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Case Comment: Novartis AG vs Union of India

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Citation:

(2013) 6 SCC 1

Court:

Supreme Court of India

Bench:

Justice Ranjana Prakash Desai and Justice Aftab Alam

Introduction

According to World Intellectual Property Organization, Intellectual Property refers to creations of the mind such as inventions, literary and artistic works; and symbols, names and images used in commerce.[1] In simple words Intellectual Property is a legal right granted to individuals or organizations over their original work, allowing them to prevent others from using such creations without their permission. A patent is category of Intellectual Property. It is an exclusive right granted to an inventor for an invention allowing him to prevent others from

[1] World Intellectual Property Organization, what is Intellectual property? https://www.wipo.int/en/web/about-ip (Accessed on 11th July 2026)

using it without permission.[2] Under Patent Act 1970, a patent is granted for 20 years to the inventor or the rightful owner.[3]

Novartis AG vs. Union of Inda is one of the most significant cases in Indian patent jurisprudence.[4] This case was decided on April 1, 2013, by Supreme Court of India it examines and interpretates section 3(d) of Patents Act 1970 which aims to prevent the practice of "evergreening" of pharmaceutical patents. [5]The dispute arose when Novartis AG's application for a patent over the beta crystalline form of Imatinib Mesylate, a life-saving anti-cancer drug marketed as *Glivec* was denied.

The judgement rendered by Supreme court of India clarified the benchmark for patentability of pharmaceutical inventions in India and upheld the balance between encouraging innovation and discouraging evergreening. Supreme Court upheld India's dedication toward ensuring availability of reasonably priced medicines, while denying extension of patents where there was no improvement in efficacy, by denying patent protection in absence of enhanced efficacy. The decision's impact can be felt all over. Not only for pharmaceutical companies, but how we perceive patent law and public health policy, and even how we speak of intellectual property rights globally particularly regarding the TRIPS Agreement.

Background and facts of the case

Novartis AG is a multinational pharmaceutical company that is based in Switzerland, it applied for the grant of a patent before the Madras patent office for an anti-cancer drug 'Glivec' which is used to treat chronic myeloid Leukaemia and gastrointestinal tumours. According to Novartis AG this drug was developed from the beta crystalline form of "Imatinib mesylate"[6] which is durable and essential and for which the patent had already been granted in several countries. As per the patent application by Novartis AG the beta crystalline form of Imatinib was better, advanced and more beneficial in terms of flow quality, enhanced thermodynamic stability, less hydrophobic, better processing and storing.

Subsequently the patent application by Novartis AG was dismissed by the Madras Patent Office for a patent on its drug 'Glivec' because the Patent Office came to a conclusion that the

[2] World Intellectual Property Organization, Patents, https://www.wipo.int/patents/en/ (Accessed: 11th July 2026)
[3] The patent Act, No 39 of 1970 § 53, India code (1970).
[4] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).
[5] The Patent Act, No 39 of 1970, § 3(d), India code (1970).
[6] *Novartis*, (2013) 6 S.C.C. 1.

invention or the drug did not qualify for patent protection under the provisions of section 3 of the Patent Act 1970 which states what all are not inventions. Section 3 (d) of the Indian Patent Act, served as the basis for the decision taken in this case. According to this provision a known compound is granted patent only if its modified forms show increased efficacy and it was found that the Glivec drug did not fulfill the requirements as per this section therefore Novartis AG was not granted a patent.

After the rejection of the patent application Novartis AG filed two writ petitions under Article 226 of the Indian Constitution before the Madras High court.[7] The first petition attempted to quash the ruling of the Madras Patent Office and the second petition argued that section 3(d) of the Indian Patent Act is unconstitutional, vague, arbitrary and inconsistent with TRIPS.

In dismissing the writ petitions by Novartis, the Madras High Court ruled that section 3(d) of Indian Patent Act aims to avoid evergreening and enabling access to medicines for the population so it cannot be seen as unreasonable and the court also stated that it lacked jurisdiction to consider whether section 3(d) infringes TIPS agreement. The case was further transferred to The Intellectual Property Appellate Board from the High Court; the board also dismissed the appeal stating that the drug did not involve any invention nor it satisfied the test of non- obviousness. Lastly a Special Leave Petition was filed by Novartis before Supreme Court.

Issues

1. Whether the invention claimed by Novartis AG qualifies for patent protection under section (d) of the Indian Patent Act 1970?
2. How does the Indian Patent Act define the terms “evergreening” and “efficacy” under section 3(d)?
3. Whether the change in properties of the beta crystalline form sufficient to establish enhanced therapeutic efficacy under section 3(d)?

