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EVERGREENING OF PATENTS IN THE LIGHT OF NOVARTIS CASE

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ABSTRACT

This paper discusses the concept of Evergreening of patents in light of the Novartis Case. Evergreening is a major concern for generic manufacturers as it seeks to obtain additional protection on the basis of minor modifications. The patent system is designed to balance the diverse interests but the concept of Evergreening seeks to extend the term of protection without the required 'inventive step.' Evergreening is prohibited under section 3(d) of the Patents Act, 1970 on the ground that 'new forms of the known substances' are not patentable. Novartis case is the only landmark case which deals with the concept of evergreening in such a detailed manner. Therefore, Novartis interpretation of section 3(d) is going to have long-lasting effects on the pharma innovator companies who are looking for the protection of their intellectual property rights in India. Despite the legal battle, the meaning of 'enhanced efficacy' is not settled for future cases as the Supreme Court's verdict has left it open for interpretation.

Keywords - Evergreening of patents, Novartis case, section 3(d) of Patents Act, 1970.

INTRODUCTION

Evergreening is a major concern of generic manufacturers as it seeks to obtain protection for an additional 20 years on the basis of minor modifications in the current composition of the existing medicines. The process does not yield any increase in the therapeutic efficacy of the medicine. [1] In many countries, minor reformulations can qualify for patent protection. So when the patentability standards are lowered the Evergreening of patents becomes easy. The result is that it prevents competition in the market and it is considered bad for the market and the consumers.[2] The patent system is designed to balance the diverse interests of the stakeholders but the concept of Evergreening seeks to extend the term of protection without the required inventive step.

The Supreme Court in the Novartis case defined evergreening as a process whereby "pharmaceutical companies make a trifling change to an existing product and then claiming it

[1] Sushmita R., *Evergreening: An Abuse of the Patent System,* ACADEMIKE (Accessed on 2 April 2020), http://www.lawctopus.com/academike/evergreening-an-abuse-of-the-patentsystem/

[2] Joli Patel, *India's Crack down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision*, 85 UMKC L. REV. 503 (2017).

as a new invention." As it has been argued a trifling change would not amount to novelty or inventive step. The Supreme Court made a distinction between a discovery and an invention. Evergreening is a process involving mere discovery and cannot be said to fall under the definition of the invention.

There are various methods of Evergreening a patent, one such method is the combination of two medicines in which minor modifications are made to the chemical composition of the existing medicine. Other processes are; the introduction of new uses of the existing medicines, sustained-release formulations of existing drugs which have patents, and chiral switching which means the new medicine is different in molecular orientation. These strategies are helpful for extending the term of protection. In this way, the companies can charge more for the medicines by taking the defence of costs incurred on the R&D. But in reality, no cost has been incurred on such compositions since it is just a combination or minor modification in the existing drugs. Due to the lack of generic medicines, evergreening results in an increase in the cost of healthcare of consumers.

Evergreening of patents mostly affects the underdeveloped and developing countries' consumers who cannot afford those braded drugs which can save them from life-threatening diseases. The diseases like HIV AIDS, Tuberculosis, etc. are a major threat to these countries. These nations do not have the financial capacity to buy branded medicines and have to rely on generic forms of medicines. Most of the African nations depend on Indian generic companies for essential and life-saving medicines. Therefore, the Indian generic Industry is a boon to most of the African nations.[3]

On the other hand, it has been argued that evergreening helps in the promotion and protection of new research. Although there are only minor modifications in the existing medicine there is some enhancement in the existing medicines. The companies defend the practice of evergreening because a lot of cost and risk is associated with the new forms of existing medicines. Sometimes the medicines do not qualify for the grant of patents but there is some enhancement in the existing medicine. Research indicates that, on average, it takes around 12 years and around 350 million dollars to progress the medicine from the laboratory to the

[3] Christabel Ligami, *India's Generics Industry is a Boon to Africa*, AFRICA REV. (Accessed on 18 March 2020), http://www.africareview.com/Special-Reports/India-genericsindustry-is-a-boon-to-Africa/-/979182/2956758/-/142k341/-/index.html

chemist shop.[4] Another research indicates that the cost of producing new medicine is going higher and higher with the course of time.[5]

However, the expenditure incurred on the medicines cannot be a ground for extending the existing term of protection. The term of protection is limited with the object of balancing the diverse interests. Once the protection period expires, the patented invention falls into the public domain and the generic medicines can then be made and sold. This works as a balance between the public right to healthcare and the innovators' right to protection. The patent law regime provides an exclusive right to the patent holder for a fixed period of time so that after the expiry of the term of protection the invention can be of some use to the society. Evergreening works contrary to the intentions of the lawmakers, it seeks to extend the term of protection without the required inventive step. Thus, it is a fraud on the patent law regime.

