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The Novartis Case: India's Gateway to Affordable Drugs

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ABSTRACT

Intellectual property falls under intangible form of property while a 'Patent' is a part of intellectual property. When a patent is granted it provides a statutory right given by the state to the inventor of the invention and to exclude others from using, making, or selling their invention for the duration which is limited by 20 years. The judgment given by the two-judge bench of the Hon'ble Supreme Court of India in the case of Novartis AG V. Union of India is one of the landmark judgments by the Supreme Court of India. Novartis made a patent application which was rejected by IPAB for Beta crystalline form of "Imatinib mesylate" later such challenge was rejected by the Supreme Court on the ground that the said drug did not produce an enhanced or superior therapeutic efficacy as compared to the known substance i.e., "Imatinib mesylate" which meant that the drug here did not involve an inventive step. In this case one of the major reasons for the rejection of the patent application of Novartis was to avoid ever-greening of already patented products by introducing minor changes.

I. INTRODUCTION

This decision emerged as a relief for millions of people all over the world to have access to medicines at low costs as well, thus preventing the vast pharmaceutical industries from "evergreening" their patents. However, the judgement can also be seen as a means to ensure the availability of life-saving drugs at a reasonable and affordable price to the people of India and elsewhere, also the decision defined the scope of Section 3(d) of the Indian Patents (Amendment) Act[2]. The Supreme Court, refused to grant Patent to Novartis stating that the drug in question here did not involve any kind of invention which can be patented under the Indian Laws.

The Article is further divided into 7 chapters which are as follows:

1. *Brief History of Patent Laws in India*

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[2] The Patents (Amendment) Act, 2005 (Act. 15 OF 2005)

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2. *Concept of Ever-greening of Patents*
3. *Brief Facts of the Case*
4. *Observation by the Madras High Court*
5. *Observation by the I.P.A.B (Intellectual Property Appellate Board)*
6. *Observation and Judgement by the Supreme Court*

II. Brief History of Patent Laws in India

Being a part of the Commonwealth, India took its intellectual property laws from the Great Britain. After gaining independence in 1947, there was a growing feeling that to give a boost tothe manufacturing restrictive product patents must be removed temporarily.India abolished product patents in 1970 by amending the Indian Patents Act but retains process patents with a reduced span of protection.

During the absence of any kind of product patent laws and regime, the Indian pharmaceutical industry grew at very a remarkable pace, ultimately becoming a net exporter.

However, in the 1990s, during the Uruguay Round negotiations of the World Trade Organization (WTO), India pledged to bring its patent legislation in tune with the TRIPS mandate in a phased manner. Later in 1999 India allowed for:

-transitional filing of product patent applications which had retrospective effect from 1995

-full product and process patent protection was brought again beginning in 2005 when all transitional regulations ended.

III. Concept of Ever-greening of Patents

"Ever-greening," is a practice where the pharmaceutical firms extend the patent life of any drug by gettingan additional 20-year of patents for a minor reformulation or change or iterations of the drug, without changing or increasing the therapeutic efficacy."Ever-greening," is referred to as the practice where the pharmaceutical firms extend the patent life of any drug by obtaining an additional 20-year of patents for a minor reformulation or other alteration or iterations of the drug, without necessarily increasing the therapeutic efficacy.

As described in the Indian Patent Act,1970[3] a patent is

> *"a grant or a right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it"*. According to the Oxford

[3]The Patents Act, 1970 (Act 39 of 1970)

Dictionary[4], it is defined as *"an official right to be the only person to make, use or sell a product or an invention"*

This monopoly right is given to someone only for a certain fixed number of years, after the expiry of this fixed duration this right is taken away from them and the product or the technology becomes easily accessible to any other person and he might not earn any more profit from his own creation.

In the Indian Patent Act, 1970 Chapter II, Section 3 deals with "what is not patentable". Sub-section(d) reads the following

> *"the mere discovery of a new form of a known substance or 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*".

