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The Indian Patent (Amendment) Act, 2005 & It's Implication on Pharmaceutical Industry, in reference to Novartis vs. Union of India

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ABSTRACT

The Indian Patent Act governs the granting and protection of patents in India, including those related to pharmaceuticals. Historically, India has implemented certain provisions in its patent laws that are aimed at balancing the interests of public health, access to medicines, and promoting innovation in the pharmaceutical sector. These provisions have had a notable impact on the pharmaceutical industry, both domestically and internationally. One significant provision is Section 3(d) of the Indian Patent Act. This provision imposes restrictions on the grant of patents for new forms of known substances, unless they demonstrate enhanced efficacy compared to the known substance. This provision is intended to prevent "ever greening" or extending the patent life of existing drugs by making minor modifications without substantial therapeutic benefits. It has been a subject of debate and has led to legal challenges by pharmaceutical companies seeking patent protection for incremental innovations. Another provision that affects the pharmaceutical industry is the compulsory licensing mechanism outlined in Section 84 of the Indian Patent Act. Compulsory licensing can be invoked in cases of national emergencies, public health crises, or when the patented drug is not available at an affordable price. The Indian Patent Act has also been a factor in the growth of the Indian generic pharmaceutical industry. India is known as the "pharmacy of the developing world" due to its ability to produce affordable generic versions of patented drugs.

I. INTRODUCTION

Abraham Lincoln described the importance of Patent as "Before then [the adoption of the United States Constitution], any man instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things".[2] Thus in later decades many nations and international organizations made a

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[2] Abraham Lincoln, *Second lecture on discoveries and inventions*, February 11, 1859. *See also* A critical

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concentrated effort to homogenize the laws governing intellectual property which eventually lead to the formation of WTO (World Trade Organization) in 1995.

However, as far as Indian patent law is concern since the day it came into existence it saw a great deal of radical change. Starting from its reform in 1950 base on the report of Chand Committee (1949)[3] to the time when India joined WTO (World Trade Organization) in 1995 and followed by various amendments that were introduced in the Indian Patent Act to meet India's obligation under TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement of WTO.

This paper is divided under various headings starting with the discussion on the history and relevance of various amendments made in the Indian Patent Act with special focus on 2005 Amendment, under the second heading of this paper we have analyzed the implications of present form of Indian patent legal regime on the pharmaceutical industry of India and the world. Further, we have analyzed in depth the 2013 Supreme Court judgment of Novartis AG *v.* Union of India and the effect of the anti-evergreening principal underlying u/s. 3(d) given through this landmark judgment. This paper undertakes a review of available studies, data and other relevant research articles to provide a perspective on the role of IP protection in developing healthcare innovations. At the end, we argue that there is merit in viewing health care access and innovation as complementary processes and that this recent judgment of the S.C. has been a boom not for the India but also for the developing nations.

II. INDIA'S PATENT LAW REGIME

India passed its first patent law (India's Act VI of 1856) in 1856 during British colonial rule. This law was based on the British Patent Law of 1852, which provided privileges to inventors for a period of fourteen years. In 1911, the Britishers replaced the Inventions and Designs Act of 1888 with the Indian Patents and Design Act, 1911. The 1911 Act provided for product and process patent, both[4] the patentability of pharmaceutical products and therefore enabled foreign companies to block the production of their patented drugs in India.[5]

Recovering from the oppressive colonial rule, the Indian government wanted a "patent system [that] was more conducive to national interests". Thus, after India's Independence in 1947 a committee in 1949 was formed under the Chairmanship of Justice (Dr.) Bakshi Tek Chand to

evaluation of the Patent (Amendment) Act, 2005 available at http://www.lawyersclubindia.com/articles/A-critical-evaluation-of-the-Patent-Amendment-Act-2005-5574.asp (last accessed on 27.08.2017 at 2300 hrs).

[3] Under the chairmanship of Justice (Dr.) Bakshi Tek Chand to review the 1911 Act.

[4] Para. 31, Novartis AG *v.* Union of India & others (S.C. 2013).

