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PATENT OR NOT TO PATENT NOVARTIS CASE STUDY IN INDIA

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ABSTRACT

In a limited area, the exclusive right given to the author for invention is classified as a patent for a set period of time. Glivec (imatini mesylate), founded by Novartis pharmaceutical company, is recommended for the chronic myeloid leukemia, one of the most common blood cancers in Eastern countries. On 1 April 2013, the Indian Supreme Court released its final judgment rejecting the appeal of the Swiss giant drug maker after more than ample legal infringement concerning their patentability.For the first time in 2006, this same Indian Patent Office rejected Glivec 's patent under Section 3(d) of the Indian Patent Act, saying it was merely a twistable copy of an existing drug, Imatinib. Novartis has responded to the Indian government by lodging legal challenges, but the final verdict ends the battle in April 2013. Indeed, although the bioavailability of the drug has grown, the High Court has argued that it has not shown improving efficiency and Glivec is not patentable

1. Introduction

IP is an intrinsical form of ownership, since an intellectual property monopoly is only an intrinsic feature. In order to prohibit any person from developing, using or selling their creation for a fixed period of 20 years, the inventor of that invention is granted the patent as a statutory right of the State. One of the most important decisions in India is the judgment including its Supreme Court of India's two judges in Novartis AG V. Union of India. In this case Novartis demanded that IPAB 's Beta Crystalline be refused."Imatinib mesylate" patent application whereby, on the grounds of either the drug is not more or better

functional than the present product, "imatinib mesylate," it was denied by the Supreme Court of India on the ground that there is not an revolutionary method. No greater or higher therapy capacity was expected on the computer. Two of the key reasons why the patent application was not approved by Novartis was to prevent seeds and minor improvements to proprietary technologies..

Facts:

One of the largest pharmaceutical companies founded in 1998, namely The application for a Glyvec patent for anticancer medication found in chronic myeloid leukemia (CML) and gastrointestinal current Tumors (GIST) discovered in beta crystalline form 'Imatinib mesylate' has been submitted by Novartis International AG to that Chennai Indian Patent office in compliance with the TRIPS agreement and was confined to a methodological award. Under the Act on Patents, Section-5 of 2005 has been amended and patents for methods or processes, but rather for products have been issued.

Novartis' patent application for Glivec drug in 2005 was rejected in accordance with Madras Patent Offic 's rationale that it was anticipated to be released in advance, and that the drug failed to meet the novelty and non-obviousness requirements. In other words, as the drug has demonstrated no substantial changes in therapeutic efficacy compared with its preexisting existence, the supposed discovery wasn't really patentable in the sense of section-3(d) of the Patent Law, 1970. Zimmermann's patented.

In the 2006 Madras High Court in compliance with Article-226 of the Indian Constitution, Novartis secured separate petitions in writing. The appeals therefore requested the paragraph 3(d) of the.

After that Novartis filed SLP (Special Leave Petition) against an order issued by IPAB under Article-136 of the Constitution of India in 2009 before the Supreme Court of India.

2. **Discussion**

1. Background*:*

India is listed as the third largest pharmaceutical industry in the world and the 14th largest. It was driven by a group of seventes of pharmaceutical markets that are expected to contribute to about 50% of the yearly growth of the pharmaceutical industry in 2013 and also named "pharmerization nations," including China, Brezil, and Russia. According to research firm IMS Health, revenues in these emerging markets will rise by 30% in overall pharmaceutical spending in 2016. In India, sales of pharmaceutical drugs are projected to rise to 74 billion dollars by 2020—more than six times in 2010. by 2010.Yet in a country where almost "70 percent of its citizens live for less than $2 a day and just 5 percent access to privacy, increasing the access to medical care is a key concern in the light of its booming pharmaceutical industry. The Indian pharmaceutical industry, which accounts for up to 90% of medication sales, is dominated by generic drug manufacturers. "India has even more facility to produce pharmaceutical drugs licensed by the United States than any country from outside United States," per the Yusuf Hamied, Chairman of the American Indian drug manufacturer CIPLA.

India is known as the "industrial world pharmacy" by many to be a leading manufacturer of generic drugs in many developing countries with some of its ability to produce large quantities at cheap, affordable prices. Indian HIV / AIDS development has, for instance, contributing to dramatically reduce the cost of care from $10,000 a year in 2000 to $150 average annual today (a combination of stavudine, lamivudine and nevirapine). India now offers HIV / AIDS care for 80% of the 6 million population in the developing world. India is currently the "second largest manufacturer of UNICEF-supplied medicines in the developing world.

"India and trips agreement:

Therefore, the 'implementation of drastically improved pharmaceutical patent rights' in India on 1 January 2005 has now become patentable. Medicines are being patented. The India Times accused the Government of selling to "fast" multinational corporations and charging public seals despite India's contributions to the TRIPS agreement. Many detractors argued that amendments in pharmaceutical law and regulation would turn India into a major producer, rather than a major contributor in the industry if India was completely compliant by 2006, as required under WTO agreements. A former leader of the local union for the drug companies commented in response;"

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2. Issues*:*

1What is a known material in compliance with section 3(d) of the Patent Act of 1970?

2. What does effectiveness mean under section-3(d) of the Patent Act 1970?

3. Under Section-3(d) of the Patent Act of 1970 if bioavailability improvements are listed as an improvement in therapeutic effectiveness?

4. Which is stronger than the material it came from, for example 'immatinib mesylate' discovery 'Beta crystalline imatinib mesylate' claimed by Novartis?

