



INDIAN PATENT LAW AND THE FUTURE OF PHARMACEUTICAL INDUSTRY

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Abstract

In April 2013, the Supreme Court of India delivered a much awaited judgment in the case of *Novartis v. Union of India*. The judgment marked the climax of an 8-year long litigation between Novartis on one side and the Patent Office, the Government of India and several Indian generic pharmaceutical companies on the other side. At the heart of the litigation was the interpretation of Section 3(d) of the Indian Patent Act, 1970.

The final judgment, which went against Novartis, is also going to have a wide-ranging impact on the grant of future Indian patents for pharmaceutical inventions, especially for those inventions derived from new chemical entities (NCEs). While the Supreme Court's observation in the case has a positive impact on the healthcare system in India by making affordable and safe drugs available to poorer section of the society in developing country like that of ours; on the other hand it discourages foreign pharmaceutical industries from inventing in preventing India's growth as the pharmaceutical hub of the world. This narrow interpretation of article 3(d) of the Indian Patent Act 1907, has raised eyebrows on the question of its compliance with TRIPS Agreement at the

World Trade organization with Doha declaration completely supporting India's freedom to frame the patent laws in accordance with its socio-economic condition.

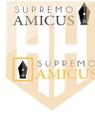
This paper traces the growth of IPR laws in India and analysis the Novartis case, concluding with the positive and negative effects that this decision will have on India's Healthcare Industry.

KEYWORDS: Section 3(d) of Indian patent Act 1970, *Novartis AG v. Union of India*, TRIPS agreement, healthcare, pharmaceutical industry.

I. INTRODUCTION

Patent system is a contract between the inventor and authority whereby the inventor gets exclusive rights for a period of 20 years in return for disclosing full details of the invention. The main purpose of patent system is to encourage innovation and eventually results in technological development.

The IPR laws of India are a boon in disguise. Intellectual property rights in India have gone through a whirlwind with the coming of the TRIPS regime and an unpleasant encounter with Novartis. The pharmaceutical industry's biggest challenge in India are its IPR laws, it is a monster that is eating into the profits of the multinational pharmaceutical companies. However this very monster has turned out to be an angel for the Indian population as it prevents the prices of important medicines from skyrocketing.



The first patent legislation of independent India was enacted in the 1970 amending and incorporating the existing laws relating to Patents and Designs act 1911 in India. Section 5 of this legislation prohibited the grant of product patents to “any substances intended for use, or capable of being used, as food or as medicine or drug.”¹ Patents for manufacturing processes were, however, allowed. Without a product patent regime and a strong domestic expertise in chemistry, India successfully built up one of the largest pharmaceutical industries in the world. By the turn of the century, the generic Indian pharmaceutical industry was referred to as the pharmacy of the world.²

Once India became a signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) it was required to stop discriminating against any field of technology and instead grant patents for any invention that met the basic requirements of patentability, that is, novelty, non-obviousness and utility and amend its own laws accordingly.³

As India approached the TRIPs implementation deadline of January 1 2005, there was significant opposition to changing Indian law, from both the Indian generic pharmaceutical lobby and

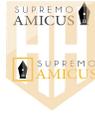
the global public health movement, because a product patent regime would restrict the number of new pharmaceutical drugs that could be manufactured by Indian generics. This would affect the profits of the Indian generics and also make it more difficult for public health movements to source more affordable versions of new drugs from India. However, as it soon became clear to the lobbies that the government was determined about amending the Indian IPR law and bring it in compliance with the international obligations under TRIPS they tried to reduce the effect of any possible amendment limiting the kind of pharmaceutical inventions that would qualify for the grant of patent. In other words they, prescribed high standards for the patentability of any pharmaceutical invention.⁴ This included demands to restrict pharmaceutical patents only to NCEs. The Government of India refused to accept the proposal, by public health activists, to restrict patent-ability to only NCEs until it was examined by an expert committee on the issue of TRIPs compatibility. An expert committee would however take time and the Government did not have time. When the proposal to limit patenting to NCEs was stalled by the Government, another proposal was made to limit the kind of pharmaceutical inventions that would qualify for the grant of patents. This proposal was Section 3(d). The provision

¹The Patents (Amendment) Act, 2005, No. 15 of 2005.

