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"CASE COMMENTARY ON NOVARTIS AG V. UNION OF INDIA & OTHERS"

~ Chandan Sha[1]

1. CASE METADATA BOX

CASE NAME: Novartis AG V. Union of India and others[2]

CITATION: Novartis AG v. Union of India, (2013) 6 SCC 1

BENCH STRENGTH AND NAMES: Division bench (2 judges); Justice Aftab Alam and Justice Ranjana Prakash Desai.

DATE OF JUDGMENT: 1st April, 2013

TECHNICAL FIELD: Pharmaceutical Patents; Chemical compounds (oncology); Chronic Myeloid leukaemia.

PARTIES:

Appellant	Respondents
Novartis AG	Union of India; NATCO Pharma Ltd.; Cancer Patients Aid Association; CIPLA Ltd.; Ranbaxy Laboratories Ltd.; and Hetro Drugs Ltd

2. INTRODUCTION AND SIGNIFICANCE

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[2] *Novartis AG v. Union of India*, (2013) 6 SCC 1, available at https://api.sci.gov.in/jonew/judis/40212.pdf

The judgment in Novartis AG v. Union of India, (2013) 6 SCC 1 is perhaps the most significant pharmaceutical patent decision in Indian history. It addresses the tension between the protection of intellectual property rights and the fundamental right to health.

The case arose during the period of legislative transition, when India moved from a process patent regime (designed to foster a robust generic industry) to a product patent regime required by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The Supreme Court was tasked with interpreting the "true import" of section 3(d) of the Patents Act 1970. This provision serves as a uniquely Indian safeguard against "evergreening" the practice whereby pharmaceutical companies obtain fresh patents on minor modifications of existing drugs to extend their market monopoly.

The court's decision to prioritise "therapeutic efficacy" over mere physical improvements cemented India's status as the pharmacy of the world ensuring that lifesaving drugs remain accessible to millions in developing nations who depend on Indian generic supply.

3. FACTS OF THE CASE

3.1 THE GENUS INVENTION- In the early 1990s Jurg Zimmermann invented a series of derivatives including a compound known as Imatinib. This was patented in the US in 1996 (the "Zimmerman patent"). The patent explicitly mentioned that these compounds could form acid addition salts, such as methanesulfonic acid.

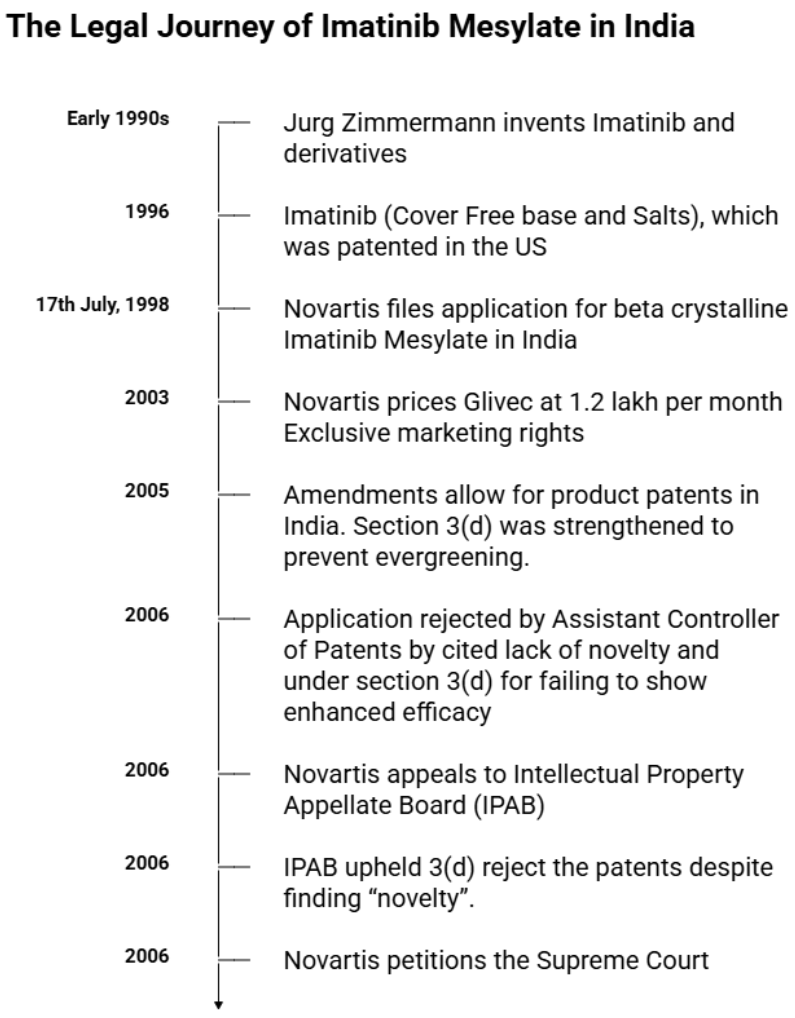
3.2 THE MODIFICATION: Novartis claimed a "two stage invention" starting from imatinib free base. First, they created the methane sulfonic acid salt (Imatinib Mesylate) and second, they developed a specific "beta crystalline" form of that salt.