Rules

In the case Novartis AG vs. Union of India, the supreme court relied on the following provisions of the Patent Act:

Section 2(1)(j) of Patent Act 1970 – “Invention”

[7] *Novartis*, (2013) 6 S.C.C. 1; INDIA CONST. art. 226.

- It defines invention as a new product or process involving an inventive step and capable of industrial application.[8]

Section 2(1) (ja) of the Patents Act 1970 – Inventive step

- Requires the invention to involve a technical advance or economic significance and not to be obvious to person skilled in the art.[9]

Section 3(d) pf the Patents Act 1970

- Provides that the mere discovery of a new form of a known substance is not patentable unless it results in enhanced therapeutic efficacy.
- States that 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 with regard to efficacy.
- The beta crystalline form of Imatinib Mesylate fell within this explanation.

Judgement

On 1st April 2013, the Supreme Court of India dismissed the appeal filed by Novartis AG and upheld the decision made by the, Madras Patent Office and Intellectual Property Appellate Board (IPAB), denying patent protection for the beta crystalline form of Imatinib Mesylate under the Patents Act 1970. [10]

The Court observed that the beta crystalline form of Imatinib Mesylate was merely a modified version of an already known substance. Although the applicant Novartis AG claimed that the modified form possessed better physical properties, such as flow quality, thermodynamic stability and is less hydrophobic, the Court held that these improvements were insufficient to grant patent protection. According to section 3(d) a new form must result in enhanced therapeutic efficacy, meaning that improved form shall be more effective on body and health.

The supreme court also clarified that the change in colour, salt composition or improved physical properties do not automatically establish that a medicine is therapeutically more effective. An invention must possess the factor of novelty that means there shall be an invention under section 2(1)(j), or it must possess an inventive step, meaning a unique and different

[8] The Patents Act, No. 39 of 1970, § 2(1)(j), India Code (1970).
[9] The Patents Act, No. 39 of 1970, § 2(1)(ja), India Code (1970).
[10] The Patents Act, No. 39 of 1970, § 2(1)(ja), India Code (1970).

technique used to produce an invention under section 2(1) (ja), or the invention must be non-obvious. Considering Novartis AG failed to provide conclusive proof that the beta crystalline form was more effective in treating patients than the already known substance, it was therefore concluded by the court that the statutory requirements under the provisions of Indian Patent Act 1970 were not fulfilled.

Furthermore, the court underlined that section 3(d) was intended to prevent the practice of "evergreening", and therefore, dismissing the patent application of Novartis AG was justified.

Analysis

The case Novartis AG vs Union of India is considered as a landmark judgement in the patent law because it strengthened the objective of the Patent Act 1970, to promote genuine innovation while protecting public health. The Supreme Court's interpretation of section 3(d) effectively curbed the practice of evergreening by requiring pharmaceuticals companies to prove that their modification of an already existing drug have enhanced therapeutic efficacy. This approach ensures the unnecessary extension of patent and facilitates the availability of generic medicines at reasonable costs, benefiting millions of people.

However, the critics have argued that the strict interpretation of section 3(d) may hinder innovations, investment in pharmaceutical research and reduce incentives for developing various versions of existing drugs. Altogether the judgement effectively balances innovation with public interest.

Aftermath of the judgement

The decision given had a significant impact on Indias's patent regime and pharmaceutical industry. The decision served as an affirmation of India's position on the prevention of evergreening of patents in the pharmaceutical industry and guaranteeing access to affordable medicines. Post the judgement, Indian generic pharmaceutical manufacturers continued producing cost- effective of life saving drugs for its citizens and other developing nations. The judgement has also helped in reinforcing the interpretation of section 3(d) of the Patents Act 1970, which is now become as a major precedent for assessing pharmaceutical patent applications.

At the same time the judgement sparked international discussion, where some multinational pharmaceutical companies had expressed their concerns that India's strict patent standard could

discourage investment and innovation. Nevertheless, the ruling enhanced Indian patent law for balancing intellectual property rights, public interest and policymaking.

Conclusion

The case of Novartis AG vs Union of India was rendered as an Important judicial Precedent that has made significant contributions to the patent law of India. Through the interpretation of the provisions of the Patent Act 1970, the Supreme Court of India ensured that patent protection is granted only to inventions which demonstrate improved medical efficacy. The ruling also becomes an example or model for future implementations and interpretations of the Trade related characteristics of Intellectual Property Rights. The decision prioritises public needs and benefits over pharmaceutical company's interest.