²Prashant Reddy Thikkavarapu, *The Indian Supreme Court's judgment in the case of Glivec—the uncertain future of pharmaceutical patents in India*, 3(2) PHARM. PAT. ANAL. 117–119 (2014).

³ Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J.L. & TECH. 15, 16–17 (2005).

⁴ Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J.L. & TECH. 15, 16–17 (2005).



was introduced into the law as a possible safeguard against the rent-seeking practice of ‘evergreening’, where a pharmaceutical company tried to patent not just incremental innovation but also trivial improvements in a bid to extend its monopoly over the drug.⁵

Therefore the law afforded protection to pharmaceuticals only if they constituted brand new chemical substances or enhanced the therapeutic “efficacy” of known substances.⁶ This law, which is codified under section 3(d) of the Patents (Amendment) Act of 2005,⁷ has not sat well with some MNCs, including the Swiss company Novartis.

II. THE CASE OF NOVARTIS

A. Facts of the case:

The tussle between the Indian Patent Regime and Novartis began long back in 1993, when it filed patents around the world for its synthesis of the molecule imatinib.⁸ The patent application for Glivec, by Novartis was made in

accordance with the “mailbox” requirement, following the formation of WTO and passage of TRIPS in 1995. In January 2006, the Madras Patent Office, rejected the Glivec patent application on the grounds that it was “an unpatentable modification of an existing substance, imatinib”⁹, and failed to show “novelty and inventiveness.”¹⁰ Novartis appealed to the high Court of Madras in May 2006 on the ground that section 3(d) was vague, ambiguous, in violation of article 14 of the constitution of India and also not in compliance with TRIPS.¹¹ The patent application was also reviewed by the Intellectual Property Appellate Board (IPAB). Both the High Court and the IPAB returned decision against Novartis.¹² Madras High Court also concluded that the TRIPS compliance issue was beyond the Court’s jurisdiction and WTO would be the proper forum for deciding on that issue.¹⁴ Novartis subsequently appealed to the Supreme

⁵Prashant Reddy Thikkavarapu, *The Indian Supreme Court’s judgment in the case of Glivec—the uncertain future of pharmaceutical patents in India*, 3(2) PHARM. PAT. ANAL. 117–119 (2014).

⁶ Shamnad Basheer, *The “glivec” patent saga: a 3-d perspective on indian patent policy and trips compliance*, (17 Dec 2017) www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc.

⁷ The Patents (Amendment) Act, 2005, No. 15 of 2005, §3(d), Gazette of India, section I(2) (Apr. 4, 2005).

⁸*Glivec Patent Case in India: Fact vs. Fiction*, NOVARTIS, (Dec. 19, 2017) http://www.novartis.com/downloads/newsroom/glivec-information-center/Fact_vs_fiction_of_Glivec_India_Case.pdf.

⁹ Basheer S, Reddy PT. *Novartis, efficacy & Indian patent law: crude yet constitutional*, 5(2)SCRIPTED 232 (2008)

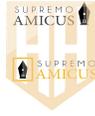
¹⁰ Shamnad Basheer, *India’s Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J.L. & TECH. 15, 16–17 (2005).

¹¹ Linda Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 299 (2008).

¹² *ibid*

¹³ Shamnad Basheer, *Novartis Loses at the High Court: Focus Now Shifts to IPAB*, SPICY IP (Aug. 6, 2007), <http://spicyip.com/2007/08/novartis-loses-at-high-court-focus-now.html>

¹⁴ Shamnad Basheer, *The “glivec” patent saga: a 3-d perspective on indian patent policy and trips compliance*, (Dec. 17, 2017) www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc.