3.3 THE INDIAN APPLICATION: Novartis filed an application in Chennai on 17th July, 1998 for the beta crystalline form of Imatinib Mesylate. Because India did not then grant Product patents (i.e., legal right given to an inventor for a final, physical item. It stops other people from making, using, or selling that exact item for 20 years.) for medicines, the application was placed in a "mailbox".

3.4 ADMINISTRATIVE REJECTIONS: After the 2005 amendments allowed for product patents the application was taken out of the mailbox. It was rejected by the Assistant Controller

of patents in 2006 for being anticipated by the Zimmermann patent and for failing to show enhanced efficacy under section 3(d) of the Act.

3.5 THE PATH TO THE SUPREME COURT: Novartis appealed to the Intellectual Property Appellate Board (IPAB). The IPAB found the drug was "new" and "non-obvious" but ultimately rejected the patent under section 3(d) noting the high standard of inventive step required for drugs in India. Novartis then filed a petition under Article 136 before the Supreme Court of India.



4. ISSUES RAISED

4.1 What is the true import of section 3(d) of the Patents Act 1970 and how does it interplay with the definitions of "invention" and "inventive step" under sections 2(1)(j) and 2(1)(ja)?

4.2 Does the beta crystalline form of Imatinib Mesylate qualify as a "new product" involving a technical advance over existing knowledge?

4.3 How should the term "efficacy" be interpreted within the context of section 3(d) for pharmaceutical substances?

4.4 Can a patent "cover" a substance for infringement without "disclosing" it in a manner that constitutes prior art?

5. STATUTORY PROVISIONS INVOLVED

Section 2(1)(j) of the Patents Act, 1970, which defines invention as a new product or process involving an inventive step.;[3] Section 2(1) (ja) of the Patents Act, 1970 defines inventive step as a feature involving technical advance or economic significance.[4] Section 3(d) of the Patents Act 1970– excludes from patentability the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy.;[5] Section 53 of the Patents Act, 1970– as previously drafted, barred product patents for food and medicine.[6]

6. ARGUMENTS ADVANCED

6.1 THAT THE APPELLANTS, NOVARTIS AG, ARGUE ON THE FOLLOWING GROUNDS ARE–

6.1.1 TWO STAGE INVENTION – They argued that moving from the Imatinib to Imatinib Mesylate, and then to the beta crystalline form, required distinct inventive research into process parameters that were not taught by Zimmermann.

6.1.2 BIOAVAILABILITY – Novartis provided affidavits claiming the beta crystalline form had 30% higher bioavailability in rats compared to the freebase, which they asserted was an "enhancement of efficacy".

6.1.3 COVERAGE VS DISCLOSURE – They contended that the Zimmermann patent "covered" the Mesylate salt (protecting it from infringement) but did not "disclose" or "enable" it (leaving it open for a new patent).

[3] The Patents Act, 1970, § 2(1)(j), No. 39, Acts of Parliament, 1970 (India).
[4] The Patents Act, 1970, § 2(1) (ja), No. 39, Acts of Parliament, 1970 (India).
[5] The Patents Act, 1970, § 3(d), No. 39, Acts of Parliament, 1970 (India).
[6] The Patents Act, 1970, § 53, No. 39, Acts of Parliament, 1970 (India).

6.1.4 INCREMENTAL INVENTION – They argued that section 3(d) was only meant to prevent "trifling" changes, not genuine technical advances.