[5] Kalyan C. Kankanala, Arun K. Narasani & Vinita Radhakrishnan, *Indian Patent Law And Practice*, 1 Oxford University Press (2010).

review the 1911 Act which lead to 1950 & 1952 amendment 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, however, in 1957 another committee was appointed under the chairmanship of the chairmanship of Justice N. Rajagopala Ayyangar to take a fresh look at the law of patent and to completely revamp and recast it to best sub-serve the (contemporary) needs of the country.[6] After collecting valuable data and analysing them in depth Ayyangar committee submitted a comprehensive Report on Patent Law Revision in September 1959 and the new Act, namely, the Patents Act, 1970, came into existence which was mainly based on the recommendations of the Ayyangar Committee report, and came into force on April 20, 1972, replacing the Patents and Designs Act, 1911.[7]

Under this new patent regime, instead of giving recognition to product patents, which was the norm among developed nations, only granting process patents were allowed. The effect of which was that the Indian drug manufacturers could copy pharmaceutical products that were otherwise patented in foreign nations, leading to a boom in the production of generic drugs.[8] Further, the Act reduced the number of years of protection granted by process patents from fourteen (14) years to seven (7) — far less time than is usually required for research, testing, and development of many drugs.[9] With the help of this IPR regime in a matter of time, Indian pharmaceutical industry developed into one of the most strong industry producing medicines at a cheaper rate as compared to other expensive medicines making India as a frontrunner in the pharmaceutical industry.

On 1st January 1995, an international platform for trading countries i.e. World Trading Organisation (WTO) came into existence (originally GATT). and with-it Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was created for providing a strong IP protection abroad by fixing minimum standards which was to be followed by every member nation of WTO. Before the WTO, the World Intellectual Property Organization (WIPO)was governing the IP rights. Under the terms of the agreement, WTO member nations could officially charge other member nations for violating the terms of TRIPS by bringing an action against them before the WTO's Dispute Settlement Body (DSB).[10]

Like many developing nations, India initially opposed TRIPS. Nevertheless, as a member of

[6] Para 34, Novartis AG *v.* Union of India & others (S.C. 2013).
[7] Para 43, Novartis AG *v.* Union of India & others (S.C. 2013).
[8] William J. Bennett, *Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India*, Vol. 13 Issue 3 541 Wash. U. Global Stud. L. Rev. (2014).
[9] Jodie Liu, *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act* 211 Harvard Int'l L. J. Vol.-56 No.-1 (2015).
[10] Art. 64 TRIPS.

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the WTO, India was required to modify its domestic intellectual property laws in order to comply with the agreement. Although India had to implement certain provisions of TRIPS immediately, however, Article 65.2 of the TRIPS granted developing nations a transition period for the implementation of other provisions[11] but during this transitional period, India had to provide `Exclusive Marketing Rights (EMR)' for products patented elsewhere (any other member country) till the patent application for that product is approved or rejected in India (which was to be done in the year 2005).[12]

Thus, to fully comply with the provisions of the TRIPS agreement amendments to the Patent Act was passed by the Indian parliament know as Patent (Amendment) Act of 1999, 2002 & 2005. The 2005 amendment introduced product patents on pharmaceuticals in India by simply deleting section 5 from the Patents Act. But at the same time, it also introduced numerous access friendly policy levers, or "TRIPS flexibilities,"[13] that the Indian generics industry could invoke to invalidate brand-name patents and bring generics to the market, despite the re-introduction of product patents.[14] A decade later these 'TRIPS flexibility' provision became the ground for legal battle.[15]

Indian patent law went through three stages between 1995 and 2005 in order to conform with TRIPS. First, in 1999, India instituted the "mailbox" requirement of Article 70.9 of TRIPS, which enabled entities to submit product patent applications for pharmaceuticals and agricultural chemicals to the patent office that would be held until examination in 2005. Second, India introduced the Patents (Amendment) Act of 2002, which further integrated Indian law by extending patent terms to twenty years as stipulated by TRIPS. Third, and lastly, the Patents (Amendment) Act of 2005 brought India into compliance with TRIPS by giving full patent protection to pharmaceutical products.[16]

In the pre-TRIPS era, no medicines had been stimulated for the use in the less-developed countries. If we look at the brighter side there were a lot of points to the benefit of the developing countries for signing the TRIPS agreement they were: [17]

