1 January, 2005, Novartis filed for a patent for this polymorph under the “mail box application”. Pursuant to the 2005 Amendment to the Patents Act, 1970, which introduced product patents for pharmaceuticals, the Novartis application was opened and examined. The grant of the patent was opposed by several generic drug companies on the grounds of lack of novelty, lack of “significantly enhanced efficacy” under Section 3(d), and obviousness. In 2006, agreeing with the arguments raised by the Assistant Controller of Indian Patent Office, rejected the patent application of Novartis covering Glivec, or “Gleevec” as it is known as in the United States, under Section 3(d). On an appeal to the Madras High Court, Novartis challenged the constitutionality of Section 3(d) and its compatibility with TRIPS. The Madras High Court ruled that Section 3(d) was constitutional, and it’s also compatible with TRIPS. Pursuant to a government notification, the High Court transferred the first petition to the Intellectual Property Appellate Board (IPAB), a specialist tribunal set up to deal with appeals from the various intellectual property offices across the country. The IPAB held that patentability of the product is hit by Section 3(d) of the Act. Reiterating the High Court’s observation, the IPAB also referred to the pricing of the drug Gleevec while the appellant held EMRs over the drug, and used to charge Rs. 1, 20, 000/- per month for a required dose of the drug from a cancer patient, not disputed by the Appellant, which was in view of the Madras High Court,

¹²² *Id.* at 1587.

¹²³ *Id.* at 1588.

¹²⁴ *Novartis AG v. Union of India (UOI) and Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors.*, Civil Appeal No. 2706-2716 of 2013.

too expensive to the poor cancer patients in India. Thus, the Court observed that grant of product patent to the appellant can create havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. So in the light of public interest and effect of the patent on the drug on the society, the Court held that grant of the patent would also be hit by Section 3(b) of the Act, which prohibits the grant of the patent on inventions, exploitation of which would create public disorder. Thus, the IPAB allowed process patent for Imatinib Mesylate in beta crystal form, and disallowed the product patent on the same.

Aggrieved by the order of the IPAB, filed a writ petition under Article 136 of the Constitution before the Supreme Court of India. the Supreme Court ruled that Imatinib Mesylate is a known substance, and thus does not qualify the test of "invention" as laid down under Section 2(1)(j) and Section 2(1)(ja) of the Patents Act, 1970. Further, the beta-crystalline form of Imatinib Mesylate is polymorph of Imatinib directly ran into Section 3(d) of the Act. Thus, beta-crystalline form of Imatinib Mesylate was a new form of a known substance which bore similar pharmacological properties of Imatinib Mesylate, thus, there is no "enhance therapeutic efficacy" as required under Section 3(d). The Court further states that while the beta-crystal form of Imatinib Mesylate has the following enhancing properties Imatinib Mesylate: (1) better thermodynamic stability (2) more beneficial flow properties (3) lower hygroscopicity, but these properties have nothing to do with therapeutic efficacy. Therefore, the beta-crystalline form of Imatinib Mesylate failed the test of both inventiveness under Section 2(1)(j) and (ja) and Section 3(d) respectively. Finally, the Court dismissed the Appeal of Novartis, in what was a 7-year long litigation saga that had gripped the country from start to end. This case is widely touted as landmark judgments in the history of pharmaceuticals in the country. Moreover, this case made the general public, health advocates sit up and take notice of the raging access to medicines debate in the country. In addition, the case is also interpreted with the intent to protect the generic drug industry of the country.

In another landmark judgment¹²⁵ involving Section 3(d), Roche, along with Pfizer (as a joint applicant), claimed that it had been granted a patent in February 2007 for "Erlotinib", the molecular [6, 7-bis (2-methoxyethoxy) quinazolin-4- yl]-(3-ethynylphenyl) amine hydrochloride. The patented product, which Roche introduced into the Indian market in 2006, was marketed under the brand name TARCEVA. In December 2007 and January 2008, Indian newspapers reported Cipla's plan to launch a generic version of 'Erlotinib', and soon after, Roche commenced patent infringement

¹²⁵ *F. Hoffmann-La Roche Ltd. And Anr. v. Cipla Limited*, 148 (2008) DLT 598, MIPR 2008 (2) 35.

