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Right to Intellectual Property in Novartis: Interpretation of Section 3(d) in the Indian Patents Act 2005

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ABSTRACT

The well-known and newly decided Novartis Glivec case[3] flickered tensions about affordability of drug & the global protection of patent rights. This Article deals with India's Section 3(d) of Patent law where we find a struggle to find balance concerning permitting patents that incentivize and promote innovation, regardless of the fact of not permitting the practice of "evergreening," which could probably delay low price generic medicines from ever reaching and serving low income patients.[4] Likewise, this Article settles to the point that the WTO Dispute Settlement Organisation would determine Section 3(d)'s efficacy standard to be an effective use of the elasticities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and that it must be taken as a suggestion to streamline TRIPS while talking issues about apprehensions about right to intellectual property. It is also established that notwithstanding the compatibility of section 3(d) by means of TRIPs agreement, it has been agreed that the words of the relevant section is insufficient as it there is lack of clarification. The act does not explicitly and unambiguously state the range of enhanced efficacy nor is there any sort of strategies stated in that consequence. And so it is imperative to modify the phrasings of section 3(d) to make straightforward the implication of improved efficacy.[5] It is determined that Section 3(d) does not encroach upon the TRIPS order rather avoids frivolous patenting devoid of overlooking valuable as well as appreciated incremental improvements in pharmaceuticals and is precisely well-matched with TRIPS agreement.

Keywords: *Novartis, section3 (d), Glivec, evergreening.*

I. INTRODUCTION

Policymakers face a complicated landscape when deciding where to set the bar for

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[3] *Novartis AG v. Union of India &Ors*., (2013) 6 SCC 1
[4] Section 3 (d) of the Patents (Amendment) Act, 2005 provides that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' is not patentable
[5] Patents (Amendment) Act, 2005

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patentability. Patients benefit from the innovation funded by pharmaceutical companies when those companies discover life-changing drugs like Glivec, but they will be harmed if patents are never allowed to expire so that low cost generics can enter the market. On the other hand, if patents are not granted on their products pharmaceutical companies lose years of monopoly profits and are not able to fund the research and development necessary for innovation. The patent balance seeks to find a compromise. Before the development of an international regime, countries made this policy decision independently, and differently, at the national level.[6] The Trade Related Aspects of Intellectual Property (TRIPS) agreement, housed in the World Trade Organization (WTO), sought to homogenize the balance by imposing minimum standards with which all WTO members must comply. The TRIPS patent balance is based on standards drawn from U.S. law, and developing countries assert that it does not take into account their unique interests.[7] Thus, developing countries have advanced a number of "balance adjusters" to alter the TRIPS standard to meet their needs.

One balance adjuster is India's Section 3(d), which seeks to prevent the practice of "evergreening" patents.[8] Evergreening occurs when a drug manufacturer makes small improvements to an old medicine, allowing it to renew its patent and to extend the time it will enjoy monopoly control rights.[9] To prevent this phenomenon, Section 3(d) does not allow patents to be granted in India for the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy . . . ."[10] Section 3(d)'s efficacy standard serves as a patent balance adjuster because it seeks to prevent the harm to patients caused by forty, sixty, eighty, or more years of monopoly control over lifesaving drugs. Part II of this Note explores the development of patent law in India, including its move in 2005 to become compliant with TRIPS. For many years, India did not allow patents on products, only on processes. A booming generics industry developed under that system and is now one of the largest contributors to India's economy. This industry has earned India the nickname of the "pharmacy of the developing world" because of the volume of generics it exports each year. That volume of generics, in combination with Section 3(d), means that many otherwise patent-

[6] WTO—TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 471 (KatrinArend, Jan Busche& Peter-Tobias Stoll eds., 2009).
[7] Karin Timmermans &Togi Hutadjulu, The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals 19 (2000), http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf (dramatic asymmetry in NorthSouth relations in ability to create and apply new knowledge).
[8] The Patents (Amendment) Act, No. 15 of 2005, § 3(d).
[9] Sara Beth Myers, Note, A Healthy Solution for Patients and Patents: How India's Legal Victory against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights, 10 VAND. J. ENT.&TECH. L. 763, 774 (2008).
[10] The Patents (Amendment) Act, No. 15 of 2005, § 3(d).