[11] See Supra note 7 at pg. 543.
[12] N. Lalitha, *Trips and Pharmaceutical Industry: Issues and Prospects*, Gujarat Institute of Development Research, Ahmedabad Pg. 6.
[13] Compulsory Licensing & Anti-Evergreening Provision are termed as 'TRIPS flexibility' in the Jodie Liu, *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act* 207-227 Harvard Int'l L. J. Vol.-56 No.-1 (2015).
[14] See Supra note 8 at 212.
[15] Ref. case of Bayer *v.* Nacto (IPAB) & Novartis AG *v.* UOI (S.C. 2013).
[16] See Supra note 7 at pg. 543-544.
[17] Shubhra Khanna, *TRIPS, Pharmaceutical Patents and Health Care For The Poor In India*, Summer Issue, ILI Law Review 74 (2016).

a) It had the potential of awakening the interest of the pharmaceutical companies in developing those medicines for the type 3 diseases (those diseases that occur exclusively or overwhelmingly in poor countries) that would help to cater the interest of the minority.

b) After the term of the patent protection is over the medicines would be able to reach out to the people of the relevant developing or third world countries which as of now is the major concern as the drugs are not being developed for the poor.

The concerns of the developing world with regard to pharmaceutical patent has been clarified and enhanced by the 2001 DOHA declaration on TRIPS and public health. They agreed that the TRIPS agreement does not and should not prevent members from taking measures to protect public health.[18] DOHA declaration was not the sole international document that stressed access to health care and public health. Various international conventions like Universal Declaration Of Human Rights, 1948, International Covenant on Civil and Political Rights, 1966, International Covenant on Economic, Social and Cultural Rights, 1966, Convention on the Elimination of all forms of Discrimination Against Women, 1979, and Convention on the Right of the Child, 1989, recognise access to health care at the international level. Article 27(2)of the Universal Declaration of Human Rights (UDHR) and Article 15(1)(c) of the InternationalCovenant on Economic Social Cultural Rights (ICESCR) also try to equate IPRs with other types of human rights, this has led many authors to conclude that they provide a human rightsbasis for patent rights and other forms of IPRs.[19]

III. INDIAN PHARMACEUTICAL INDUSTRY

The evolution of the domestic pharmaceutical industry constitutes one of success stories of the Indian economy. The Indian pharmaceutical industry has a strong generic base with almost 60,000 generic brands in 60 therapeutic categories in the market which was fostered by the then legal structure regarding patent. 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 products and its annual exports turnover is in excess of $1.5 billion. This could be possible only because there was no product patent system for drugs and pharmaceuticals.[20]

[18] See Supra note 16 at pg. 78.
[19] Joseph Millum, *Are Pharmaceutical Patents Protected By Human Rights?* 25 Journal of Medical Ethics 34 (2008).
[20] Nidhi Joshi, *Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India* 1 Delhi L Review 104 (2005). *See Also* Shubhra Khanna, *TRIPS, Pharmaceutical Patents And Health Care For The Poor In India*, Summer Issue, ILI Law Review 74 (2016).

The Indian pharmaceutical industry today is "considered as the world's third-largest by volume" and, as of 2010, produces approximately 20% of the world's generic drugs. Experts anticipate India's pharmaceutical industry to grow to a value of $74 billion by 2020, solidifying India as "a global leader in the pharmaceutical industry." India is one of only two countries in the world where generic drug manufacturers control a larger share of the domestic pharmaceutical market than big MNCs. A few indigenous firms are capable of both generic drug production and research and development, while many smaller companies specialize exclusively in reverse-engineering drugs from overseas.[21]

World War II[22] marks the beginning of the significant growth of the international pharmaceutical industry. The need for antibiotics during the war led many companies to invest more time and resources into the research and development of new drugs.[23] Whereas the evolution of Indian pharmaceutical industry began in 1910s when private initiatives established Bengal Chemical and Pharmaceutical Works in Calcutta and Alembic Chemicals in Baroda and setting up of pharmaceutical research institutes for tropical diseases like King Institute of Preventive Medicine, Chennai (in Tamil Nadu), Central Drug Research Institute, Kasauli (in Himachal Pradesh), Pastures Institute, Coonoor (in Tamil Nadu), etc. through British initiatives.[24] However, the development of pharmaceutical industry in the post-independence period can be divided into the following 3 phases:-

FIRST PHASE: 1950s–60s

During this phase foreign firms, enjoyed a strong patent protection under the Patent and Design Act 1911, where instead of local production, they mostly opted for imports from home country. The pharmaceutical industry was largely dominated by foreign enterprises and it continued to rely on imported bulk drugs. Given the inadequate capabilities of the domestic sector to start local production of bulk drugs and hesitation of foreign firms to do so.