proceedings. In response to Roche's claims, Cipla filed a detailed defence and counterclaim arguing that Roche's patent was invalid because 'Erlotinib' was a derivative of Quinazolin, which had been used in cancer treatment. Pursuant to S.3(d) of the Indian Patents Act, a derivative of a known compound is not patentable. In addition, the huge difference in price between Roche's drug (Rs.4,800 tablet (approx. US\$ 100) and Cipla's drug (Rs.1,600 (approx US\$ 33) should be taken into account when deciding whether or not to grant an interim injunction. Cipla strongly argued that because the drug in question was a life-saving drug, the public interest issue was an important factor to be taken into account. While hearing the case, the judge noted that the generic drug version of 'Erlotinib' manufactured and marketed by Cipla is available at one-third the price of Roche's drug, Tarceva. Further, the Court noted that Tarceva is not manufactured in India, it is imported. The Court noted that the right to access to life-saving drugs, and the need for secure long term supplies, is a serious issue in India. In cases of this sort, the injury that would be caused to the general public if the generic version of the drug were not available is a strong point in favour of a refusal to grant an injunction.

The doubts about the validity of the patent raised by Cipla on the ground of obviousness, and 'Erlotinib' being a derivative of a known compound which did not meet the 'increased efficacy' requirement provided for in s.(d) of the Patents Act, were dismissed by the judge as having been adequately dealt by the Patent Office at the opposition stage. The Court reviewed the observations that had been made by the Controller while granting the patent, and concluded that Cipla had not substantiated this objection. Overall, the judge was of the view that while Roche had established a strong case in support of its patent infringement claim, the 'public interest' and lower pricing of Cipla's drug tilted the balance in favour of Cipla. Roche filed an appeal against the Order of the single judge, primarily arguing that since it had made out a prima facie case of infringement, an injunction should have been granted. Roche further argued that a failure to protect the rights of the patentee is contrary to the public interest of encouraging further research in the pharmaceutical field. The Court dismissed Roche's appeal, and upheld the order of the single judge. The Court did not fully elaborate the public interest point relating to the pricing of the drugs, basing its judgment instead on the ground that Cipla had raised a credible challenge to the validity of the patent.

However, in a case that is flip side of the coin, the Patent Office has recently granted patent for the polymorph of a known compound¹²⁶, notwithstanding the objections raised under Section 3(d) of the Act. An application was filed for “Polymorphic Forms of Rixamixin, Process for their production and use thereof in medicinal preparations”, on January 3, 2008. Some of the procedural objections raised by the Controller of Patents were “some of the claims fell under Section 3(d) as they are defined as merely a new form of a known substance without any enhancement in known therapeutic effect thereof”. Following the arguments of the Applicant’s counsel in favour of the amended claims, the Controller held that the invention under consideration comprises a synergistic composition and has improved pharmaceutical properties. The enhancement in efficacy lay in the fact that the polymorph had an in vivo absorption level of about 100 times lower than the original form, resulting in reduction of the toxicity 100 times due to absorption. Therefore, the Controller was of the opinion that the disclosure by the Applicant for proving efficacy (i.e. same therapeutic value with 100 times less toxicity of the new polymorph of this invention) was appropriate until someone interested proved contrary to it. Hence the claims were set free of the clutches of S. 3(d), with the qualification that they might be examined in stricter sense in the proceeding if arising out of the opposition u/s. 25 and/or revocation. The other technical and procedural objections by the Examiner were also set aside by the Controller. The patent was granted to the polymorph on the basis of the amended claims.

This decision may well indicate the beginning of a trend by the Patent Office to be willing to overlook S. 3(d) objections to the grant of patent to a polymorph in the presence of proven enhanced efficacy of the original form. This will be welcome news indeed for the proponents of the school of thought firmly believing that polymorph patents will increase cost efficiency.

In *Ajanta Pharma v. Allergan Inc. and Controller of Patents and Designs*¹²⁷, Allergan, the US-based drug company had obtained patents for combination derivatives of the Bimatprost and Timolol, and Brimonidine and Timolol, used for the treatment of Glaucoma. The Appellant sought to revoke the patents on the grounds of obviousness. The combination showed advantages over single therapy of either of the drugs (Bimatprost, Timolol, or Brimonidine). The Court held that derivatives of either of the drugs was not unknown, and hence indicated that the invention was an obvious one. Also,

¹²⁶ 106/DELNP/2008; Shovik Kumar Guha, *Patent Office grants Polymorph Patent after rejecting S.3(d) Objection*, Jan. 1, 2013, available at: <http://spicyip.com/2013/01/patent-office-grants-polymorph-patent.html> (last visited: April 26, 2015).

¹²⁷ Order No. 172 of 2013.

since the combination of the drugs had only significant advantages over single therapy, and thus, “efficacy” could be shown in the respondent’s combination derivative. Section 3(d) excludes patentability of “derivatives of known substances, unless they differ significantly in properties with regard to efficacy”. On the stated grounds, the patent of the respondent was revoked. This decision may have also encouraged the generic ophthalmological drug industry, in competition with the pharmaceutical MNCs.

