



The Indian Journal for Research in Law and Management

Open Access Law Journal – Copyright © 2025

Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896

This is an Open Access article distributed under the terms of the Creative Commons Attribution- Non-Commercial-Share Alike 4.0 International (CC-BY-NC-SA 4.0) License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium provided the original work is properly cited.

NOVARTIS AND ANR V. ADARSH PHARMA AND ANR

Joshini Aksharha G¹

Court: Madras High Court

Citation: 2004 (29) PTC 108 (Mad.)

Coram : Hon'ble Justice R. Balasubramaniam

Theme: Patent Case and Exclusive Market Rights in Pharmaceutical sector

Subject: Intellectual Property Rights

Judgement: India

PLAINTIFF

"Novartis AG is a Swiss multinational healthcare company based in Basel."² The firm specializes in finding and developing new therapies for severe medical conditions.

RESPONDENT

Adarsh Pharma is also a manufacturing company in India. It engaged in the manufacturing and marketing of generic versions of the anti-cancer drug called imatinib mesylate, which Novartis had claimed exclusive rights to under an Exclusive Marketing Rights (EMR). Adarsh Pharma and its associates were not licensed by any authority or Novartis Company to sell or manufacture the drugs.

FACT

¹ Student, 4th year, B.A. LL.B.(Hons), School of Excellence in Law, TNDALU

² Novartis AG, Britannica Money, <https://www.britannica.com/money/Novartis-AG> (accessed on July 16, 2025).

Novartis is a global pharmaceutical firm headquartered in Switzerland, which initiated legal proceedings in the Madras High Court for the patent for the medicine named imatinib mesylate. It filed a patent application in 1998 under the mailbox provisions of the Indian Patents Act, in compliance with the TRIPS Agreement (Trade Related aspects of Intellectual Property Rights). Novartis has already secured the patent for the same drug in other countries like the United States and Australia. The Defendant, Adarsh Pharma was illegally and without getting the patent from the consent authority, they were selling the drug in generic version. Novartis, after knowing this, approached the court to protect their cancer drug and requested to grant Exclusive Marketing Rights (EMR).

ISSUE

- Whether the case have Locus Standi?
- Whether Adarsh Pharma have patents for manufacturing and marketing inside India?
- Whether Novartis AG has the authority to file patent applications?
- Whether the TRIPS Agreement is applicable in this case?
- Whether the Exclusive Market Right (EMR) holder can seek injunction over the infringement?

PROVISION

The Patent Act, 1970 (Pre-2005 Amend)

- **Section 24A** - Application for the grant of Exclusive Market Rights

It grants permission to file for the Exclusive Marketing Rights (EMR) applications when the particular invention is not patentable under Indian Laws but that particular invention already has patent and marketable rights in other WTO member countries.

NOTE: While Examining the Exclusive Marketing Rights (EMR), Section 3 and section 4 of the act are applicable. Section 12 and Section 13 is excluded in the matters of Exclusive Marketing Rights (EMR). Section 3 and Section 4, which defines the non patentable inventions. Section 12 and Section 13 specifies about the pertaining to examination of applicable patent

- **Section 24B** - Grant of Exclusive Marketing Rights for certain inventions.

It empowers the controller or authority to give the Exclusive Marketing Rights for 5 years or until the grant or rejection of such particular application, whichever is earlier. This section

protects the marketing rights of the applicant to distribute and market the product inside India.

TRIPS Agreement ((WHO)

- **Article 70.9** - Protection of existing subject matter

“Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”

Simply, this section mandates WTO member countries for providing the means for filing the patent application for pharmaceuticals and the protection of pharmaceutical and agricultural chemical products even if the patent is not yet available in the domestic country. It also speaks about the grant of Exclusive Marketing Rights which shall be given for the period of five years or until the patent is granted or rejected, whichever period is earlier, provided that the product is:

- Patented in the WTO member country
- Has patent rights or approval in such particular country
- Has approval for marketing in the country where Exclusive Marketing Right (EMR) is sought.

PLAINTIFF’S ARGUMENT

- **Prima facie case:** Novartis AG argued that their rights were infringed because Adarsh Pharma sold the same, exact product in the market without the proper authorization.
- **Exclusive Marketing Rights (EMR):** They argued that the product was already patented in Australia. They have also obtained marketing approval in Australia. Hence, they fulfilled the conditions under TRIPS (Article 70.9) and Indian patent law for EMR.
- **Injunction:** Since EMR grants marketing rights, Novartis sought an interim injunction against Adarsh Pharma to restrain them from manufacturing, marketing and selling the product, imatinib mesylate in India.

- **Loss:** They further argued that they got irreparable loss because of Adarsh Pharma's unauthorized marketing. They asserted that EMRs should be authorized and maintained like patents

RESPONDENT'S ARGUMENT

In their defense, the respondents, Adarsh Pharma, challenged the validity of the Exclusive Marketing Rights (EMR) granted to Novartis AG, asserting that the pharmaceutical product in question beta crystalline form of Imatinib Mesylate was not novel and had already been in public use, thereby lacking the criteria for patentability under Indian law. They contended that granting EMR over a substance already present in the public domain contravened the purpose of such rights. Further, Adarsh Pharma questioned Novartis's locus standi to file the suit, especially in light of the alleged invalidity of the EMR. They also emphasized that no full patent had been granted in India for the said product at the time, and thus, Novartis should not be entitled to exclusive or monopolistic protection.

JUDGEMENT

The Madras High Court granted the interim injunction against Adarsh Pharma as requested by Novartis AG. They were also restricted from selling, manufacturing or distributing the drug Imatinib Mesylate. Novartis has been granted Exclusive Marketing Rights under Section 24 A and Section 24 B of the Acts, 1970 (Pre-2005).

CASE ANALYSIS

In this case the main issue was about the Exclusive Marketing Rights (EMR) granted under the Patents Act, 1970 (pre-2005 amendment) and its alignment with India's obligations under the TRIPS agreement. Novartis sought an interim injunction against Adarsh Pharma for manufacturing, selling or distributing the drug around India. The Court primarily focused on whether EMR rights shall be given or not or enforceable to Novartis. Crucially it did not venture into aspects which come under section 12 and section 13 of Patent Act, 1970. The court instead gave weightage to the procedural aspects with section 24A and 24B.

The defendant raised objections for each and every argument stated by the plaintiff. The Hon'ble court also considered section 24D and addressed it. This case became more significant because its role in shaping the intellectual property rights during the period of TRIPS implementation was marked important.

CONCLUSION

The decision of the court was seen as an inclination to uphold procedural legitimacy. At the same time, it carefully balances this with the recognition that public interest concerns must be addressed, though not by undermining proprietary rights directly, but through dedicated legal provisions laid out for that purpose. Through this case we can understand the significance of EMR and Patent.

REFERENCE

- Novartis AG v. Adarsh Pharma & Anr., 2004 (29) PTC 108 (Mad.) (India Apr. 28, 2004), <https://indiankanoon.org/doc/1454766/>, accessed on July 16, 2025.
- Novartis AG, Britannica Money, <https://www.britannica.com/money/Novartis-AG> (accessed on July 16, 2025).
- Novartis AG v. Adarsh Pharma & Anr., No. 29 PTC 108 (Mad. High Ct. Apr. 28, 2004), <https://www.the-laws.com/Encyclopedia/browse/Case?caseId=214002798000&title=novartis-ag-vs-adarsh-pharma> (accessed on July 19, 2025).
- Patent Enforcement Trends in India, Asia IP Law (Nov. 12, 2012), <https://asiaiplaw.com/article/patent-enforcement-trends-in-india> (accessed on July 19, 2025).