Court of India.¹⁵Supreme Court confirmed the previous Courts decisions that Novartis failed to demonstrate Glivec’s enhanced or superior efficacy in accordance with section 3(d).¹⁶However the apex Court did not provide a definitive definition of “enhanced efficacy.”¹⁷

B. Supreme Court’s judgment:

In its judgment, the Supreme Court interpreted ‘efficacy’ as meaning only ‘therapeutic efficacy’. In the pertinent part, the Court stated *“What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy”*¹⁸.

Such an interpretation is a rather narrow interpretation when compared with the ‘unexpected properties’ standard followed in countries such as the USA, where any property of the new invention, as long as it is ‘unexpected’, can rebut a presumption of obviousness in favor of a salt form or a structurally similar compound. Therefore, a drug that demonstrates unexpected thermodynamic stability, making it easier to store, can be patented in the USA but not in India because the same would not increase the therapeutic efficacy of the drug.

C. Interpretation of section 3(d):

Section 3(d) of the said act reads as follows,

“ What are not inventions – the following are not inventions within the meaning of this Act, –[SEP]... (d) the mere discovery of a new form of a known substance which does not result in increased efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.”

From the first reading of the section, it is apparent that in order that Section 3(d) is attracted, the following conditions must be satisfied:

- What is claimed must be a mere discovery;
- What is claimed must be a new form of a known substance; and
- Such substance claimed does not result in increased efficacy over known substance.

If any of the above-mentioned three conditions are not met, Section 3(d) cannot and should not be applicable. Therefore the applicability of the section lies on the difference between ‘discovery’ and ‘invention’. According to the Webster’s Third International Dictionary of the English Language, the expression “discovery” refers to *“the act, process or an instance of gaining knowledge of or ascertaining the*

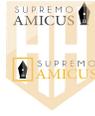
¹⁵ *ibid.*

¹⁶ *India’s Novartis Decision*, N. Y. TIMES (Apr. 4, 2013), <http://www.nytimes.com/2013/04/05/>

http://www.nytimes.com/2013/04/05/opinion/the-Supreme-Court-in-india-clarifies-law-in-novartis-decision.html?_r=0.

¹⁷ *Novartis v. Union of India*, (2013) 6 SCC 1

¹⁸ *Novartis v. Union of India*, (2013) 6 SCC 1



existence of something previously unknown or unrecognised.” Therefore, unlike “*invention*” which refers to a new product or process involving inventive step and capable of industrial application (Section 2(1)(j) of the Patents Act, 1970), “*discovery*” essentially refers to finding out something which already existed in nature but was unknown or unrecognised.

Furthermore going by its literal reading, Section 3(d) seeks to target two kinds of pharmaceutical inventions structurally similar chemical compounds and new salt forms of existing chemical compounds. In both cases, the person applying for a patent was required to demonstrate that the structurally similar chemical compound or the new salt form demonstrated significantly increased ‘efficacy’ when compared with the ‘known substance’.

At issue in the Glivec case was the patentability of the beta crystalline form of Imatinib Mesylate. The NCF in this case, Imatinib, was a path-breaking discovery but could not be patented in India because it was discovered before 1995, the cut-off date for TRIPS. The beta-crystalline form of Imatinib Mesylate was derived from Imatinib Mesylate, which in itself was a salt form of Imatinib. According to Novartis, the beta crystalline form of Imatinib Mesylate should have been patentable since it had better bioavailability than the Imatinib free base, that is, it could dissolve better in blood than the known form from which it was derived. The

main hurdle faced by Novartis was the word “*efficacy*”¹⁹ in section 3(d) of the Indian Patent Act, 1970. The word was not defined in the law and the issue of its interpretation was contested all the way up to the Supreme Court in the Glivec case.