In another case of *Gilead Pharmasset, LLC v. Union of India and Anr*¹²⁸, Gilead, a US-based pharmaceutical company, had filed for a patent application for their product Sovaldi, a Hepatitis-C drug, more effective against the disease than the existing prior art, and sold at an extremely high rate in the USA. The complete course of Sovaldi was expected to cost around \$84, 000 in the USA, and approximately \$ 60, 000 worldwide. As the Times of India reported, Sovaldi would be available at a price of \$900 for 12 weeks in India. It is estimated that 3% of the world’s population is infected with the disease, and 170 million chronic carriers at risk of developing liver cancer, Hepatitis-C (HCV) is fast-overshadowing HIV/AIDS in urgency and severity. India alone has an estimated 12 million people who are chronically infected with HIV, with 96,000 deaths annually due to the infection. Coupled with the fact that majority of the HCV patients are poor and uninsured, the issue of access to medicines for patients becomes more acute. Due to the extremely high costs associated with the drug, Gilead had voluntarily licensed and allowed seven Indian generic manufacturers to market the drug, while the patent application was still pending. The patent application was opposed by NATCO Pharma and patient interest groups Delhi Network of Positive People, Initiatives for Medicines, Access and Knowledge. In spite of the voluntary license made by Gilead Sciences to Indian generic companies, the cost of the drug was still very high due to the number of restrictions imposed upon these drug companies. The patent application was rejected under Section 3(d), as Gilead could not show “therapeutic efficacy” as compared to closest prior art. On appeal before the Delhi High Court, the Court ruled in favor of Gilead Sciences, however, not on the grounds of Section 3(d), whereas the Patent Office had rejected the application under Section 3(d). The Court, while allowing the writ petition, held that when the appellant’s petition under Section 14 of the Act was pending, two pre-grant oppositions were filed by NATCO and IMAK. The appellants were not issued any notice under Section 25 of the Act. The Court also accepted the Gilead’s claim that the Patent Office’s order was influenced by the pre-grant oppositions, including the typographical errors made

¹²⁸ WP(C) 687/2015 and CM No.1222/2015.

in them. In view of the elements of bias and flouting of procedural requirements as laid down under the Act, the order of the Patent Office violated principles of natural justice, and thus, the Court remanded the case back to the Patent Office for fresh proceedings, and decision be made only after holding hearings for both Section 14 and 25, and issuance of prior notice to all the parties.

In another case¹²⁹ dealing with Section 3(d), US-based Schering Corporation (now Merck Sharp), sought to patent Vorapaxar, a crystalline polymorph of bisulfate salt of thrombin receptor antagonist, which was yet to be fully developed. In 2009, the Assistant Controller of Patents and Designs dismissed the application view of the absence of “therapeutic efficacy” as required under Section 3(d) and Section 2(i)(j) (a) on the grounds of lack of “inventive step” as required under Patents Act, 1970. On careful consideration of the order passed by the Assistant Controller of Patents and Designs, the IPAB ruled that the Controller passed a cryptic and non-speaking order; and the claims raised by the appellant were not properly considered. Under Section 15 of the Patents Act, 1970, the Controller has the option to either afford opportunity to the applicant to make amendments in the Application, or refuse the application on failure to submit any amendments. However, as mandated under Section 15 of the Act, the Applicant was given an adequate opportunity to make his submission. Secondly, the Controller rejected the claims of the appellant on the grounds of “lack of inventive step”, however, no substantial reasons were given, without going into details of the entire document. In view of the above reasons, the order of the Assistant Controller was set aside, and ordered the Controller to hear the matter afresh, and dispose of the matter within three months from the date of receipt of the amended claims of the appellant. Foreign applicants typically seek patent protection by filing PCT applications designating India. Since proof of efficacy relating to the crystalline form of pharmaceutical drugs is a unique requirement under Indian patent law, many patent applications belonging to foreign MNCs, are either refused or invalidated, as oftentimes the specification does not include data showing proof of enhanced “therapeutic efficacy”¹³⁰.

2.9.3. Section 8: Requirement of Details in case of foreign applications

As required by Section 8, Applicants must also “disclose the source and geographical origin of any biological material in the specification, when used in the invention”. According to Section 8,

¹²⁹ 201 126 DLT (2013).