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worthy drugs are already "known substances" that will require a showing of increased efficacy in order to be patentable. Glivec faced this exact problem, as Part III explains. Glivec, also spelled Gleevec, is produced by the pharmaceutical company Novartis and makes chronic myeloid leukemia a manageable disease. A generic version of the Alpha form was already being produced in India before the 2005 move to become TRIPS compliant. The patent office ruled that the new Beta form was not more therapeutically effective at treating the cancer, despite increases in bioavailability, thermodynamic stability, and shelf life.

In court, Novartis challenged

(1) the patent office's decision on the patentability of Glivec,

(2) the TRIPS compliance of Section 3(d), and

(3) the constitutionality of Section 3(d).

The Madras High Court and the Intellectual Property Appellate Board upheld the denial of the patent, held Section 3(d) to be constitutional, and held that there was no jurisdiction to decide the TRIPS issue. Novartis appealed only the first patentability issue, and the Supreme Court of India ruled on April 1, 2013, that the patent had been properly denied. Part IV explores how the India Supreme Court's ruling will affect various stakeholders and explores a number of balance adjusters other than Section 3(d), including compulsory licenses and discounted drug sales. Finally, this Note argues that Section 3(d) should be understood either as a valid use of the flexibilities of TRIPS for developing nations to adjust the patent balance in domestic implementation, or as a proposal to amend TRIPS to prevent evergreening practices that upset the patent balance. This final section concludes that the Dispute Settlement Body (DSB) of the WTO would find Section 3(d) to be compliant with TRIPS.

II. THE NOVARTIS CASE

Glivec (imatinibmesylate), produced by the Swiss pharmaceutical giant Novartis, is used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST), and is patented in 35 countries across the world.[11] According to Lee[12], studies have shown that Glivec is "almost ten times more effective than traditional interferon therapy", due to its ability to target specific cancer proteins. However, "the drug does not give a permanent cure from cancer … it only stalls its progress. For patients, the drug needs to be taken lifelong[13]". For this reason,

[11]Ecks S. Global pharmaceutical markets and corporate citizenship: the case of Novartis' anti-cancer drug glivec. BioSocieties. 2008; 3:165–181.doi: 10.1017/S1745855208006091

[12]Lee L. Trials and TRIPS-ulations: Indian patent law and Novartis AG v. Union of India. Berkeley Technol Law J. 2008;28(298):281–290.

[13] Hannon E. How an Indian patent case could shape the future of generic drugs. Time Mag. 2012.

along with the fact that 95% of Indians do not possess private health insurance, its pricing plays a critical factor in cancer patients' ability to access a continuous supply of Glivec for effective treatment.[14] What is important to bear in mind, is that there is a significant price gap between the patented version of Glivec and its generic copy, as a monthly dose of the former can cost as much as USD$5,000 in the U.S., whereas a monthly dose of the latter can be purchased for just USD$200 in India.[15] In 2006, the Indian Patent Office rejected Novartis' patent application for Glivec under Section 3(d) of the Indian Patents Act, stating that the drug was a modification of an existing substance, imatinib, and therefore represented a case of 'evergreening'.[16] Section 3(d) articulates that reformulations of pre-existing drugs, which do not improve the efficacy of the product, are ineligible for extended patents. This provision was included primarily to safeguard public health interests.[17]Unfortunately, "neither the Indian patent statute nor its implementing rules define 'efficacy'", and there are no available guidelines for companies like Novartis seeking second-generation patents (i.e., extended patents on modifications of previous products).[18] Thus, the interpretation of the word "efficacy" is central to this case.[19] The Novartis case is a landmark case because it represents critical issues related to intellectual property protection and access to medicines, which will impact how multinational pharmaceutical companies conduct business in India in the future, as well as India's role as the "Pharmacy of the Developing World".[20] India's verdict is likely to serve as a model for other developing countries in terms of how they choose to interpret their obligations pursuant to the TRIPS Agreement.[21]

(A) History of the case

Novartis' efforts to patent Glivec in India went well over a decade. In 1993, Novartis filed patents worldwide for imatinib, the precursor for the current version of its drug Glivec.[22] However, it did not do so in India as India at the time did not offer product patent protection.