This provision aims to prevent evergreening and protect genuine innovators and this was visible in the judgment of Novartis case which shows that there is a change in the development pattern of production and usage of technology. In earlier days India was just a consumer of the technology hence the laws then did not provide a strong protection to the intellectual property but India has now become a producer of technology and thusgives a stronger protection to intellectual property.

(A) IN CONTEXT TO THE NOVARTIS CASE:

In the year 2005 a condition was inserted in Section 3 (d)[5] of the Patent Act which was related to the efficacy of a drug, efficacy referred to the "therapeutic efficacy"while the alterations and changes in the "stability" or "physical characteristics" of the product were irrelevant. Novartis filed an application for a drug name *"GLEEVEC"* before the Chennai patent office which had a slight difference from the 1993 version patent for its "Anti Leukaemia drug".

But the Assistant Controller of Patent and design in Chennai Patent Office rejected the application under section 3(d) of the Patent Act. Novartis later prayed the Court for declaring section 3(d) of Patent (Amendment) Act 2005 in non-compliance with the TRIPS Agreement and in violation of Article 14 of the Constitution. The argument, which related to violation of Article 14 of the Constitution of India, was based on arbitrary discretionary power that was

[4]Definition of ***patent noun*** from the Oxford Advanced Learner's Dictionary, *available at*: https://www.oxfordlearnersdictionaries.com/definition/english/patent_1?q=patent (last visited on June 18, 2020).

[5] The Patents (Amendment) Act, 2005 (Act. 15 OF 2005)

vested in the Patent Controller in determination of enhanced efficacy.

The court said that here the motive of the patent system is to discourage the increasing of patent period of a patent beyond the expiration of the patent term of 20 years. This will enable other firms to produce and market the drug. The Court said that the Amendment was intended to:

1. Preventing ever-greening;
2. To provide easy access to the denizens of this country for life saving drugs; and
3. To discharge their constitutional obligation of providing health care to its citizens.

IV. Brief Facts Of The Case

Novartis International AG, one of the largest international pharmaceutical company filed an application as per the TRIPS agreement before the Chennai Indian patent office in 1998 for the granting of a patent for an anticancer drug known as 'Gleevec' which was used to treat *"Chronic Myeloid Leukaemia"* and *"Gastrointestinal Stromal Tumours"* , it was invented from Beta crystalline form of "Imatinib mesylate". This drug was used as cancer treatment drug and the patent for the same was granted in more than 35 countries.

As defined under section-5 of Patent Act, 1970the grant used to be restricted to methods or processes and not for products in India during the time Novartis filed its patent application. Afterthe Patent (Amendment) Act,[6]section-5 was repealed and then the patents came to be granted not only for methods or processes but also for products.

In 2005 patent application of Novartis for the drug Gleevec was taken into for consideration and the was rejected by the Madras Patent Office on the grounds that the drug was anticipated by prior publication and failed to satisfy the requirements of novelty and non-obviousness, further stating the alleged invention as an un-patentable invention under the provision of section-3(d) of Patent Act, 1970. The said drug did not exhibit any major changes in the therapeutic efficacy over its pre-existing form i.e. Zimmermann patent.

V. Observation by the Madras High Court

In the year of 2006Novartis filed two writ petitions in Madras High Court under Article-226 of Constitution of India. The first appeal stated that the section-3(d) of Patent Act, 1970 is unconstitutional because it does not comply with TRIPS agreement and also violates Article-14 of Constitution of India and the secondappeal was filed against the order passed by the

[6]*Ibid*

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Madras Patent Office.

The Madras High Court transferred the case to the IPAB (i.e. Intellectual Property Appellant Tribunal) in the year 2007.