¹³⁰ Madhulika Vishwanathan, *IPAB Sets Aside Patent office Order for Refusing Crystalline Form of Patent of Vorapaxar*, available at: <http://spicyip.com/2014/02/ipab-sets-aside-patent-office-order-refusing-crystalline-form-patent-of-vorapaxar.html> (last visited: April 20, 2015).

“an application filed for grant of patent in India, the Controller may require the applicant to furnish the details related to the processing of the application in any country outside India, within the prescribed period of time.” This provision was added in the Act in 2005. In *Ajanta Pharma v. Allergan Inc. and Controller of Patents and Designs*¹³¹, Ajanta Pharma, an Indian pharmaceutical company dealing with drugs used for the treatment of Glaucoma filed an application before the IPAB to revoke the patents for drugs to achieve enhanced treatment of ocular hypertension with reduced side effects, as granted to Allergan Inc., a branch of the U.S. pharmaceutical major, Allergan. Allergan had been granted a patent for “Ganfort”, a patented fixed dose combination of bimatoprost and timolol, and “Combigan”, patented fixed dose of brimonidine and timolol. Both the combinations were used for topical ophthalmological treatment. Ajanta sought to revoke the patents on the grounds of obviousness and non-compliance of Section 8 of the Act. In the present case, the Court found that the respondent failed to furnish information regarding any of its foreign applications for the same invention, even when it had agreed to do so. On the grounds of non-compliance of Section 8, the patent of the respondent was revoked.

2.9.4. Role of Judiciary: Recent Trends and Interpretation of Patent Law by Leading Courts

A number of judgments of the High Courts and the IPAB show their inclination to protect the generic drug industry of the country. In *Ajanta Pharma v. Allergan Inc. and Controller of Patents and Designs*¹³², Ajanta Pharma succeed in revoking the patents for drugs for ophthalmological treatments of Allergan, a U.S. based pharmaceutical company. Thus, the decision proved to be a boon for generic companies of the country vis-à-vis medicines for treatment of eyesight and blindness.

However, judgments have also been given in favor of the leading pharmaceutical giants and thus, protect the rights of the patent holders. In a recent judgment of the IPAB, Novartis was granted an interim injunction against Indian generic company Wockhardt¹³³. Novartis is the patent holder of the anti-diabetic pharmaceutical ingredient, Vildagliptin, and its combination with Metformin Hydrochloride. The defendant, Wockhardt, filed a petition for revocation of the patent before the IPAB. The plaintiff was granted an interim injunction as a strong prima facie case had been made out for the grant of the injunction and the balance of convenience in favor of Novartis.

¹³¹ Order No. 172 of 2013.

¹³² Order No. 172 of 2013.

¹³³ *Novartis AG & Ors v. Wockhardt Ltd.* CS(OS) 646/2014.

While the case has not reached its conclusion, the interim injunction granted by the judge of the Delhi High Court indicates the intention of the judiciary to protect the rights of the patent holders.

In *Abraxis Bioscience LLC v. Union of India and Ors.*¹³⁴, a U.S. based biotechnology company, had filed for a patent for its invention, "composition and method for delivery of pharmacological agents", or protein-based nano particles chemotherapeutic cancer treatment clinically approved in several countries. NATCO, the respondent in the present case had had launched Albupax, generic bio-similar drug, and thus, filed a pre-grant opposition. Based on this opposition, the Assistant Controller of Patents and Designs had rejected the application. Abraxis appealed against this rejection before the IPAB. The order of the Patent Office was set aside and the matter was remanded by the Board to the Assistant Controller of Patents for fresh consideration as the order was found to be given with blatant violation of the principles of natural justice. Under Section 25 of the Act, both the parties should be heard before an order is passed under any pre-grant opposition proceedings. Moreover, an order under Section 14 and 15 of the Act is an appealable order, however, the appellant was deprived of his right to appeal. Based on the above grounds, the order was set aside and matter was remanded for fresh consideration.

For the first time, a Court has granted a *quia timet*¹³⁵ injunction in a case involving the Indian pharmaceutical giant, Ranbaxy¹³⁶, in favour of Novartis, in one of the six suits filed by the company against six Indian generic companies to guard its patented anti-diabetic compound Vildagliptin, marketed under the name, Galvus. On the question of whether the injunction should be granted or not, the Court noted that the Defendant has applied for revocation of the patent in the year 2014, showed that the Defendant wanted to launch its own patented compound. The Court also considered the fact that the balance of convenience also lies in preserving the status quo as the Defendant is yet to launch Vildagliptin. Thus, the Defendant was restrained from manufacturing, selling, or offering for sale either through its website or by any other means, directly or indirectly dealing with active pharmaceutical ingredients, compounds or formulations containing Vildagliptin or Vildagliptin in combination with any other compound as may amount to infringement of the plaintiff's patent. However, the Court did not lay down the standard of proof required for the

¹³⁴ M.P.NO.57/2010 IN OA/3/2010/PT/DEL; OA/3/2010/PT/DEL.