<http://world.time.com/2012/08/21/how-an-indian-patent-case-could-shape-the-future-of-generic-drugs/>

[14] Supra 8

[15]Medicines sans Frontières. Q&A: patents in India and the Novartis case <http://www.doctorswithoutborders.org/publications/article.cfm?id=5769&cat=briefing-documents>

[16] Roderick P, Pollock AM. India's patent laws under pressure. Lancet. 2012;380(9846):e2–e4. doi: 10.1016/S0140-6736(12)61513-X.

[17] Lofgren H. Novartis vs. the government of India: patents and public health, (July 8,2021, 12.30PM), http://www.eastasiaforum.org/2013/04/26/novartis-vs-the-government-of-india-patents-and-publichealth/

[18] Chandra R. '3(d)' effect: the novartis-glivec case. Econ Polit Wkly. 2011; XLVI (37):13–15.

[19] (2013) 6 SCC 1

[20]Venkatesan J. Landmark verdict gives big boost to cancer patients. The Hindu. 2013., (July 8, 2021), http://www.thehindu.com/news/national/landmark-verdict-gives-big-boost-to-cancer-patients/article4569056.ece.

[21] Supra 5

[22]Ecks S. Global pharmaceutical markets and corporate citizenship: the case of Novartis' anti-cancer drug glivec. BioSocieties. 2008; 3:165–181.doi: 10.1017/S1745855208006091.

In 1997, when Novartis developed the beta crystalline form of imatinib – imatinibmesylate – which it found to have 30% more bioavailability than its non-salt form (i.e., absorbed 30% more easily into the bloodstream), the company applied for a second round of patents, this time including India. The patent application was received under India's 'mailbox' provisions, a scheme which allowed companies to request patents while the Indian government transitioned towards a revised intellectual property legal system in 2005 at the behest of the World Trade Organization. However, Indian generic producers were manufacturing and selling Glivec at less than 10% of the patented version's price, compelling Novartis to put pressure on the Indian government to take a stance on intellectual property protection.[23] In response, the Indian government granted the company Exclusive Marketing Rights (EMR) until its application came up for review. This decision put a stop to the majority of the production of generic versions of Glivec in India, thereby resulting in massive access restrictions for individuals seeking affordable cancer treatment.[24] Several generic companies and not-for-profit organizations such as the Cancer Patients Aid Association (CPAA) rallied together to protest against Novartis' EMR status, and filed an opposition against the company's patent application, which was due for examination in 2005, the year when India would officially begin to look at both new and 'mail-boxed' patent requests. In 2006, pursuant to Section 3(d) of the Indian Patent's Act, the Indian Patents Office rejected Novartis' patent application for its drug Glivec, citing that it did not demonstrate any significant changes in therapeutic effectiveness over its pre-existing form, which was already patented outside India. In rebuttal, Novartis filed two legal challenges against the Indian government later that year – one appealing the rejection of its patent request, and the second contesting Section 3(d) of the Indian Patents Act, claiming that it did not comply with TRIPS, which India had ratified in 1994.[25] In August 2007, the Madras High Court ruled against Novartis's attempt to overturn Section 3(d), and in 2009, the Intellectual Property Appellate Board in India rejected the company's appeal against the rejection of its patent application.[26] Novartis then filed a new case with the Indian Supreme Court, disputing the basis of these decisions, and the final decision came out in early April 2013.[27]

[23]Novartis Ag v. Union of India, (2013) 6 SCC 1.

[24] How Does EvergeeningResticts Access to Medicines?, MEDICINES SANS FRONTIERES,(July 10, 11.20 AM), http://aids20 12.msf.org/2012/the-trans-pacific-partnership-agreement-evergreening.

[25] Ravindra Gabble, To patent or not to patent? The case of Novartis' cancer drug Glivec in India, Globalization and Health, (July 12, 2021. 10:04 AM), https://www.researchgate.net/publication/259605891_To_patent_or_not_to_patent_The_case_of_Novartis'_cancer_drug_Glivec_in_India/references.

