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Novartis AG v. Union of India: A Landmark Judgment Against Patent Evergreening

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Meta Description: Novartis judgment and its principles, sec 3(d), preventing patents from evergreening in India

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- therapeutic efficacy
- Evergreening
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- Invention

Introduction

The decision of the Supreme Court in Novartis AG v. Union of India is often seen as one of the more important judgments in Indian patent law, kinda generally speaking. This case was about how Section 3(d) of the Patents Act, 1970 should be understood, and also about when pharmaceutical inventions can be patented. It came out of Novartis AG's request for patent protection for the beta crystalline form of Imatinib Mesylate, which is a medication used in

cancer treatment. The judgment matters because it basically clarified what “enhanced therapeutic efficacy” means within Section 3(d), and it also touched the ongoing worries about patent evergreening in the pharma industry. With this ruling, the Supreme Court set out key yardsticks and guidelines on the patentability of new forms of already-known substances and the kinds of proof that are expected if someone wants patent protection in India. In this article, I will go through the case background, the questions before the Court, what the Court ultimately held, and the main principles it laid down in the Novartis matter, and then look at how that decision has influenced Indian patent jurisprudence.

1. Facts of the Case

- Novartis AG, a Swiss pharmaceutical firm, had this drug called Imatinib Mesylate. Now the thing is, the base compound Imatinib was already known, and in 1993 it was patented in some countries too. Then India, in 2005, amended its patent law so it could match the TRIPS Agreement, basically letting product patents for pharmaceuticals go through. After that, Novartis submitted an application in India, not for the whole compound in general, but specifically for the beta crystalline form of Imatinib Mesylate. But the Indian Patent Office rejected it under Section 3(d) of the Patents Act, 1970. They said, sort of, that this was just a new form of a known substance, and also that it had not shown any stronger “therapeutic efficacy”, or any improved medicinal effect, whatever phrasing you want. So Novartis fought back, first by challenging the refusal before the Madras High Court, then also questioning whether Section 3(d) itself was constitutionally valid. Later on, the matter was appealed up to the Supreme Court of India. And eventually the whole dispute landed at the Supreme Court.
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2. Issues Before the Supreme Court

- 1: Whether the beta crystalline form of Imatinib Mesylate qualifies as an “invention” under Section 2(1)(j) of the Patents Act.
- 2: Whether the claimed invention is hit by Section 3(d) of the Patents Act, 1970.

Section 3(d) states that:

A new form of a known substance is not patentable unless it results in enhancement of known efficacy.

So, the core legal question was:

Does the beta crystalline form of Imatinib Mesylate show “enhanced therapeutic efficacy” over the known substance?

3.What is the meaning of the term “efficacy” under Section 3(d)?

Findings from Supreme court Judgement

Patents Claim for patent for beta crystalline form of Imatinib Mesylate-The beta form gave some beneficial properties like more beneficial flow properties, better thermodynamic stability and lower hygroscopicity than alpha form- Novartis made application for EMR (Exclusive Marketing Rights) on March 27, 2002 and was granted in Nov 10, 2003-Five pre-grant oppositions filed before the application was taken up for prosecution-Patent rejected on four grounds: anticipation, non-obviousness, not an invention under section 3(d) and wrongful priority-IPAB dismissed the appeal on June 26, 2009 and reversed all the findings of the Controller except the one on section 3(d) Novartis did not appeal to the Supreme Court for the writ petitions challenging the constitutional vires of section 3(d)Only the appeal over the substantive merit of the case from the IPAB was continued Held, any attempt to challenge

the IPAB order directly before the Supreme Court side-stepping the High Court needs to be strongly discouraged and this case cannot be treated as a precedent (para 22) Distinction between "invention" and "patentability" as two distinctly separate concepts (para 91) Appellant argued that section 3(d) is not meant to be an exception to clauses (j) and (ja) of section 2(1)-