SECTION 3(D) OF THE PATENTS ACT, 1970: AN ANTI-EVERGREENING KEY

Section 3 of the Indian Patents Act, 1970 is the key provision for deciding patentable subject matters in India. It provides for non-patentable subject matter when it comes to registration. One such non-patentable subject matter is enumerated under section 3(d) of the Act:

> ***"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 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,*

[4] Nsikan Akpan, *Evergreen Drugs Extend Pharma Patents, May Have Cost Swiss Consumers 30M Euros*, MEDICAL DAILY (Accessed on 18 March 2020), https://www.medicaldaily.com/evergreen-drugs-extend-pharma-patents-may-have-cost-swiss-consumers-30m-euros-246489

[5] Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B*, SCIENTIFIC AMERICAN (Accessed on 18 March 2020), https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/

> *combinations and other derivatives of known substance shall be considered to be the same substance, unless they* ***differ significantly in properties with regard to efficacy."***

Basically, section 3(d) of the Act strives to prevent a concept commonly called "evergreening of patents" by stating that only those pharmaceutical derivatives which have significantly enhanced efficacy are patentable. The idea behind section 3(d) is that derivatives which are structurally similar to known substances are likely to be functionally equivalent.[6] And if it is otherwise, then it is up to the patent applicant to justify his claims on the ground that new form works better than the old one. This is where the difference lies between evergreening and incremental innovations. The purpose of granting incremental innovations a patent is that it encourages the sequential development of existing products which brings improved products in the market.

The term "efficacy" meant therapeutic efficacy. In the Novartis case, the court took the help of medical dictionary to come to the conclusion that the expression "efficacy" means "the ability of a drug to produce the desired therapeutic effect" If we see the dictionary meaning of 'therapeutic' then it is the healing of disease which has a good effect on the body. The Hon'ble Court also stated that "efficacy is independent of the potency of the drug," and also hold that: "the position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect... Going by the meaning for the word 'efficacy' and 'therapeutic' extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body?"[7]

According to the above definition, the kinds of derivatives which can qualify for patent protection will be limited. Evergreening is the major concern of the human rights activists as it seeks to enlarge the duration of protection by introducing minor modifications in the composition of essential drugs.

[6] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232 (2008).
[7] Novartis AG & Anr. v Union of India & Others, (2007) 4 MLJ 1153.

NOVARTIS V. UNION OF INDIA

Novartis case is one of the landmark cases where the concept of evergreening has been discussed in detail. The Novartis claim was a major threat to the poor people around the world because most of the generic medicines come from the Indian generic medicine industry. India has been termed as the "pharmacy of the developing world".[8] Thus, a change in the policy of India would certainly affect the rest of the world. A survey indicates that 80 percent of the antiretroviral medicines come from India, which is used to treat patients from more than 30 countries.[9] Also, the Indian population is mostly poor and cannot afford branded medicines. So there is a need to protect the generic industry of India.

Novartis AG is a pharmaceutical company having it's headquarter in Switzerland. In the year 1994, the company filed for a patent on Imatinib free base. Subsequently, in 1998, Novartis also filed a patent application at the Chennai Patent office claiming a patent over its cancer drug called Imatinib Mesylate (in beta crystalline form) also known as Gleevec. Gleevec is an improvement on Imatinib free base drug. Novartis was not granted a patent on this drug instead the application was put under the mailbox provisions. As a result, the application was put on hold until 2005.

Meanwhile in 2002 Novartis made an application for the grant of EMRs. EMRs used to provide exclusive marketing rights for a fixed period of time or until a decision is made on the patent application. In November 2003, EMRs were received by the Novartis. Following the grant of EMRs the company filed infringement suits against the generic companies who were producing generic versions of Gleevec. Injunctions against generic companies like Cipla, Ranbaxy, and others were granted by the Courts.[10] This led to a tremendous increase in the prices of Gleevec in India.