6.2 THAT THE RESPONDENTS (OBJECTORS AND UNION OF INDIA) ARGUE ON THE FOLLOWING GROUNDS ARE –

6.2.1 PRIOR ART – they maintained that imatinib Mesylate was a "known substance" fully disclosed in the Zimmermann patent and 1996 scientific literature.

6.2.2 STRICT EFFICACY – they argued that bioavailability is a pharmacokinetic property and does not equal therapeutic efficacy.

6.2.3 EVERGREENING – the objectors argued that Novartis was attempting to artificially extend its monopoly on a drug they were already selling under EMR at "unaffordable" prices.

6.2.4 TRIPS FLEXIBILITY– the Union of India argued that section 3(d) was a legitimate use of TRIPS flexibilities to protect public health.

7. JUDGMENT AND DECISION

The Supreme Court dismissed the appeals filed by Novartis AG with costs. The court held that the beta crystalline form of Imatinib Mesylate did not qualify as an "invention" under section 2(1)(j) because it was already a "known substance" from the Zimmermann patent. Furthermore, it failed the second tiers test of patentability under section 3(d) as it did not demonstrate an enhancement of therapeutic efficacy over the known substance.

8. RATIO DECIDENDI AND LEGAL REASONING

8.1 INTERPRETATION OF SECTION 3(d)- The court ruled that section 3(d) is not just a provision of "abundant caution" but a substantive requirement. It sets a "higher invention threshold" specifically for medicines.

8.2 THE EFFICACY TEST- The court defined efficacy strictly as therapeutic efficacy[7]. Physical attributes such as better flow properties thermodynamic stability and lower

[7] *Novartis AG v. Union of India*, (2013) 6 SCC 1, ¶ 180.

hygroscopicity were rejected as they only improve "processability" or "storability" and do not enhance the drugs curative effect on the body.[8] While Novartis showed a 30% increase in bioavailability the court held this was not "therapeutic efficacy" unless research data proved it led to a superior treatment outcome.[9]

8.3 REJECTION OF THE COVERAGE DISCLOSURE GAP- The court firmly rejected the idea that a patent coverage could be wider than its disclosure.[10] "We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent...where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims..."[11]

8.4 LEGAL FORMULA FOR SECTION 3(d) PATENTABILITY- If substance (s1) is a new form of known substance (s0), then it Must show Efficacy (s1) more than the efficacy (s0). Where efficacy is equal to Therapeutic efficacy only (but physical process improvements are not equal to therapeutic efficacy). If the result is proven, then patentable (Genuine invention); if the result is not proven, then reject the patent (Evergreening).

9. OBITER DICTA

The court expressed concern over the haste with which the 2005 amendments were passed, leading to unclear drafting in some sections. It also took judicial notice of the international community's concern specifically referencing letters from WHO and UNAIDS which highlighted that if India stopped producing generic cancer and AIDS medications, it would have devastating consequences for global health.

10.IMPACT ANALYSIS

The Novartis judgment is a landmark in purposive statutory interpretation. It prevents the "repetitive patenting" of known drugs through minor chemical modifications a practice that would otherwise choke competition and keep prices high.

Table 1

[8] *Id.* ¶¶ 187, 332.
[9] *Id.* ¶¶ 189, 335.
[10] *Id.* ¶¶ 139, 264.
[11] *Id.* ¶¶ 156, 287.

Market Reality Comparison Pre and Post Judgment

Metric	**Pre- judgment**	**Post judgement**
Monopoly status	Novartis held exclusive marketing rights	Monopoly rejected; market opened to generic manufacturers
Drug pricing	Approx ₹1,20,000 per month	Approx ₹8000 to 10,000 per month
Interpretation of Efficacy	Broad- any beneficial property	Strict- therapeutic efficacy only
Generic availability	Restricted- NATCO was forced to stop UK sales	Generic versions widely available for ailing humanity

While the judgement provides a clear bar, it leaves some ambiguity regarding the exact data required to prove therapeutic efficacy. Pharmaceutical companies must now navigate a system where pharmacokinetic improvements like bioavailability are secondary to clinical therapeutic outcomes, potentially requiring more expensive clinical trials for incremental innovations.

11.REFERENCE

- *Novartis AG v. Union of India*, (2013) 6 SCC 1, available at **https://api.sci.gov.in/jonew/judis/40212.pdf**