The Supreme Court, in order to provide greater clarity on the matter observed that, “*Efficacy means the ability to produce a desired or intended result. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the junction, utility or the purpose of the product under consideration. Therefore, in the case of medicine that claims to cure a disease, the test of efficacy can only be ‘therapeutic efficacy’.*”²⁰

Therefore it is found that the Novartis’ patent application for the beta-crystalline form of Imatinib Mesylate (polymorph B) did not pass the test of section 3(d) as it did not have any enhanced therapeutic efficacy. The Supreme Court thereby upheld the observation of the High Court and Indian Patent office and rejected the patent application filed by the petitioner.

D. Is 3(d) in confirmation with TRIPS:

Whether section 3(d) of the patents act 1970, actually meets the requirements of TRIPS depends on the construction of the

¹⁹ Basheer S, Reddy PT. *Novartis, efficacy & Indian patent law: crude yet constitutional*, 5(2), SCRIPTED 232 (2008).

²⁰ *Novartis v. Union of India*, (2013) 6 SCC 1.



word “efficacy.”²¹ If efficacy is given a fairly narrow construction, so as to essentially reserve patent protection for new chemical entities only, then section 3(d) may in fact violate TRIPS.²² However, the significant provisions in TRIPS clearly indicate that member nations have been given significant flexibilities to frame patent laws, which reflect their social and economic needs.²³ Article 27 of the TRIPS Agreement states, “*Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*”²⁴ Fortunately for WTO member states such as India, many of the terms included in TRIPS have been left undefined, including “inventive step”, “industrial application” and “invention” providing flexibility to establish the criteria of patentability.²⁵ In the absence of a precise definition of patentability, there is nothing to prevent the Section 3(d) from using an “efficacy” requirement,²⁶ i.e. a higher level of inventiveness for determining patentability of new forms of known substances. Accordingly, in order to

acquire patent protection in India, the substance has to go beyond establishing the novelty, inventive steps, non-obviousness and industrial application test set forth in TRIPS agreement and also fulfill the additional improved efficacy incorporated under section 3(d). Moreover, in India, international treaties are not directly enforceable and municipal law prevails over international law.

Additionally the **Doha declaration** has also helped in softening the tone of international debates concerning access to medicines in the context of TRIPS. The declaration clearly states that TRIPS Agreement shall not prevent members from taking measure to protect public health.

“... 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

²¹ Shamnad Basheer, *The “glivec” patent saga: a 3-d perspective on indian patent policy and trips compliance*, (Dec. 17, 2017) www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc.

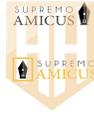
²² *ibid.*

²³ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, (Dec. 18, 2017) <http://www.iprcommission.org>.

²⁴ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, [L][SEP] Marrakesh Agreement, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

²⁵ Linda Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 299 (2008).

²⁶ Former WIPO director, Nuno [L][SEP] Pires de Carvalho, when asked about section 3(d)'s compliance with TRIPS, stated, WTO members can individually define the term invention for purposes of patentability, subject to meeting the TRIPS criteria of “novelty,” “inventive step” and “industrial application potential,” of the substance concerned. Therefore, what India did through Section 3(d) was to make it clear that a number of technical creations are not inventions, unless they present a significant increase in efficacy.



*access to medicines for all.*²⁷

Article 5 of the Doha declaration protects the rights of countries like India by cogently stating that,

“... 5(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted....

5(c) Each Member has the right to determine what constitutes a public emergency...

5(d) [TRIPS leaves] each member free its own regime for exhaustion [of intellectual property rights] without challenge ... (International exhaustion permitting parallel importation permitted)...”²⁸

III. CONSEQUENCES AND FUTURE OF PHARMACEUTICAL INDUSTRY:

The ruling in the Novartis’s case represents a major victory for community’s access to inexpensive

medicines in developing countries and influences the access of medicines to the poor. Apart from protecting public interest this interpretation of the section 3(d) of the patent’s act 1970, is an effective means of preventing the practice of ‘evergreening’ by large MNCs. But there is a negative side too, to the interpretation given by the Supreme Court in the said case.