In 2005, the Indian Patents Act substituted section 3(d) to deal with the issue of evergreening. When Novartis' application was opened by the Patent office in 2005, it was challenged by many companies in the pre-grant stage. After the review of opposition received, the Indian patent office denied a patent to Novartis on the touchstone of section 3(d). It was notified to

[8] Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INTL. 786 (2011).
[9] Tara Leevy, *Intellectual Property and Access to Medicine for the Poor,* 12 AMA J. ETHICS, 834 (2006).
[10] Zoee Lynn Turrill, *Finding the Patent Balance: The Novartis Glivec Case and the Trips Compliance of India's Section 3(d) Efficacy Standard*, 44 GEO. J. INTL. *1555,* 1563 (2013).

Novartis that the active ingredient in the new Gleevec drug was already known and therefore it is hit by section 3(d). In response to section 3(d) opposition, the company provided an affidavit in the support of its claim. The affidavit stated that the beta crystalline form of Imatinib Mesylate had a higher bioavailability which means that the rate at which the medicine is absorbed is higher. Therefore, the patent application of Novartis was rejected on the ground that it fails to satisfy the "enhanced efficacy test". It was held that the active ingredient, Imatnib Mesylate in beta crystalline form, is a known substance as it has been disclosed in the previous patent. Although the affidavit submitted in support of the application states that it has a higher bioavailability but the Controller was not satisfied with the contents of the affidavit.

As a result of the refusal, two writ petitions were filed before the Madras High Court challenging the above decision along with the constitutionality of section 3(d). The argument on the constitutionality of section 3(d) was based on two grounds:

a. Section 3(d) is arbitrary, vague, and illogical and thus violates Article 14 of the Indian Constitution.

b. That section 3(d) is violative of India's TRIPS Agreement obligations.

On the second ground, the Madras High Court held that it lacks jurisdiction to decide such questions. However, the Court is competent to decide on the constitutionality of section 3(d). It was argued by Novartis that section 3(d) gives an unguided discretion to the patent Controller in deciding the enhanced efficacy of any medicine. Novartis said that this unguided and arbitrary discretion amounts to an infringement of equal protection provisions contained under Article 14 of the Indian Constitution. The government counsel pleaded that what is sufficient enhancement of efficacy is clearly established by the experts in the field and there is a good amount of understanding among the patent office members.

Moreover, if the application has been rejected wrongly then the wrongdoing can be corrected by having recourse to the appellate bodies. It was held by the Madras High Court that section 3(d) of the Indian Patents Act, 1970 does not violate Article 14 of the Indian Constitution since it is not vague, arbitrary, or ambiguous. The Court stated that the purpose of not giving a fixed definition to the term "enhanced efficacy" is that the Parliament wanted that the criteria be applied according to the facts and circumstances of the case. Moreover, the legislators are not experts in the field of the intellectual property thus it becomes necessary to bestow such

power to the Patent office. The Court further noted that:

> *"It is not in violation of Article 14 of the Constitution of India, as we have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens."*

However, before the Madras High Court could decide on the Novartis application, a new forum called IPAB was established to deal with the appeals arising from the decisions of the Controller. Thus, the matter was transferred to the IPAB. The IPAB held that the application does satisfy the novelty and non obviousness requirements but it has failed to satisfy the requirement of enhanced efficacy enumerated under section 3(d) of the Amended Act.

Novartis then filled a special leave petition under Article 136 of the Indian Constitution before the Indian Supreme Court in the year 2009. It was contended by Novartis that section 3(d) should be liberally interpreted to provide patent to Novartis. It was also contended that section 3(d) of the Indian Patents Act is inconsistent with TRIPS obligations of India. Along with these issues the court had to find the true meaning of section 3(d) and whether the Novartis application deserves patent protection.

A. Whether Section 3(d) is in compliance with TRIPS Agreement Obligations

The Supreme Court in Novartis recognized that India, being a member of the WTO, is bound by the obligations under the TRIPS Agreement. Various Articles of the TRIPS Agreement were reviewed in order to find out the compliance. The Doha Declaration on Public Health was also kept in mind while examining this issue. It was held by the Supreme Court that the amendments undertaken in 1999, 2002 and 2005 made notable changes in the patent law regime and has aligned the Indian patent law with the TRIPS. The Court relied on the statement of objects and purposes of these amendments and came to the conclusion that these amendments were introduced to align the Indian law with that of the TRIPS.

The Court also took note of the fact that section 3(d) was introduced with the object of preventing evergreening. Parliamentary debates were also analyzed to see the object of section 3(d) of the Act. One of the legislators used the example of Gleevec and said that these branded medicines are way costlier than their generic counterparts. He also pointed out that the Novartis' Gleevec application is simply evergreening and cannot be said to be an invention.