3. Judgement:

In April 2013, the five judge bench of the Supreme Court of India dismissed the case of Novartis and found the beta-crystalline form of Imatinib Mesylate

to be a distinct variant of both the current medication, i.e. Imatinib Mesylate, which has a strong strength. Within case of 'Effectiveness' drugs in section 3(d), the Supreme Cour found it extremely clear. quality and design' and states that all of the drug's properties are irrelevant, their quality and design is the attributes that lead in particular to drug effectiveness. The third issue was that, according to section-3(d) of the 1970 Patente Act, improving bioavailability by about 30 percent was seen by the Supreme Court as increasing medicinal strength. In terms of delivery properties, strengthened entropy stability and lower hygroscopicity, "beta Crystallina Imatinib Mesilate" was distinguished by the Supreme Court.".

4. Perspective of government of India:

It is claimed by the Indian Government that the Glivec Patent Application from Novartis should be refused, as the enhanced drug design does not exemplify the substantial progress in clinical effectiveness in its previous kind. The selection with salt for the active ingredient to enhance bioavailability is infamous in the pharmacy arts. Patent laws and regulations contain certain requirements, such as Article 3(d), which prohibit this form of operation to ensure public access to medical care.

India also argued that its actions were appropriate as in Doha Resolution on the TRIPS Accord and Public Health 2001. This section states that, as well as protecting public health, the TRIPS Agreement should constantly be implemented, and particularly encourage availability for all to medicines, in line with WTO members' interests. Though not explicitly stated in TRIPS Section 3(d) of both the Indian Patent Act, the Republic of the Indians and its supporters shall enforce their patent laws in compliance with global health interests. Instead of the claim made by Novartis legal leaders, Indian patent laws are also legally applicable.In comparison, imatinib mesylates are 30% more bioavailable yet stable when processing. These developments led to the approval also in United States of America of a native born patent in 2001. Specifically, Novartis claimed that the 'Indian patent laws would differ, in order to protect the innovation, from substitute prescription medicine to proprietary products.

5. Novartis' perspective:

Paragraph 3(d) of the Indian Patents Act, according to Novartis, shouldn't have even extended to Glivec at all. The business claims that imatinib was the original propritary form of the medication and could not be provided to patients as just the first step in the development of the current product. This could only become a suitable option by rendering the remedy in its current shape of salt, imatinib mesylate. Novartis scientists quote this new strategy, which allows people to access the medicine "for a simple , easy, and water saving pill."Imatinib mesylate is, in contrast, 30% more bioavailable but more robust during processing These developments led to the award of a second-generation patent in 2001 in the United States of America. Novartis specifically claimed that 'Indian patent laws will vary from the variant in prescription medicines to

patented products.' The company has secured a patent upon this original molecule to safeguard the invention.India could also easily undermine the very process which contributes to the generation of new life-saving drugs for those living who need it by refusing a patent from Glivec.

Moreover, Novartis was against the decision of nepal once again to deny its trademark registration for Glivec but also challenged the validity of paragraph 3(d) according to the TRIPS Agreement. Article 25 of the TRIPS, which "within new technologies, usually includes patentability, comprises an inventive process or is not evident and worthy (or useful) of industrial application." Novartis argues that, due to its better bioavailability, imatinib mesylate was indeed a "inventive step" in the drug discovery cycle. Naturally, the Kyoto protocol is abstract but does not explicitly define what it entails.Nonetheless, under TRIPS, India is technically able to display regional socio-economic parameters. Novartis, by contrast, rejected the suggestion that poor patents as those in India could continue to stifle pharmaceutical innovation. The research and development process is long and expensive, according to Novartis and other pharmaceutical companies, and a secure system that protects intellectual property rights is necessary for businesses to recover. According to Novartis, the accessibility for people in India and also the third countries to new lifesaving drugs depends on patent protection. India could also easily undermine the very process which contributes to the generation of new life-saving drugs for those living who need it by refusing a patent from Glivec.

6. Implications of India’s supreme court rejection of novartis’ appeal:

The Novartis litigation began in 1998 that whenever a patent claim being filed by the corporation and rejected in 2006. Only in April of 2013, when Glivec ruled that beta-crystalline material is not patentable was a final decision given by the Supreme Court of India. In this instance , the court held that "the therapeutic efficacy has to be enhanced in order to qualify an effective drug beyond inclusion of Section 3(d). Section 3(d) of the Indian Patent Act, which stipulating minor changes in existing molecules will not be deemed suitable for further trademark security, was necessary." The decision to suspend the Novartis patent 'has global significance as India's generic market in pharmaceutics estimates at around US$ 26 billion provides the majority of cheaper medicines in the third countries' It shows how the government's case "confirms the right of the Indian Parliament to extend community health protections provided by the TRIPS Convention."In that case it is appropriate to obey Section 3(d)-like law in both Argentina and the Philippines. This Decision was "no standard" as "patents on scientific breakthroughs will be given from now on and repeated patents will not be granted for minor modification to the existing model" said Pratibha Singh, Indian Brand Management lawyer for Cipla.

3. Conclusion

The decision of the Hon'ble Court is to prohibit the continued use of patented medicinal drugs and to give relief to those who can not afford expensive the lifesaving medicinal drug, as these pharmaceutical firms sell such lifesaving medicines to the very high prices and are not affordable and for common citizen. It was stated in its judgment by the Supreme Court that India is a developing country, which is essential to the lives of one billion people for the provision of accessible drugs. Section 3(d) of the Patent Act of 1970 forbids a secondary patent from requiring slight changes to existing technology for certain large pharmaceutical enterprises.Novartis has had difficulties in demonstrating that "Imatinib Mesylate's Beta Crystalline Form" 's therapeutic effectiveness is more close to "Imatinib Mesylate's therapeutical effect."

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