It has no application to the case of the subject product-The product having been classified the test of invention under section 2(1)(j) and (ja) cannot be denied patent for failing to satisfy section 3(d) Held, there is no force in the submission that section 3(d) is a provision ex majore cautela-This submission misses the vital distinction between the concepts of invention and patentability (para 102)-Section 3(d) sets up a second tier of qualifying standards for chemical and pharmaceutical substances in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds (para 103) Section 3(d) as representing patentability-But section 3(d) can also be seen as an extension of the definition of invention and thus links section 3(d) with section 2(1)(j) and (ja) (para 104) Reading them, it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes and for medicines and drugs and chemical substances, the Act sets the invention threshold further higher-Held, the Court was unable to see how Imatinib Mesylate can be said to be a new product (paras 131 & 132 & 133) It is a known substance from the Zimmermann patent-Distinction between coverage and disclosure (paras 134 & 135)-Held, the Court rejected the claim that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann patent (para 157)-Held, Imatinib Mesylate is a known substance from the Zimmermann patent, its pharmacological properties are also known-Held, Imatinib Mesylate does not qualify the test of invention under section 2(1)(j)(ja)-Beta crystalline form of Imatinib Mesylate is a new form of a known substance-The efficacy of Imatinib Mesylate is known It attracts section 3(d)(para 161) In whatever way therapeutic efficacy may be interpreted, this much is clear: that the physic-chemical properties of Beta crystalline form of Imatinib Mesylate, namely more beneficial flow properties, better thermodynamic stability and lower hygroscopicity, may be otherwise beneficial, but these properties cannot even be taken into account for the purpose of the test of section 3(d), since these properties have nothing to do with therapeutic efficacy (para 187)—

Issue of increased bioavailability (para 188)—Just increased bio-availability alone may not necessary lead to an enhancement of therapeutic efficacy It fails the test of section 3(d) whether for setting up the standards of 'patentability' or for extending the definition of 'invention'(para 190)-Held, beta crystalline form of Imatinib Mesylate does not qualify the test of section 3 (d) But that is not to say that section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substance It will be a grave mistake to read that section 3(d) was

amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5-For patents for new forms of a known substance with known efficacy, then the subject product must pass, in addition to the clauses (j) and (ja) of section 2 (1), the test of enhanced efficacy as provided in section 3(d) read with its explanation (para 192) Beta crystalline form of Imatinib Mesylate fails in both the tests of invention and patentability as provided in section 2(I)(j) and (ja) and section 3(d) respectively- Appeal by Novartis fails, dismissed with cost.

The Novartis standards

These principles can be listed out from the Supreme Court decision as follows:

1. Identifying the new form of the known substance and its pharmacological properties such as efficacy
2. Comparing the pharmacological properties of the known substance with the new form of the known substance
3. Providing comparative material on enhanced efficacy in the patent application or by affidavits
4. Excluding physio-chemical properties like "more beneficial flow properties", "better thermodynamic stability", and "lower hygroscopicity" for considering therapeutic efficacy
5. In the case of medicines, the test of efficacy can only be therapeutic efficacy which should be judged strictly and narrowly;
6. The applicant has to specifically claim and establish by research data correlating bioavailability to enhanced therapeutic efficacy
7. For patents involving new forms of known substances in chemicals and pharmaceuticals, the test of enhanced efficacy should be proved in addition to the fact that the patent application is an "invention" and involves an "inventive step"

Comment

This case pertains to a patent over the beta crystalline form of Imatinib Mesylate. Now, this was a new form of Imatinib Mesylate, which existed before and Novartis patent did, but due to the regime change in India they could not have an earlier patent which was prior to 1995. So, they filed for a patent in 1998. Novartis had an exclusive marketing right granted to it is patent in 2002 and this was preliminary right it was not actually a right granted on complete scrutiny of the patent application. Soon 5 pre grant oppositions were filed by competitors and some NGOs, because drug involved an anti-cancer drug in which some public health groups were interested. Now the opposition proceeded and the patent was eventually rejected by the patent office. Now it was rejected on 4 grounds, you can see the 4 grounds here,

1. anticipation
2. non obviousness,
3. not an invention under section 3D,
4. and wrongful priority.