The government decided to intervene through starting public-sector enterprises which led to the establishment of the Indian Drugs and Pharmaceuticals Ltd. (IDPL) plant at Rishikesh and Hyderabad in 1961 and the Hindustan Antibiotics at Pimpri, Pune, in 1954 to manufacture penicillin. The starting of the public-sector enterprises has been an important feature in the evolution of the pharmaceutical industry as it simulated initiative roles in producing bulk drugs

[21] See Supra note 7 at pg. 538.
[22] 1st Sept 1939 – 2nd Sept. 1945.
[23] See Supra note 7 at pg. 537.
[24] Saurabh Chandra, Impact of Trips Over Indian Patent Regime Vis A Vis Indian Pharmaceutical Industry, Vol.1 No.1, Galgotias J.L.S., 44 (2013).

indigenously and led to significant knowledge spill overs on the private domestic sector.[25]

SECOND PHASE: 1970s-90s

The enactment of the Indian Patent Act (IPA) in 1970 and the New Drug Policy (NDP) in 1978 were two important milestones in the history of the pharmaceutical industry in India. IPA reduced the scope of patenting only to processes and not pharmaceutical products & also shortened the period of grant to 7 years only. Compulsory licensing was also recognized by this Act.

The enactment of the process patent contributed significantly to the local technological development via adaptation, reverse engineering, and new process development. The NDP further increased the pressure on foreign firms to manufacture bulk drugs locally from the very initial stage. Foreign ownership up to 74% under the Foreign Exchange Regulation Act (FERA), 1973 was permitted to only those firms who were producing high-technology drugs.

The outcome of this strategic government interventions in the form of a soft patent policy and a regime of discrimination against foreign firms affected the industry in a very positive way and provided strong growth incentive to the domestic pharmaceutical sector.[26]

The drug prices in India were brought under control based on the recommendations of the Hathi Committee (1975), which observed that since the drugs industry has a social responsibility, it should operate much above the principles of trade for profit. However, due to the repeated pleas of the industry that the drug production was becoming unprofitable, in 1986, the government reduced the number of drugs under control from 347 to 166. Yet in spite of the price reductions in India, over a period of 15 years from 1980, there has been a general rising trend in prices, especially of essential life-saving drugs.[27]

THIRD PHASE: 1999s & ONWARDS

After the ratification of TRIPS agreement by India, the first amendment to the Patent Act was made in 1999, through which the Government of India has facilitated the `Mail Box' system and the Exclusive Marketing Rights (EMR) for products patented elsewhere. Under the Mail box system, patent applications from 1st January 1995, were kept in a box which were to be processed in 2005. Further, under the Doha Declaration, it was made clear that each member nation has the right to grant Compulsory License (CL) and the freedom to determine the grounds upon which such licence would be granted. This CL was however subjected to certain

[25] *Ibid.* at pg. 45.
[26] *Ibid.*
[27] See Supra note 11 at pg. 5.

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conditions like- authorisation of such use will have to be considered on its individual merits; the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms (except in cases of national emergencies); legal validity of the CL decision and the remuneration will be subject to judicial or other independent review and the CL can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.

Three years after the 1999 amendment, the Patents (Amendment) Act, 2002 (Act No. 38 of 2002) came to be enacted on June 25, 2002. The Bill defined the term "invention" in consonance with international practices and consistent with TRIPS Agreement; modification to section 3 of the Act were done to include exclusions permitted by TRIPS Agreement and also subject-matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention. It also aligned the rights of patentee as per article 28 of the TRIPS Agreement, and amendments to several provisions of the Act were introduced with a view to simplifying and rationalising the procedures aimed at benefiting the users.[28]

One final step to make Indian Patent Law compatible with the mandate of TRIPS was to allow for grant of product patents for pharmaceutical and agricultural chemical substances, but the draft Bill lapsed in February 2004 and again in December 2004 thus in order not to default on its obligations under the TRIPS Agreement, the Government brought the Patents (Amendment) Ordinance, 2004 (Ordinance No. 7 of 2004) with effect from January 1, 2005. By this Ordinance, section 5 of the Patents Act, 1970, which barred the grant of patent for substances intended for use or capable of being used as food or as medicine or drugs or substances prepared or produced by chemical processes was done away with, opening the doors for grant of patents to, amongst others, pharmaceutical products.[29] But this Ordinance was to lapse on March 31 2005, thus the parliament passed the Act, replacing Ordinance No. 7 of 2004 and amending the Patents Act, 1970.