The High Court observed the following:

> *"We state that in this case we have already found, analysing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent ever-greening; 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."*[7]

VI. Observation By The I.P.A.B (Intellectual Property Appellate Board)

The IPAB, however, held that the patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d)

The IPAB observed the following:

> *"Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of Page 11 inventive step in the law particularly for the drug/pharmaceutical substances."*

The Supreme Court in reference to I.P.A.B observed the following:

> *The IPAB also referred to the judgment of the Madras High Court, dismissing the appellant's writ petitions challenging the constitutional validity of section 3(d) where the High Court had observed: "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 the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."*[8]

VII. Observation and Judgement by the Supreme Court

The issues in the current case can be summarized with the following questions:

[7] Novartis AG Vs Union of India, W.P. Nos.24759 and 24760 of 2006
[8] Novartis AG Vs Union of India, CIVIL APPEAL Nos. 2706-2716 of 2013

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1. What according to the provision of section-3(d) of Patent Act, 1970 a known substance?
2. What according to section-3(d) of Patent Act, 1970 the meaning of Efficacy?
3. According to section-3(d) of Patent Act, 1970 whether increase in bioavailability qualify as increase in therapeutic efficacy?
4. Is the invention "Beta crystalline form of *"imatinib mesylate"* claimed by Novartis more efficacious than the substance that it was derived from i.e. *"Imatinib mesylate"*?

The Arguments presented in front of the Supreme Court were as follows:

(A) NOVARTIS

The legal team of Novartis was led by the Ex-Solicitor General of India Gopal Subramaniam and senior advocate T. R. Andhyarujina. Novartis attempted to patent imatinib mesylate in beta crystalline form instead of imatinib or imatinib mesylate, they sought to prevent extant literature on imatinib or imatinib mesylate from being considered as "prior art".

The spirit of the arguments by Novartis' legal team was two-fold:

The first argument was that the Zimmerman patents and the journal articles which were published by Zimmerman and others do not constitute prior art for the beta crystalline form as it is only one polymorph of imatinib mesylate, hence providing the required novelty and inventive step.

The second argument was that imatinib mesylate in beta crystalline form has "enhanced efficacy" over imatinib or imatinib mesylate required to pass the test of section 3(d).[9]

(B) RESPONDENTS

The respondents *(UNION OF INDIA & OTHERS)* were led by Additional Solicitor General of India Paras Kuhad.

Various arguments were brought before the court but the main focus was on proving that:

"Imatinib mesylate in beta crystalline form" is neither new (novel)nor is it non-obvious due to publications about imatinib mesylate in Cancer Research and Nature in 1996, disclosures in Zimmerman patents, disclosures to FDA and that the efficacy as referred in the section 3(d) should be interpreted as therapeutic efficacy and not just physical efficacy.

The respondents also quoted extensively from the Doha Declaration, they took excerpts from parliamentary debates, various petitions by NGOs, WHO, etc. to highlight the public policy

[9] *Ibid*

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dimension of the arguments relating to easy affordability and availability of life saving drugs.

(C) THE SUPREME COURT OBSERVED THE FOLLOWING:

The Apex Court observed that the product was not a new substance but a new form of the existing substance and it had always existed in the original amorphous form.

Thus, the product has to qualify the test which is laid down in Section 3(d) of Patent Act, the section blatantlymentions that a "new form" of a known substance in not patentable under Indian law until it enhances its "known efficacy".

Supreme Court also ruled that about 30% increase in bioavailability qualifies as increase in therapeutic efficacy under section-3(d) of Patent Act, 1970 if proper evidence is provided for the same.

The Court made comparison between the efficacy of "Beta Crystalline form of Imatinib Mesylate" and "Imatinib Mesylate" with reference to its

-flow properties,

-better thermodynamic stability and

-lower hygroscopicity

The Court stated that in case of medicines, the term efficacy refers to "therapeutic efficacy" and these properties (i.e. the physio-chemical properties of the polymorph form of the imatinib molecule) while they may be beneficial to several patients do not meet this standard, also Novartis did not provide any document which proves that the efficacy of "Beta Crystalline form of Imatinib Mesylate" is better or enhanced when compared to the efficacy of "Imatinib Mesylate".