This or was appeal by Novartis to the intellectual property appellate board, the intellectual property appellate board also dismissed the appeal and finally, the matter ended up in the Supreme Court. Now, there is a small detail here Novartis initially filed writ petitions before the Madras high court challenging the constitutionality or section 3D of the Patents Act. They had also appealed to the high court, because when the order of rejection team from the patent office the IPAB the intellectual property appellate board was not in force, it has not been constituted the yet. So, there were 2 writ petitions, 2 batches filed: one questioning the constitutionality and the other raising the substantial merits of the decision of the Indian patent office. The high court decided the constitutionality up holding the constitutionality of section 3D, but it transfers the case soon to the intellectual property appellate board, when the appellate board was constituted, this was constituted when writ petitions were pending before the Madras high court. Now so that decision of the Madras high court up holding the constitutional was not questioned by Novartis before the Supreme Court. What eventually came to the Supreme Court was the decision of the IPAB on merits over the decision of the controller. Now when this came up the Supreme Court very clearly mentioned that; it is not the right way to challenge decision of the IPAB directly in the Supreme Court, they said that side-stepping the high court needs to be strongly discouraged

and they will not allow this to be treated as a precedence. So, if you need to agitate any order of intellectual property appellate board both the case has to go to the high court first. Now the Novartis case did discuss various other things the distinction between invention and patentability, it also had a look at what are the major qualifying standards for pharmaceutical and chemical substances. And the case eventually was decided by the court by holding that the court was unable to see that Imatinib Mesylate is a new product. Now that is paragraph 131, 132 and 133. Now the court also held that it that it rejected the claim that Imatinib Mesylate is a new product and outcome of an invention That is in paragraph 157 the efficacy of Imatinib Mesylate, efficacy is something the applicants needs to prove if he comes with a pattern for a new form of a known substance under section 3D. The court held that the efficacy criteria that Novartis had put forward was not sufficient to demonstrate enhanced efficacy. And ultimately the patent was rejected. Beta crystalline form of Imatinib Mesylate fails in both the tests of invention and patentability as provided in section 2(1)j and 2(1)ja, and section 3D respectively. The appeal failed dismissed with cost.

[The principles in 7 broad steps. So, the Novartis standard pertains](#)

- 1.to identifying the new form of the known substance. So, you have to first identify the new form of known substance. We have given the paragraphs from the judgment in brackets;
- 2.then, comparing the pharmacological properties of the known substance with the new form of the known substance. So, the first step is to identify the known substance, the new form of the known substance and comparing the properties of the known substance with the new form of the known substance.
- 3.providing comparative material on enhanced efficacy, comparative material to show and this is an obligation on the patent applicant. The applicant has to show comparative material on enhanced efficacy. So, it is the applicant claims that the new forms has an enhanced efficacy, the applicant has to demonstrate that by producing material.
4. excluding physio-chemical properties like beneficial flow, better thermodynamic stability, lower hygroscopicity from the consideration of therapeutic efficacy. Now, the Madras high court earlier had interpreted efficacy as therapeutic efficacy which was also followed by the Supreme Court.

5. In cases of medicine, the test of efficacy can only be therapeutic. Now this is reiteration of a decision of the Madras high court which happened some time ago and it should be judged strictly and narrowly.

6. the applicant has to specifically claim and establish by research data correlating bioavailability to therapeutic efficacy. Now one of the arguments in this case was that demonstration of bioavailability amounts to enhanced therapeutic efficacy. So, the court said that mere demonstration is not enough, you have to establish by research data that the bioavailability correlates to enhanced therapeutic efficacy.

7. that for patents involving new forms of known substances, the test of enhanced efficacy should be proved in addition to the fact that the patent application is an invention and involves an inventive step.

Now, this reiterates that section 3(d) is an additional layer over the tests of patentability. So, this was the standard that was developed by the Supreme Court.

Significance of the Judgment

Supreme court while discussing the meaning of efficacy stated that the ability to produce a desire or intended result. The test of efficacy depends upon the functions utility or the purpose of the product under consideration .

In matters of medicine the efficacy can only be "therapeutic efficacy " and parameters to determine the therapeutic efficacy would depend upon the enhancement or increase in desire or intended result.

Decision

The Supreme Court upheld Section 3(d) as a safeguard against evergreening and denied Novartis a patent for lack of enhanced therapeutic efficacy as a mere new chance in the form of a known substance with enhancement in efficacy .