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Novartis AG v. Union of India: An Analysis of Section 3(d)

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ABSTRACT

The patent Act 1970 does not explain what inventions are; rather, it outlines what are not inventions. Section 3 of the Act provides for various situations where the invention cannot be patentable. It provides for about 15 kinds of inventions that cannot be patentable. One such is 'mere discovery of a new form of known substance envisaged under clause (d) of section 3. It says that mere discovery of a new form of a known substance that does not result in enhancement of known efficacy of that substance cannot be patentable. However, there was no clarity to the term's 'efficacy', 'enhancement' and 'known-substance.

Novartis AG v. Union of India is a landmark case of Supreme Court concerning section 3(d) of Patents Act, 1970. It is a case where the beta-crystalline form of the known substance 'Imatinib Mesylate' was in question as to whether it constitutes a new invention and can be patentable. It played a significant role in analysing section 3(d) and discussed the meaning of the term's 'efficacy' and what constitutes 'enhancement of efficacy' of a known substance. Through the analysis of this case, we can under the rationale taken by the supreme court behind rejecting the patent.

Keywords: *Efficacy, Enhancement, known substance, Patent, Section 3(d)*

I. TITLE

Novartis AG V. Union of India

Civil Appeal Nos. 2706-2716 of 2013

II. BENCH AND QUORUM

- In the Supreme Court of India
- Justice Aftab Alam, Justice Ranjana Prakash Desai
- Division Bench

III. PROCEDURAL HISTORY OF THE CASE

Novartis filed for a patent for its original drug 'Imatinib' and was granted a patent by the United States Patent and Trademark Office (USPTO) in 1992. It also received United States Food and Drug Administration (FDA) approval for one of the salt forms of 'Imatinib' known as 'Imatinib Mesylate', which is a solution in the human body, unlike the original form. Also, in 1997 Novartis claimed a patent for 'beta crystalline form which

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enabled oral administration of Imatinib mesylate and was granted a patent by USPTO. On July 17, 1998, it claimed a patent for Imatinib Mesylate in crystalline beta form at Chennai Patent Office in India but was refused patent under section 3(d) of the Indian Patent Act, 1970 as the mere discovery of known substance without an increase in efficacy is not patentable. Novartis filed two writ petitions before madras court challenging the validity of section 3(d) and raising substantial merits of decisions of Patent Officer; the high court upheld the constitutionality of the section but transferred the case to Intellectual Property Appellate Board (IPAB). On June 26, 2009, the IPAB held that patent could not be granted as section 3(d) required a higher standard of inventive step. Aggrieved by order of IPAB, Novartis, through Article 136 of the Constitution, came before Supreme Court.

IV. FACTS OF THE CASE

One of the largest pharmaceutical companies, Novartis AG, applied for a grant of a patent for their anti-cancer drug called 'Glivec' used to treat Chronic Myeloid Leukemia (CML), and Gastrointestinal Stromal Tumors (GIST)[2] invented through 'beta crystalline form' of original free base Imatinib Mesylate. It was granted a patent in the US Patent and Trademark office for both original free base and crystalline beta form of 'imatinib Mesylate'. When Novartis filed for a patent for a crystalline beta form of the original form in India, there were five pre-grant oppositions filed by a few NGO's and Public health groups having an interest in anti-cancer drugs on the ground that 'beta crystalline form' of the salt Imatinib Mesylate is not a new invention but mere discovery of known substance. The patent was rejected on the ground of anticipation, non-obviousness, not an invention under section 3(d) and having wrongful priority. Novartis challenged the Constitutional validity of section 3(d) and said that it violated Article 14 of the constitution and TRIPS agreement.

V. ISSUES OF THE CASE

1. Whether Section 3(d) is violative of the TRIPS agreement?
2. Whether Section 3(d) is unconstitutional as it is vague, arbitrary and violative of Article 14 of the Constitution?
3. Whether the crystalline beta form of Imatinib Mesylate is more efficient than the original form of Imatinib Mesylate?
4. What is the meaning of 'known - substance' and 'Enhancement of efficacy' according to section 3(d) of the Patent Act, 1970?

VI. ARGUMENTS

Arguments by Appellant:

The learned counsel for the petitioner argued that the amended section was in contravention with the TRIPS agreement as India being a member country, violated its obligation under the TRIPS agreement. The right to have an invention

[2] Anamika Tiwari, Efficacy in Pharmaceutical Products : Novartis AG vs Union Of India , Indian Review of Advanced Legal Search. Available: https://www.iralr.in/post/efficacy-in-pharmaceutical-products-novartis-ag-v-union-of-india.[2022, January 12]

patentable under TRIPS was taken away from the petitioner. They also argued that the amended section was violative of Article 14 of the Constitution of India as it was vague and arbitrary. It gave arbitrary powers to the controller general of a patent in deciding as to what is 'enhancement of efficacy'. Such discretion was given to statutory authority without any regulatory guidelines making it violative of Article 14.

According to Appellant, the beta crystal form of Imatinib Mesylate has more beneficial flow properties, better thermodynamic stability and lower hygroscopicity than the alpha crystal form of Imatinib Mesylate.[3] He says that the aforesaid benefits make the product new and superior.