The Supreme Court held that the true intention to enact section 3(d) was to prevent the concept of ever-greening of patents and thus a patent cannot be granted to an invention if it does not fulfil the test as laid down by the Section 3(d). The Supreme Court also specified that this case should not be interpreted to mean that the Section 3(d) "bars all incremental inventions". The court further said that in cases of life-saving drugs as the one in the present case"a great acre and caution needs to be taken so as to protect the right to life of the masses".

"We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was

amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment. 192. Section 2(1)(j) defines "invention" to mean, "a new product or …", but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind"1. However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is 1 The New Oxford Dictionary of English Edition 1998 Page 96 claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation. 193. Coming back to the case of the appellant, there is yet another angle to the matter. It is seen above that in the US the drug Gleevec came to the market in 2001. It is beyond doubt that what was marketed then was Imatinib Mesylate and not the subject product, Imatinib Mesylate in beta crystal form. It is also seen above that even while the appellant's application for grant of patent lay in the "mailbox" awaiting amendments in the law of patent in India, the appellant was granted Exclusive Marketing Rights on November 10, 2003, following which Gleevec was marketed in India as well. On its package1, the drug was described as "Imatinib Mesylate Tablets 100 mg" and it was further stated that "each film coated tablet contains: 100 mg Imatinib (as Mesylate)". On the package there is no reference at all to Imatinib Mesylate in beta crystalline form. What appears, therefore, is that what was sold as Gleevec was Imatinib Mesylate and not the subject product, the beta crystalline form of Imatinib Mesylate. 194. If that be so, then the case of the appellant appears in rather poor light and the claim for patent for beta crystalline form of Imatinib Mesylate would only appear as an attempt to obtain patent for Imatinib Mesylate, which would otherwise not be permissible in this country. 195. In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost."[10]

VIII. Conclusion

The SC judgement came as a huge relief for those people who could not afford the necessary lifesaving drugs produced by these big pharma giants at high prices. These companies made

[10] *Ibid*

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billions of dollars every year and prevented the common people from purchasing the drugs at low price thus risking and endangering the very life of the poor people by acquiring patents over their drugs. The importance of patent is not in question and it cannot be denied to prevent a new invention, provided such invention is available to all the individuals at reasonable rates. On the other hand, companies like Novartis are putting the life of these poor people at stake by obtaining a monopoly over these kinds of life-saving drugs.

The Supreme Court made it clear that India is a developing country and medicines should be available at an affordable price to safeguard the lives of billions of people. The Supreme Court is thus justified and reasonable in its decision thereby prohibiting the liberal approach in granting patents and granting patents only to genuine inventions as against frivolous inventions.

The judgement garnered widespread support from international organisations and advocacy groups like Médecins Sans Frontières,WHO, etc, the decision against evergreening of pharmaceutical patents was welcomed internationally.

The judgement also faced some criticism, Ranjit Shahani, the then vice-chairman and managing director of Novartis India Ltd, told the reporters in Mumbai that the pharmaceutical company would continue to introduce new products in the nation but would shift its Research and Development investments to "favourable destinations".[11]Chip Davis, the executive vice president of advocacy at the Pharmaceutical Research and Manufacturers of America was quoted by The New York Timessaying:

"It really is in our view another example of what I would characterize as a deteriorating innovation environment in India," said, the industry trade group. "The Indian government and the Indian courts have come down on the side that doesn't recognize the value of innovation and the value of strong intellectual property, which we believe is essential."[12]

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[11]Shift in Novartis strategy, *available at*: https://www.telegraphindia.com/business/shift-in-novartis-strategy/cid/1549637#.UV3-TcV49_M (last visited on June 18,2020)
[12]Low-Cost Drugs in Poor Nations Get a Lift in Indian Court, *available at*: https://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?ref=world (last visited on June 18,2020)

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