[26] India's drug-patent rules: test cases. (July 12, 2021. 10:04 AM), http://www.economist.com/blogs/schumpeter/2012/09/indias-drug-patent-rules.

[27]Shamnad Basheer & Prashant Reddy, 'Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of

The SC had made an exception and admitted the SLP side-stepping the jurisdiction of the Madras High Court, in view of the importance of the case and the number of seminal issues that were involved in the case. The SC noted that this was an exception and any attempt directly challenging an IPAB order before the SC side-stepping the High Court was strongly discouraged. We have examined below each concept discussed by the Supreme Court:

(B) Invention vs. patentability

A product in order to get the grant of patent under the Act has to clear the test of Invention and Patentability, individually being separate concepts. For a subject matter to clear the test of Invention it must assure the following conditions as mentioned under Section 2(1) (j) as well as Section 2(1) (ja) of the Act[28]

i. It must be "new";
ii. It must be "capable of being made or used in an industry"
iii. It must have inventive step a. entails technical advance over existing knowledge; Or

a) has an economic significance And
b) makes the invention not obvious to a person skilled in the art.

Once that product or a process has cleared the experiment of Invention it in addition has to pass the analysis of Patentability.[29]

(C) Patentability Analysis – Section 3 (d)

The major argument was that the Product was not patentable under the debatable Section 3 (d). Section 3 (d) reads as follows:

"... [(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation : For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ

Section 3(d)

[28] As per section 2 (j) of the Patents Act, invention means a new product or process involving an inventive step and capable of industrial application.

[29] Section 3 of the Patents Act, 1999 provides a list of all inventions, which are not „inventions" under the provisions of the Act whereas Section 4 provides that all inventions dealing with atomic energy are not patentable under the Act

significantly in properties with regard to efficacy;]…"[30]

In order to pass the restriction of Section 3(d) it was necessary to be established that the product has improved efficacy greater than the known form of the matter.

(D) What was the known substance?

After examining the pleadings and expert affidavits, the SC observed that Novartis' allegation was that the known substance was Imatinib as revealed in Zimmerman patent grant from which betacrystalline form of ImatinibMesylate was resulting and that the substance just preceding beta crystalline form of ImatinibMesylate was Imatinib and not ImatinibMesylate as the Zimmerman patent did not unveil ImatinibMesylate. The SC discarded this argument for the reason that it had made a ruling that the Zimmerman patent did reveal ImatinibMesylate. Further, the Apex Court also discarded this argument in sight of the fact that this was in disparity to the oral as well as written submissions of Novartis before the SC, in which Novartis had claimed that its invention included two stages detached from Imatinib in free base, and the substance immediately prior the subject product is ImatinibMesylate. Therefore, the SC reached to conclusion that the known substance was ImatinibMesylate from which beta-crystalline form of ImatinibMesylate was obtained. Efficacy under Section 3(d) given that the expression "efficacy" is not clearly defined in the Act, the Apex Court referred to the Oxford Dictionary and observed that the word Efficacy implies "the ability to produce a desired or intended result".[31]Hence the Supreme Court observed that the test of efficacy relies "upon the function, utility or the purpose of the product under consideration". Thus, the SC opined that in matter of medicines, whose utility is to heal ailment, the test of efficacy can simply be "therapeutic efficacy".[32]With regard to "enhanced efficacy", the Apex Court held that the parameters for establishing enhanced therapeutic efficacy particularly in case of medicines should entertain a narrow and a strict interpretation of statutes.[33] To hold this interpretation Supreme Court emphasized on

[30] Section 3 (d) of the Patents (Amendment) Act, 2005 provides that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' is not patentable.
[31] The New Oxford Dictionary of English, Edition 1998; Novartis AG v. Union of India &Ors.; Para 180, p. 90.
[32] Shalini S. Lynch, Drug Efficacy and Safety, MSD Manual, (July 20, 2021, 10:04 AM), https://www.msdmanuals.com/professional/clinical-pharmacology/concepts-in-pharmacotherapy/drug-efficacy-and-safety.
[33]Basheer S, Reddy TP. The "efficacy" of Indian patent law: ironing out the creases in section 3(d)SCRIPTed. 2008; 5(2):232–266. doi: 10.2966/scrip.050208.23.2