¹³⁵ Latin word which means "because he fears or apprehends". In legal terminology, it has been defined as an action by which a person may obtain an injunction to prevent or restrain some threatened act being done which, if done, would cause him substantial damage, and for which money would be no adequate or sufficient remedy.

¹³⁶ *Novartis AG And Ors. v. Ranbaxy Laboratories Ltd.*, I.A. No. 17139/2014 in CS.

granting of quia timet injunctions, or what constitutes “proof of imminent threat”. Therefore, this is still a grey area in India.

In another case, Pfizer/Sugen was granted a patent¹³⁷ on anti-cancer drug Sunitinib on October 5, 2007. Five years later, Cipla initiated a post-grant opposition, and the patent was revoked by the Patent Office. After patentees (Pfizer/Sugen) filed a writ petition before Delhi High court, the first revocation decision was set aside, on the grounds that the recommendations of the opposition board were not furnished to the patentee.

The Sunitinib patent was revoked¹³⁸ by the Controller of Patents for the **second time** around in mid-February this year. On April 5, 2013, the IPAB stayed the revocation of Sunitinib patent. Sugen's appeal against the revocation was fixed for hearing on May 14th 2013, subject to the undertaking given by the appellant (Sugen) that they will not use the revoked patent against the second respondent (Cipla) in other proceedings. Sugen argued that Section 25(2) (b) should have not been taken into account by the Controller since that ground was not specifically pleaded by Cipla (respondent); and hence the decision of the Controller based on prior publications wasn't valid. The IPAB, however held that S 25(2)(e) had been raised by the respondent, and Section 25(2)(e) is a ground for revocation if that *the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim*; The IPAB thus held that Section 25(2)(e) clearly and unambiguously takes Section 25(2)(b) within its ambit and rejected this ground. It also held that if a ground has been pleaded in the written statement, but not listed in the grounds then the Controller may apply it provided the patentee is in the know.

The IPAB expressed disapproval at the manner in which the Controller had dealt with the opposition proceedings and reiterated the importance of providing sound reasons for arriving at conclusions. The IPAB then held that the Opposition Board should be constituted again and a different Controller should hear the matter afresh within a strict time-frame.

3. CONCLUSION

¹³⁷ Madhulika Vishwanathan, *The Sunitinib Saga Continues: Third Time's the Charm?*, Jun. 8, 2013, available at: <http://spicyip.com/2013/06/the-sunitinib-saga-continues-third.html> (last visited: June 1, 2015); *India's Patent Office Revokes Suten cancer drug patent*, Feb. 14, 2013, available at: <http://www.worldipreview.com/news/india-s-patent-office-revokes-suten-cancer-drug-patent> (last visited: May 26, 2015).

¹³⁸ *Id.*

A perusal of the evolution of patent law in India, will demonstrate that the changes made by the Government in the law are largely a response to international developments. Since the enactment of the 1970 Act, the Government has consciously tried to enact a patent regime that serves best the interests of the society. Even after accession to WTO and resultantly, the TRIPS Agreement, India cleverly enacted provisions that caters to the health-care needs of the society, maintaining its position as the “pharmacy of the developing world”, while fulfilling its international obligations.

The judiciary, too, has played its part in interpreting the provisions of the patent law which manifests the intention of the legislature to protect the public health needs of the society.

As stated by a leading author, Amy Kapczynski, the Indian example shows that TRIPS leaves developing countries with wide-ranging set of flexibilities, and India has been able to adopt and implement its flexibilities to their full potential. Because of India's leading role as a generic supplier in the world pharmaceutical market, and given the novelty and expansiveness of the implementation approach it has taken, the flexibilities adopted in the Indian patent context may well become central to new interpretive conflicts over TRIPS.

Indian firms and health activists were drawn into the terms of IP law through their encounter with TRIPS, and played an important role in recasting the terms of TRIPS as they pressed India to adopt the substantial flexibilities that it chose.

Rather than reject TRIPS, Indian government actors have engaged in creative acts of legal interpretation that take extensive advantage of known TRIPS flexibilities, and that have also generated new ones. In the process, India has paved the way for new interpretive disagreements over the meaning of TRIPS. The dynamic has clearly operated beyond India as well.

The process of TRIPS implementation has more generally led developing countries to make new demands with regard to TRIPS reform, and to become more active participants in global IP debates.