On December 18, 2004, the Bill to further amend the Patents Act, 1970, which was materially the same as Ordinance No. 7 of 2004, was introduced in Parliament. The Bill evoked a highly insightful and informed debate on the issue concerning the public health and access to drugs.

Finally, after three days of debate (March 18, 21 and 22) the Bill, along with the amendments proposed by the minister, was passed by the Lok Sabha on March 22, 2005. Some of the very

[28] Para. 68, Novartis AG *v.* Union of India & others (S.C. 2013).
[29] Para. 74, Novartis AG *v.* Union of India & others (S.C. 2013).

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important amendments that were incorporated in the Bill related to section 2(1) (ja) and section 3(d), and the insertion of the provision for pre-grant opposition to the grant of patent. After being passed by the Lok Sabha, the Bill was presented in the Rajya Sabha where it was passed on March 23, 2005. It received the assent of the President on April 4, 2005, and was published in the official gazette of April 5, 2005.[30] These amendments gave a new *avatar* to the Patent Act, 1970.

IV. NOVARTIS AG *V.* UNION OF INDIA & OTHER CASE

In the case of State of Punjab *v.* Mohinder Singh Chawla[31] Supreme Court stated that right to health has not been recognised directly by the constitution of India but the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion and political belief, economic or social condition. Right tohealth is an integral component of right to life[32] enshrined in the Indian Constitution.

But India's introduction of product patent protection under the Indian Patent Act in 2005 affected the developing and third world countries in two ways:

a) By directly undercutting the supply of affordable medicines and;

b) Indirectly by removing the generic competition on which India had been for long surviving by supplying copies of the patented medicines cheaply throughout theworld's poor regions.[33]

India is the world's second most populous country and the second-fastest growing major economy, but has 70% of its population living on less than $2 per day,[34] with Novartis AG challenging the legal validity of the section 3(d) of the Patent Act, it was in the hands of the apex court to strike a balance between the need to promote research and development in science and technology and to keep private monopoly (called an 'aberration' under our Constitutional scheme) at the minimum.[35]

BRIEF FACTS

Gleevec is used for the treatment of Chronic Myeloid Leukemia (CML), a disease that afflicts nearly 5,000 new patients in the United States each year.[36] Gleevec targets specific cancer

[30] Para. 85, Novartis AG *v.* Union of India & others (S.C. 2013).
[31] (1997) 2 SCC 83.
[32] See Article 21 of Indian Constitution.
[33] See Supra note 16 at pg. 72.
[34] Linda L. Lee, *Trials And TRIPS-Relations: Indian Patent Law And Novartis AG v. Union Of India*, Berkeley Technology L. J., Vol. 23:281 (2008).
[35] Para. 4, Novartis AG *v.* Union of India & others (S.C. 2013).
[36] American Cancer Society, *How Many People Get Chronic Myeloid Leukemia?*

proteins and is almost ten times more effective than traditional interferon therapy. The Novartis patent application (also referred to as the Zimmerman patent in the decision) was first rejected in 2005, for lacking novelty as well as on grounds of not meeting the 'efficacy' requirement inS 3(d).[37] The original patent for Imatinib in free base form (the Zimmerman patent) was grantedin the US in 1993.[38] The application that was rejected in India was for Imatinib Mesylate, specifically the beta crystalline form, a salt of the free base disclosed in 1993. The Indian patentin question for Imatinib Mesylate in beta crystalline form (hereafter IMBCF) was filed in 1998and claimed that the beta crystalline form was a new product because of new and superior properties, such as a better beneficial flow, better thermodynamic stability and lower hygroscopicity. These properties allegedly allowed, among other uses, for better processing and storage.

The Novartis application claimed that by starting with Imatinib in free base form, they produced IMBCF, and then produced the beta crystalline form of the salt Imatinib. In pharmaceutical chemistry, a different crystalline form of the same chemical substance is called a polymorph. The application compares the beta crystalline form with the free base Imatinib tosay that 'all the indicated inhibitory and pharmacological effects are also found with the free base'. In 2003, the Patent Office granted Novartis Exclusive Marketing Rights (EMR) in India.