(i) the clarification to Section 3 (d) which requires derivatives to "vary considerably in properties with regard to efficacy", as a result not all profitable and beneficial parameters would lead to improvement of efficacy;[34] and

(ii) The central text of Section 3 (d) which says "enhancement of known efficacy". The Apex Court held that the innovative form of a known substance has to have significant valuable as well as beneficial properties over already known material in order to get ahead of the restriction of improved therapeutic efficacy as per Section 3 (d). Nonetheless, the SC pointed out that just for the reason that the expression efficacy has to be worked with a strict interpretation in Section 3 (d) that does not imply that it restrictions all progressive inventions of chemical with pharmaceutical substances. Fundamentally Section 3 (d) provides a restriction that all progressive inventions of chemical and pharmaceutical substances call for passing the bar in order to be granted patent. As talked about above the Apex Court had reached to a conclusion that the known substance was not free base Imatinib but ImatinibMesylate. Nevertheless, all the evidence presented by Novartis weighed against the efficacy of medicine with Imatinib, there was no proof provided by Novartis which evaluated the efficacy of the drug with that of ImatinibMesylate. Nevertheless, Apex Court went on to scrutinize the expert affidavits provided by Novartis with regard to the subsequent properties shown by the product confirmed its enhanced efficacy more than Imatinib:

- More advantageous flow properties
- Enhanced thermodynamic stability
- Lower hygroscopicity
- 30 % increase in bio-availability

The Supreme Court held that the initial three properties of the product associated with enhancing processability as well as storage, therefore they did not exhibit enhancement of therapeutic efficacy as a requisite to clear the test of Section 3(d). The Apex Court concluded that even if the affidavits provided by Novartis weighed against the product over Imatinib. The Supreme Court following this was left with 30 % enhancement in bio-availability, with respect to this the Apex Court held that boost in bioavailability could lead to improvement of efficacy however it has to be distinctively claimed as well as established by research statistics. In this case the Supreme Court did not hit upon any research data other than material "to point out that the beta-crystalline form of Imatinib-Mesylate will create a superior efficacy on molecular

[34] Supra 24.

basis than that could be attained with Imatinib free base in vivo animal".[35] In the outlook of the abovementioned findings the Apex Court held and concluded that Novartis claim utterly failed both the test of invention and patentability according to Section 2(1) (j), Section 2(1) (ja) as well as Section 3 (d) of the Act.

III. CRITICAL ANALYSIS

The SC did not have any direction from the Act in interpreting and deducing Section 3 (d). Therefore it referred to the parliamentary debates along with the conditions surrounding enactment of Section 3 (d) to a huge extent to give a purposive elucidation. Further, bearing in mind that Section 3 (d) is very distinctive to India, it was very imperative both for the pharma industry as well as the patent office to have assistance on its interpretation.[36]Although SC has attempted to illuminate certain aspects, some core matters are still open. The SC has made it understandable that efficacy for pharmaceuticals refer to merely therapeutic efficacy. The SC ruled that improved therapeutic efficacy should be interpreted stringently and properties such as improving process-ability, storage as well as intrinsic pharmacological properties do not leadin any way to enhancement of therapeutic efficacy. Therefore, there is a little direction on parameters that do not lead to improved therapeutic efficacy however there is no direction as to what parameters gives rise to therapeutic efficacy. The SC does state that enhancement in bioavailability can lead to enhancement of therapeutic efficacy if recognized by research statistics. One can obtain a sign from this that proper research data isrequired to be provided to demonstrate improvement of therapeutic efficacy but the issue of what sort of research data would be adequate to meet this obligation has been kept open. Another significant aspect highlighted in the ruling is the need to spot correct prior substance against which the comparison of invention should be done. The practical intricacy in obtaining comparative information will need to be determined once it is apparent as to the nature of information that will be established to establish therapeutic efficacy. One troublesome issue preceding to this ruling faced by patent applicants was whether the evidence required for establishing enhancement of therapeutic efficacy should be incorporated in the specification or else external proof would be sufficient. This question seems to have been laid to rest, from the time when the SC has relied on external evidence that is expert affidavits to settle on improvement of efficacy in this matter. The SC has clarified that the decision in this case should not be

[35] Supra 26.