The legislators were also concerned about the problems of non-availability of generic

medicines in other jurisdictions. Therefore, it is clear from the parliamentary debates that section 3(d) was introduced with the object of dealing with the evergreening issue. It is also to be noted here that patentability criteria have not been defined under TRIPS. Under the TRIPS flexibility, India is free to decide its patentability criteria which suit their specific national interests. Thus it can be said that Section 3(d) is TRIPS compliant. Further, the Supreme Court held that the WTO Dispute Panel can be approached if there is any disagreement.

B. Interpretation of Section 3(d)

The words "known substance" and "enhancement of known efficacy" were analyzed at length by the court. The court held that "known" means something which is proven and well established. The court took the help of the Oxford dictionary to explain the meaning of the word "efficacy". According to the dictionary meaning, it means "the ability to produce the desired result."[11] In the case of medicines, it can only be therapeutic efficacy. Although the exact scope of the term "therapeutic efficacy" is not determined and the court left it to the future courts to determine the real scope by taking into account the facts and circumstances of each case.

Enhancement of the efficacy would mean that the properties of the new medicines should be different from the existing one. A slight change in the inherent properties of existing medicine will not qualify for a patent. A proper way to show the enhanced efficacy can be through empirical research. Novartis AG filed three-fold arguments in the support of enhancement of efficacy; firstly it argued that the new medicine has more beneficial flow properties; secondly, it was argued that it has better thermodynamic stability and thirdly it was argued that it has 30 percent more bioavailability. Applying this interpretation to the Novartis application, the court held that there does not meet the requirements of section 3(d) as it lacks therapeutic efficacy. Thus, Novartis cannot be granted a patent for its drug Gleevec.

It is to be noted that the Supreme Court does not hold that increased bioavailability cannot amount to enhanced efficacy rather it was held that Novartis could not establish the same by providing relevant data and empirical research. This case is a simple affirmation by the Indian Supreme Court that patent rights cannot prevail over the rights of humans to get generic

[11] *Efficacy*, Oxford Dictionary of English, (3rd ed. 2010).

medicines.[12]

REACTIONS TO THE NOVARTIS JUDGMENT

It is one of the most vigorously analyzed judgments around the world. Some viewed this judgment as a win for the healthcare sector whereas some consider it a defeat to the intellectual property right holders.[13] The pharmaceutical companies with branded medicines, developed nations, and other legal critics condemned the judgment on the ground that it discourages innovation and research. Novartis AG also released a press note and said that this will discourage innovative drug discovery which is essential for the advancement of medical science for the patients.[14]

Other big pharma companies like Pfizer also gave negative reactions to the judgment saying that it will affect the environment for innovation and investment in India. Some described it as setting up new and stricter patentability standards for the grant of patents in India. This may force the big pharmaceutical companies to outsource in other markets such as China. Even Novartis also set up its new institute for biomedical research in China.[15] Chip Davis, a representative from PRMA (Pharmaceutical Research and Manufactures of America) commented that the "innovation environment of India is deteriorating and the Indian government does not recognize the value of innovation and the strong intellectual property.[16] India has failed to promote broader protection for medicines and thereby run the risk of dampening the type of inventions which lead to the creation of new medicines.[17]

On the other side of the debate are the people who advocate affordable medicines and the NGOs who are lobbying for better healthcare facilities. They stated that this judgment is a huge relief for millions of people who can survive with the aid of generic medicines. Most of

[12] Javier Esparza, *Indian Patent Law: Working within the TRIPS Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health*, 24 J. TRANSNAT'L L. & POL'Y 205 (2014-2015).
[13] Krista Mahr, *The Novartis Decision: Is the Big Win for Indian Pharma Bad News for Investment?*, TIME (Accessed on 1 April 2020), http://world.time.com/2013/04/01/the-novartis-decisionis-the-big-win-for-indian-pharma-bad-news-for-investment/
[14] *Id.*
[15] R. Jai Krishna & Jeanne Whalen, *Novartis Loses Glivec Patent Battle in India*, WALL ST. J. (Accessed on 1 April 2020), http://www.wsj.com/articles/SB10001424127887323296504578395672582230106
[16] Gardiner Harris & Katie Thomas, *Low-Cost Drugs in Poor Nations Get a Lift in Indian Court*, N.Y. TIMES (Accessed on 1 April 2020), http://www.nytimes.com/2013/04/02/business/global/top-court-inindia-rejects-novartis-drug-patent.html?_r=0
[17] Kaustubh Kulkarni & Suchitra Mohanty, *Novartis Loses Landmark India Cancer Drug Patent Case*, REUTERS (Accessed on 1 April 2020) http://www.reuters.com/article/2013/04/01/us-india-novartispatent-idUSBRE93002I20130401

the underdeveloped and developing countries praised the decision and said that it is a victory for the poor patients looking for medicines.[18]

