Jus Corpus Law Journal
Open Access Law Journal – Copyright © 2022 – ISSN 2582-7820
Editor-in-Chief – Prof. (Dr.) Rhishikesh Dave; Publisher – Ayush Pandey

Case Comment: Novartis vs Union of India

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Received 15 July 2022; *Accepted* 03 August 2022; *Published* 05 August 2022

INTRODUCTION

The present case analysis is a landmark judgement given by the apex court of India where the court prevented the pharmaceutical industries from patenting lifesaving drugs. The court also highlighted the scope and nature of ***Section 3(d)[1] of the Patents Amendment Act, 2005***. It emphasized on the meaning of "enhanced efficacy" and how a product or invention shall comply with these rules laid down in Section 3(d). The court also helped those millions of poor people who could not originally afford these lifesaving drugs if these were patented by these big companies like "Novartis" and helped them by providing such drugs at an affordable price.

Novartis AG v Union of India[2] is one of the most prominent cases of the Supreme Court of India and the judgment given by the Hon'ble Court was one of the landmark judgments. This judgment acted as a relief for so many people in the world as after this judgment people were able to get access to medicines at a very low cost. This judgment restrained the pharmaceutical industries from "evergreening" their patent rights. This judgment not only defined the scope of

[1] Patents (Amendment) Act, 2005, s 3(d)
[2] *Novartis AG v Union of India* (2013) 6 SCC 1

Section-3(d) of the Patents Amendment Act but it also ensured that the people in India get these lifesaving Drugs at a reasonable and affordable "price".

FACTS MATRIX

In 1977, "Novartis" filed an application to grant a patent to a drug "Glivec" which is an anti-cancer drug used to treat "Chronic Myeloid Leukemia"(CML) and "Gastrointestinal Stromal Tumors" (GIST). It filed such an application claiming that it invented the "Beta crystalline salt form" which is a critical drug and has been patented in 35 countries of the world. India at that time did not have any provisions relating to granting of patents for products with medicinal value. In 2005 with the amendment in the Patent act, these pharmaceutical products mainly 'Drugs' became eligible to be subjected to patent.

In 2006, "Novartis" again filed an application where the Patent Office of Madras declined the patent for the drug "Glivec" as there was no big difference or change in the drug by the discovery of "Novartis" which has not been already patented in other different countries of the world. This decision was supported by section-3(d), there could not be found any new or 'enhanced efficacy' and hence, the drug was not capable of getting the patent under the said section. In 2006, when the application was rejected by the Madras Patent office, "Novartis" wrote two writ petitions to the Madras High Court under *Article226*[3] of the Constitution, appealing against the order of the Madras Patent Office and claiming that the *Section 3(d)*, on the grounds of which the application was rejected, are not in compliance with the rules of trade related aspects of intellectual property rights and also that the section is vague and arbitrary and violates our Article-14[4] of the Constitution which is "Equality before the Law".

The Madras High Court also rejected the writ petition on the grounds of incompetency of the court to decide the such issue relating to the compliance of Indian (domestic) law with Trade-related Aspects of Intellectual Property Rights. Further, it said that the motive behind amending the patent act was to help people to get access to lifesaving drugs with much ease, and hence,

[3] Constitution of India, 1950, art.226
[4] Constitution of India, 1950, art.14

the amendment and section-3 (d) cannot be called vague or violating Article-14 of our Constitution or arbitrary. This led to a discussion in the board (Intellectual property appellate board) which recognized the discovery as "a new and inventive discovery" but refused to grant the patent because it was in contradiction to section 3 (d) of the act. In the end, "Novartis" challenged the High court order in the Supreme Court of India by filing a Special Leave Petition (SLP).

ISSUES RAISED BEFORE THE HON'BLE COURT

There were three main issues raised:

1. Firstly, whether or not the Invention is inconsistent with section 3 (d)of the patent act?
2. Secondly, what is the interpretation of Section-3 (d) of the said act?
3. Thirdly, whether or not said invention qualifies to be "enhanced efficacy" for the alleged product?

THE COURT'S OBSERVATION

The Hon'ble Supreme Court said that "the product was one of the new forms of the substance and not a new substance. It has always existed in its original amorphous form. The product thus has to qualify for the test laid down in section 3 (d) of the Patent act. The court also observed that section-3 (d) specifically mentions that a new form of the substance is not patentable under the Indian law unless it qualifies to be enhancing its known efficacy". 'Novartis' further contended that the properties of the alleged product better the stability and lowers hygroscopicity which in turn increased or improved the efficacy and hence shall be patentable. This argument was further rejected by the apex court of India and the court stated that in the case of pharmaceuticals or in simple words life saving drugs which act as medicines, efficacy means "therapeutic efficacy" and these properties shall be beneficial to the patients which in the case of this is not beneficial to the patients and hence, is not efficacy and patentable.

JUDGMENT

The Supreme Court decided the matter by considering the facts and the law and analyzed that as raised by the appellant that in the "Zimmerman patent" there was no new discovery yet it was granted the patent permission, it did not even qualify the invention test laid down under sections- 2(1) (j) and 2(1) (ja)[5] of the patents act. The court said that "for the sake of argument, it may be accepted that the alleged product is a new invention as compared to the Zimmerman patent but that issue is not to be raised now". The court further observed that when we apply section-3(d), the word efficacy has to be interpreted as **"therapeutic efficacy"** because the matter concerns medical value. The court said that the physical value has increased and it might as well produce enhanced efficacy but still it does not qualify for the test. Thus, the Indian Supreme Court held that "under Indian Patent Act for granting of pharmaceutical patents there shall be inventive steps and application apart from proving the traditional tests of novelty and there is a new test of 'enhanced therapeutic efficacy' for claims that cover incremental changes to existing drugs."

The Court said that the major drawback was that the application was filed when the patent law was going through major changes, especially with regard to striking Section 5[6], which had barred product patents, and adding section 3(d), for which there was no case law yet. The Court also stated the decision was intended to be narrow: "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."

CONCLUSION

The Supreme Court Judgment gave relief to people in the whole world who were not able to afford these medicines or we can say lifesaving drugs manufactured by these huge industries. These companies had already dominated the market in order to earn millions and billions of

[5] Patents (Amendment) Act, 2005, ss 2(1) (j) and 2(1) (ja)
[6] Patents (Amendment) Act, 2005, s 5

dollars ignoring the fact that the sole purpose of this manufacturing is to save people's lives. The court further realized that giving patents to these industries would endanger the lives of the people in the country, especially the poor ones who are unable to buy these costly and overpriced drugs or medicines. The motive behind providing patents is to prevent new inventions when there is already a similar invention available at a reasonable rate to citizens but by providing patents to these lifesaving drugs would not do any good to the citizens of the country mainly the poorer sections of society. The court took this decision by keeping in mind that there is a very huge population in India most of which are mainly poor who can't afford high price medicines to keep the price low, the government had to take steps and the court hence refused the patent to 'Novartis'.