[36] Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495, 536-37 (2007) ("India has been a net exporter of drugs since 1988-89 ... "); Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, at 2 (India), (July 21, 2021. 10:04 AM), http://supremecourtofindia.nic.in/outtoday/patent.pdf.

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understood to denote that Section 3(d) inhibits all incremental inventions of chemical as well as pharmaceutical substances. Nonetheless, the restriction that has been set by the SC to overcome the obstacle of Section 3 (d) is extremely high. As a matter of law if hindrance of ever-greening of patent is the actual mischief that is required to be remedied by Section 3(d), then it is vital to take into deliberation whether prior substance was in reality commercialized.[37] The reason being frequently the prior substance is in free base form and therefore not the salt form. A free base form usually cannot be administered to humans while a salt form can be administered as a result the free base form cannot be commercialized. In a medicine discovery cycle it is the free base form which is discovered and exposed first, thus usually pharma companies file for a patent for the free base form encircling all salt forms in a manner not to be unable to find the priority, at this juncture the pharma companies are not usually aware as to what sort of salt form of the free base would have most therapeutic efficacy. This finding is usually made subsequent to conducting extensive human otherwise animal clinical trials. This issue becomes extremely imperative because if a salt form cannot be claimed independently due to Section 3 (d). In that case in order to impede a patent infringer from using and commercializing the salt form of its drug, the pharmaceutical company has to rely and form its arguments based on its patent covering its free base form. Nonetheless, the foremost argument raised in its counter claim by the defendant is that the salt form is not covered within the free base patent in addition to a broad allegation which claims the entire salt forms is not enabling. As a result, there is no infringement of the patent. This concern in the Merck v/s. Glenmark suit is sub judice before the Delhi High Court.[38]Therefore, this is a big problem for pharmaceutical companies and has to be addressed. The intention of Section 3(d) is to thwart pharmaceutical companies from extending their protection period of monopoly that is evergreening of patents however it should not suppress inventions.[39]For this reason, the parliament along with judiciary should re-examine the provision so that it is just the new form of the known “commercialized” substance may not be approved for patent protection except enhanced therapeutic efficacy is proven.[40]

[37] Supra 36.

[38]Balaji Subramanian, Questionable Witnesses and Unquestionable Reasoning: Observations on Merck v. Glenmark**,** De-Coding Indian Intellectual Property Law, (July 21, 2021. 10:30 AM) https://spicyip.com/2015/10/questionable-witnesses-and-unquestionable-reasoning-observations-on-merck-v-glenmark.html

[39] Interview of A.C. (Jan. 9, 2013). A.C., a patent attorney who has requested anonymity, stated in response to the question, "Does 'evergreening' occur in India?": "It depends on how you define it. Evergreening happens if having a secondary patent is evergreening."

[40]Christopher M. Holman, Timo Minssen, and Eric M. Solovy, Patentability Standards for Follow-On Pharmaceutical Innovation, Biotechnology Law ReportVol. 37, No. 3, (July 22,2021, 12:50 PM)https://doi.org/10.1089/blr.2018.29073.cmh.

IV. CONCLUSION

The Novartis case debatably sets a significant paradigm for access to medicines by putting the pharmaceutical industry on the reach of law of patent. The SC of India's judgment may very well serve as a prospective model for other emerging countries in how they decide to deduce and put into practice the TRIPS Agreement. This matter illuminates how India is regarding its global obligations pertaining to intellectual property laws while ensuring that local needs are appreciated by interpreting its legal obligations in a way that is proportionate with domestic preferences. The verdict puts social justice above commercial interests as well as also helps India's own domestic business. This is the initial time that Indian law has been implemented to forbid patents on drugs with only slight changes to an already existing one.[41] At this instant, only beyond doubt novel and innovative medicines by way of real therapeutic impact will be protected through patenting. What we observe in the case of India is a multifaceted game that results in apprehension amid global trade commitments as well as domestic public health concerns. The latter in this case has evidently taken priority.

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