Under the prevailing interpretation of section 3(d), it is very difficult to acquire a patent for a drug with incremental improvements because it will likely fail to meet the “enhanced therapeutic efficacy” threshold.²⁹ This will eventually harm the domestic drug companies because India’s major domestic pharmaceutical companies have yet to accrue the infrastructure and capital to make major leaps in drug innovation, a number of them have focused on “incremental innovation.”³⁰ “Indian scientists do not have the know-how or capital to come up with new chemical entities, but do have the know-how to make improvements.”³¹ This is unfortunate for a country, which is emerging as powerful player in the

²⁷ Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Dec. 30, 2017), available at <http://www.wto.org/english/tratop-e/implem-para6-e.htm>.

²⁸ Doha declaration on the TRIPS Agreement and Public Health, WT/L/540 (Dec. 30, 2017), available at <http://www.wto.org/english/tratop-e/implem-para6-e.htm>.

²⁹ Rumman Ahmed & Amol Sharma, *Novartis Fights India for Cancer Pill Patent*, WALL ST. J. (Dec. 19, 2017),

<http://online.wsj.com/article/SB10000872396390444233104577594973786074692.html>.

³⁰ Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, UNITED NATIONS UNIVERSITY INSTITUTE FOR NEW TECHNOLOGIES, <http://www.who.int/intellectualproperty/studies/PadmashreeSampath Final.pdf>

³¹ Lok Sabha Debate, Mar. 22, 2005, <http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm>



realms of science and technology. This will at least in the near future, discourage foreign investment in India. While the Supreme Court requested that its decision not be read as a prohibition on patents for

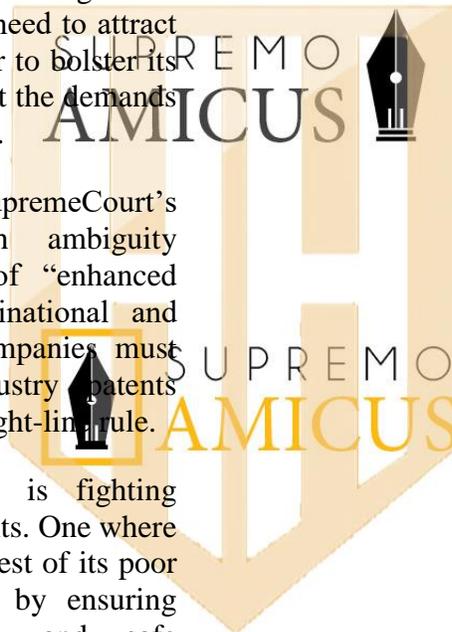
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all incremental innovation, the reality is that many MNCs will question their ability to secure patents for their products in India. Foreign firms will simply abstain from investing in India, perhaps by withholding the introduction of new products to the Indian market, or by refusing to create new high-paying jobs there. This possibility is troubling in the face of India's increasing need to attract foreign investment in order to bolster its weak currency, and to meet the demands of its growing middle class.

Moreover, The Indian Supreme Court's decision leaves enough ambiguity regarding the meaning of "enhanced efficacy" that both multinational and Indian pharmaceutical companies must continue to pursue industry patents without the benefit of a bright-line rule.

Having said this, India is fighting simultaneously on two fronts. One where it seeks to protect the interest of its poor and middle class citizen by ensuring availability of affordable and safe medicines to promote healthy and better lives. While on the other hand it needs to protect the interest of the foreign and domestic Pharmaceutical interest by providing patent protection to ensure enthusiastic research and development in the field of medicines. This seems to be a never-ending tussle. Having weighed the

pros and the cons on each side only time can tell us the future of pharmaceutical industries in India and its position in the world.



³²*Novartis v. Union of India*, (2013) 6 SCC 1, at 95.