Pre-grant oppositions were filed by Natco Pharma Ltd., M/s Cipla Ltd., M/s Hetro Drugs Ltd., M/s Cancer Patient Aid Association and M/s Ranbaxy Laboratories Ltd., India they were the generic companies that had been selling their generic versions of Gleevec at USD 177 to 266 per patient per month as compared to Novartis which was selling Gleevec at USD 2666 per patient per year.[39]

On January 25th 2006, the Madras Patent Office refused to grant Novartis a patent for imatinib mesylate.[40] The first major ground for rejection was that because imatinib mesylate was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib in its 1993 patents, the Indian application, therefore, lacked novelty and inventiveness. The second major ground for rejection was based on Section 3(d) of the 2005 Amendment, which

[37] Sivaramjani Thambisetty, *Novartis v. Union of India and the Person Skilled in the Art: A Missed Opportunity*, pg. 4, LSE Law, Society and Economy Working Papers at: www.lse.ac.uk/collections/law/wps/wps.htm and the Social Sciences Research Network electronic library at: http://ssrn.com/abstract=2336497.
[38] US patent number 5,521,184.
[39] K. D. Raju, *Interpretation Of Section 3(d) In The Indian Patents Act 2005: A Case Study Of Novartis* pg. 3, available online at http://www.commonlii.org/in/journals/INJlIPLaw/2008/2.pdf (last accessed on 26.09.2017 1530 hrs).
[40] Posting of Shamnad Basheer to Spicy IP, *First Mailbox Opposition (Gleevec) Decided in India*, https://spicyip.com/2006/03/first-mailbox-opposition-gleevec.html (last accessed on 18th Sept. 2017 1427 hrs).

required that new forms of a known substance could only be patented as a product if they demonstrated "enhanced efficacy".[41]

Novartis India Ltd., filed writ petitions, in the Madras High Court challenging the decision of the Controller. The petitioner alleged that Section 3(d) of the Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005, is invalid, illegal and unconstitutional & non-compliance with the TRIPs Agreement. The High Court refused to look into the question of whether a private party has a right to enforce an international agreement or whether the Patents (Amendment) Act, 2005, is compatible with the TRIPs Agreement. With regard to the declaratory jurisdiction of the court, after referring to earlier decisions of the Supreme Court of India, it held that it is not going to be of any use for the petitioner and so the petitioner is not entitled to any declaratory relief. The Court also rejected the argument of the petitioner that the discretion vested in the patent examiners can be misused and the decision to reject the petitioner's patent application was due to the excess discretionary power entrusted with the statutory authority and, thus, it violates Article 14 of the Constitution of India[42]

Before the judgment of High Court, the case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB). The challenges on TRIPS compliance and constitutionality of Section 3(d) were heard by the Madras High Court, judgment against Novartis was given on August 8, 2007.[43] Whereas IPAB gave its detailed judgment[44] dated June 26, 2009 The IPAB reversed the findings of the Assistant Controller on the issues of anticipation and obviousness. It held that the appellant's invention satisfied the tests of novelty and non-obviousness, and further it was held that in view of the amended section 133, the appellant was fully entitled to get July 18, 1997, the date on which the patent application was made in Switzerland, as the priority date for his application in India. The IPAB, however, held that the patentability of the subject product was hit by section 3(d) of the Act.[45]

However, Novartis AG decided to appeal only the against the order of IPAB[46] under Article 136 of Constitution and thus in special leave petition was filed before the Supreme Court of India & the primary issue raised by the petitioner was whether the beta crystalline form of the drug sought to be patented, stands the test of patentability as specified in section 3(d) of the Patents Act, 1970 or not?

[41] *Ibid.*
[42] See Supra note 38 at pg. 14-15.
[43] See Supra note 33 at pg. 299.
[44] Cases were numbered as TA/1 to 5/2007/PT/CH.
[45] Para. 17, Novartis AG *v.* Union of India & others (S.C. 2013).
[46] Para. 21, Novartis AG *v.* Union of India & others (S.C. 2013).

SUBMISSIONS OF NOVARTIS AG BEFORE THE HON'BLE SUPREME COURT

The primary submission of Novartis AG was that the beta crystalline form of the drug for which the patent applied for in India was developed through two distinct inventions–firstly, from imatinibtoimatinibmesylate and secondly, from imatinibmesylateto the beta crystalline form. The Supreme Court of India, however, ruled that Imatinib Mesylate was a known substance atthe time of application of the patent, thereby not qualifying as an "invention" under the PatentsAct and does not satisfies the criteria of therapeutic efficacy as laid down in Section 3(d) of thePatents Act. The Court also recorded a finding that the pharmacological properties of ImatinibMesylate were known in the Zimmermann patent and in an article published in a Cancer Research Journal, thereby further justifying the lack of criteria for an "invention" in Novartis case.