Learned counsel for the petitioner also argued that section 3(d) is ex-major cautela which ensures that mere discovery would not come under the term ‘invention’. The main purpose of this section is to prevent ‘evergreening,’ i.e., "a mere discovery of a new form of a known substance". According to them, the beta crystal form of Imatinib Mesylate meets the requirements of novelty and inventive step under clauses (j) and (ja) of Section 2(1). About Zimmermann Patent, the petitioners contended that the examples in Zimmermann Patent do not teach a skilled person to select a particular salt and that Imatinib Mesylate from a free base was the result of the invention and not just a mere discovery of existing knowledge. Appellants contended that neither Imatinib nor Imatinib Mesylate had any ‘known efficacy’, so there was no question of showing that the crystalline beta form of Imatinib Mesylate had any enhanced efficacy over Imatinib or Imatinib Mesylate.

Appellant stated that Imatinib in its free base is an active therapeutic ingredient, and its administration in solid form would be insoluble, having no therapeutic effect, whereas the crystalline beta form has definite and enhanced efficacy over the free base.

Arguments By Respondents:

The respondents argued that the amended section is not violative of TRIPS. Even if it is considered violative, Indian courts do not have jurisdiction to try the case as there is a separate body called dispute settlement body constituted under TRIPS who has the authority as well as a jurisdiction to hear all disputes arising concerning the TRIPS. The learned counsels representing Respondents argued that the TRIPS agreement along with the Doha declaration was flexible, which enabled member states to control the patent rights and to avoid adverse effects on public health.

As to the question of vagueness and arbitrariness, the counsels argued that the petitioner is expertise in the pharmaceutical field and has the knowledge of what constitutes 'enhancement of efficacy'. Also, they argued that if the petitioner feels that the decision taken by the controller general of a patent is unreasonable, then they have the remedy to go for an appeal, but they cannot strike down to amended section as unconstitutional.

They argued that in the field of pharmaceuticals, efficacy has a well-known meaning and refers to

[3] Novartis AG v. Union of India , SC 2013.

the capacity of the drug to produce an effect. Bioavailability does not demonstrate enhancement of efficacy.

VII. LAWS APPLIED

- TRIPS, 1995– Agreement on Trade-Related Aspects of Intellectual Property Rights
- Constitution of India, 1950.

Article 14 – Equality before law The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India Prohibition of discrimination on the grounds of religion, race, caste, sex or place of birth.

- Indian Patent Act, 1970

Section 2(1) - (j) "invention" means a new product or process involving an inventive step and capable of industrial application;

(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both, and that makes the invention not obvious to a person skilled in the art;

Section 3- (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 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 significantly in properties concerning efficacy;

VIII. JUDGEMENT

The TRIPS Agreement is the most comprehensive multilateral agreement to set detailed minimum standards for the protection and enforcement of intellectual property rights and aims at harmonising national intellectual property systems.[4] Amendments were required to be made in the patent law to make it fully compliant with the TRIPS Agreement.

It is seen that Imatinib Mesylate is a known substance with known efficacy from the Zimmermann Patent, and while granting patent by USPTO it was said that the drug has undergone extensive clinical research and was capable of multiple-dose tolerability and also in the treatment of Ph+ leukaemias. Hence, efficacy was evident. However, concerning the crystalline beta form of Imatinib Mesylate, it is seen that all of its therapeutic qualities can be found in the original salt base.

Efficacy means “the ability to produce a desired or intended result”. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In the case of medicine, the test of efficacy would only mean ‘therapeutic efficacy, which must be judged strictly and narrowly. The wordings in

[4] Novartis AG v. Union of India, SC 2013.

section 3(d), 'enhancement of efficacy', requires the derivative to be significantly different in properties concerning efficacy. Unless it differs significantly in property concerning the efficacy, it won't be qualified for a new invention. A mere change of properties would not amount to 'enhancement of efficacy'. Hence, the crystalline beta form of imatinib mesylate does not satisfy the test of section 3(d).

On the other hand, section 2(1) (j) defines invention, but it does not necessarily mean a completely new product in chemical properties. Here, the subject matter for the patent was Imatinib Mesylate and not crystalline beta form, and hence it was not a new invention under (ja) (j) of section 2(1).

IX. RATIONALE

Evergreening of already patented products with minor changes cannot be patentable. This ensures the originality of the patent.

X. CONCURRING AND DISSENT

There was no dissenting opinion in this case.

XI. CRITICAL ANALYSIS

Novartis AG v. Union of India is a landmark Judgement given by the divisional bench of Supreme Court regarding section 3(d) of Patents Act, 1970. A patent is a subset of Intellectual Property and is treated as intangible property and plays a vital role. In this case, Novartis filed for a patent of a crystalline beta form of Imatinib Mesylate in India and was rejected by the High court of Madras as well as the Intellectual Property Appellate Board. When they approached the Supreme court by special leave petition, the case was rejected on the ground that the drug did not have enhancement of efficacy and did not provide a therapeutic effect different from its free base.

Section 3(d) says 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 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. [5] The main purpose of this section was to prevent 'evergreening' of already patented products with minor changes.

Earlier to this judgement, there were questions relating to what is an enhancement of efficacy and what constitutes therapeutic effect. The Supreme court has played a very significant role in analysing section 3(d) of the Patents Act, 1970 and gave a strict and narrow meaning to these terms. According to them, enhancement of efficacy means producing a superior result than the known substance. Here, Imatinib Mesylate is a known substance from Zimmermann Patent

and the beta crystalline form did not possess superior therapeutic qualities than the free base of Imatinib and therefore it was not granted patent.

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[5] Section 3d of Patent Act, 1970.