The Author is of the view that due deference should be given to the judgment of the Indian Supreme Court as it is an independent body with the power to decide to take into account the socio-economic conditions of the country. The Supreme Court did not place any additional burden on the patent seekers but it has merely explained section 3(d) of the Act. Furthermore, a fair hearing was given to Novartis to substantiate its claim. It is not to be understood that section 3(d) bars all the incremental innovations rather it strikes at evergreening of patents.

IMPLICATIONS AND CONCLUSION

The Novartis interpretation of section 3(d) is going to have long-lasting effects on the pharma innovator companies who are looking for the protection of their intellectual property rights in India. Since the Novartis case, the patent office also denied other patent applications on section 3(d) grounds. One such example is that of Boehringer, a German company, filing an application for the protection of its HIV drug called nevirapine.[19] In response to the above application, patient advocacy collective groups filed oppositions in the pre-grant stage by placing reliance on Novartis interpretation of "efficacy."[20]

On the other hand, Boehringer claimed that the new form of the drug has additional stable particle size allocation which leads to increased stability. But the application was denied on the ground that there is a lack of evidence to show enhanced therapeutic efficacy compared to the known forms. The interpretation of enhanced efficacy has led to the insertion of a new condition for patentability for new forms. This new condition of increased efficacy lacks quantitative as well as qualitative guidance as to what constitutes a sufficient enhancement in the efficacy of the drug.[21] The controller has been given wide discretion to decide on it. The

[18] *Indian Supreme Court Decision on Novartis Case a Victory for Access to Medicines in Developing Countries*, MEDECINS SANS FRONTIERES (Accessed on 1 April 2020), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/indian-supreme-court-decision-novartis-case-victory-access-medicines
[19] Indian Patent Application No. 2485/DEL/1998, "Pharmaceutical Composition."
[20] Boehringer Ingelheim Pharmaceuticals v. Indian Network for People Living with HIV/AIDS (INP+) and Positive Womens Network (PWN), (Application No. 2485/DEL/1998), http://www.i-mak.org/pharma-patent-decisions/
[21] Yousuf A. Vawda, *After the Novartis Judgment - Evergreening Will Never be the Same Again!*, 18 LAW DEMOCRACY & DEV. 305 (2014).

uncertainty as to what constitutes a substantial enhancement in the efficacy has discouraged the innovators who are looking for the protection of their IP in India.

This uncertainty will have a substantial effect on the life cycle management techniques of the pharma companies. These companies always relied on the method of coming first to the market and then retaining the patent protection with the improved versions of the drugs. The rigid test for enhanced efficacy will discourage them to come to the Indian market. These companies invest so much capital for inventing new pharmaceutical drugs and then they try to recover the money which they have invested in the research and development of new drugs.

Scholars argue that the Indian policy of protecting the generic companies may harm India in the long run. This will directly affect the inflow of new medicines in the market and consequently, the Indian consumers will be affected.[22] These companies will have to shift their investments to other countries where the policies are more flexible. Therefore, there is a need to provide clarity on what constitutes enhanced efficacy.

Paul Herrling, the head of corporate research at Novartis, hoped before the judgment that the judgment will result in some clarity over section 3(d) of the Act. He told Reuters that "the patent for Glivec is not really the issue here...it is just an example of us wanting very clear legal clarity about what kind of innovation is patentable."[23] But the result was completely opposite and the Supreme Court chose to conclude that it is not necessary to come to a definite standard for enhanced efficacy which could be used in future cases. Rather the new cases will be judged on a case to case basis.

[22] Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J.L. & TECH. 198 (2010).
[23] *Novartis Argues for Glivec Patent at India's Top Court*, REUTERS, (Accessed on 2 April 2020), http://www.reuters.com/article/2012/09/1 1/us-india-novartis-glivec-idUSBRE88ABN20120911