According to SC[47] on a combined reading of causes (j), (ac) and (ja) of section 2(1), in order to qualify as "invention", a product must, therefore, satisfy the following tests:

(i)It must be "new";

(ii) It must be "capable of being made or used in an industry"

(iii)It must come into being as a result of an invention which has a feature that:

(a) entails technical advance over existing knowledge;

Or

(b) has an economic significance

And

(c) makes the invention not obvious to a person skilled in the art.

The S.C. further stated that the amended portion of section 3(d) clearly sets up a second tier ofqualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.[48]

EFFECT OF THE NOVARTIS JUDGMENT

The immediate reaction of the judgment was widespread acclaim and support, particularly from organisations such as the WTO and Médecins Sans Frontières (Doctors Without Borders)

[47] Para. 90, Novartis AG *v.* Union of India & others (S.C. 2013).
[48] Para. 103, Novartis AG *v.* Union of India & others (S.C. 2013).

amongst others that welcomed the judgment as a stronghold against 'evergreening'.[49]

It must be appreciated that in the Novartis case, the Supreme Court has taken a stance wherein it is not only justified to deny where incremental innovation is trivial as in the present case, but one must also prove and demonstrate the therapeutical efficacy of the product. The Division Bench[50] has given great consideration to the impact or rather damage the same, if granted would have to society and has highlighted the relevance of specific conditions of a country for deciding the appropriate patent regime.[51]

This judgment will have a direct effect on 'Evergreening' as it will be harder for producers to prove therapeutic efficacy, now a strict criterion for patent protection in India. The direct benefit of the above will be to the consumer as medicines which otherwise would have been patented having high monopoly prices will now not be patentable, thereby being affordable. The present ruling in the Novartis case is a relief to the Indian market, as pharmaceutical companies are now essentially unable to extend the life of patents by minor, trivial modifications to their protected products.

Thus, it paved the way for generic companies to sell the anticancer drug and other drugs in the future, at a fraction of the exorbitant prices charged by Novartis and pharmaceutical giants for the product. It has been suggested, although yet to be seen that the strict patent requirement laid down by the Apex Court would actually enhance innovation as pharmaceutical companies would have to invest more in research and development to come up with new cures rather than repackage known compounds. It must be appreciated that at present, as per India's Economic Development Stage, India has more net user of medicines than as a developer of such lifesaving drugs. Therefore, the grant of patent protection in pharmaceutical products as in Novartis case would cause greater harm to the economy than benefit as the same would essentially bereft Indian pharmaceutical companies of the opportunity of penetrating a market deep enough to sustain and grow by handing over this opportunity to a global conglomerate.

V. CONCLUSION

The judgment of Supreme Court against Novartis has, and will continue to have, broad implications for MNCs, the Indian pharmaceutical industry, and people around the world in need of affordable drugs.[52] This judgment has tremendous significance for the patent regimes

[49] Harekrishna Ashar, *The Supreme Court On Therapeutical Efficacy And Section 3(D) Of The Indian Patents Act*, RGNUL Student Law Review, Vol. 1 Issue 1, Pg. 180.
[50] Justice Aftab Alam & Justice Ranjana Prakash Desai.
[51] Para. 55, Novartis AG *v.* Union of India & others (S.C. 2013).
[52] Gardiner Harris & Katie Thomas, *Low-Cost Drugs in Poor Nations Get a Lift in Indian Court*, N. Y. Times (Apr. 1, 2013), http://www.nytimes.com/2013/04/02/business/global/top-court-inindia-rejects-novartis-drug-

in developing countries. Yet while the production of drugs is not a problem in India, general access to drugs is. The affordability of pharmaceuticals and lack of a comprehensive health insurance system have heavily influenced the evolution and development of India's patent laws and its participation in international intellectual property agreements.

The ruling of Supreme Court and section 3(d) of the Act, paves the way for easing the accessibility and availability of drugs in India & protecting genuine innovators in India at the same time thus protecting from 'Evergreening' effect. Needless to say, that now the MNC's would be considerably more cautious in their approach, keeping in mind the depth of the judgment.

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