# Novartis AG v. Union of India

Civil Appeal Nos. 2706-2716 of 2013

**Country**: India
**Region:** Asia
**Year:** 2013
**Court:** Supreme Court
**Health Topics**: Chronic and noncommunicable diseases, Medicines
**Human Rights:** Right to health

**Facts**

In 1998, Novartis AG, a multinational pharmaceutical company based in Switzerland, filed a patent application in India for the beta-crystalline form of imatinib mesylate, a drug used to treat chronic myeloid leukaemia, a type of blood cancer. In 2005, the Chennai Patent office heard patent oppositions to this application, including one filed by the Cancer Patients Aid Association. The challenge was prompted by concern about the high price Novartis set for its version of the drug, marketed in India as â€˜Gleevecâ€™. Novartis set the price at Rs 1,20,000 (approximately US$ 2,400) per month, compared with generic versions that were available for Rs 8,000 to 12,000 (approximately US$ 160 to 240) per month.

In 2006, the Patent Office rejected Novartisâ€™s patent application on several grounds. In particular, it concluded that the application had not met the standard established in section 3(d) of the Indian Patent (Amendments) Act, 2005 (the Act). Section 3(d) states that the following are not considered â€œinventionsâ€• within the meaning of the Act and are thus not patentable:
â€œ[T]he 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 reactantâ€• [emphasis added].
Novartis brought two challenges to the decision of the Patent Office. First, it challenged the constitutional validity of section 3(d) before the Madras High Court. In 2007, the Madras High Court dismissed these proceedingsÂ and held that the word â€œefficacyâ€• had a definite meaning in the pharmaceutical field, namely â€œtherapeutic efficacy.â€•

Second, Novartis appealed the decision on its merits, arguing that the Patent Office had not correctly applied the criteria of section 3(d), particularly the "enhanced efficacy" criterion. In 2009, the Intellectual Property Appellate Board rejected Novartisâ€™s appeal. Novartis appealed to the Supreme Court, arguing that Gleevec should be granted a patent on the grounds that the improved stability and flow of beta-crystalline imatinib mesylate, as well as its increased bioavailability as compared to the free base, constituted "enhanced efficacy".

**Decision and Reasoning**

The Court held that Novartisâ€™s beta-crystalline form of imatinib mesylate did not meet the standards of â€œpatentabilityâ€• under the Indian Patent (Amendments) Act, 2005.

The Court first examined the intent of the Patent (Amendments) Act, 2005, including the standard of enhanced efficacy established in section 3(d). The Court noted the concern that patent protection of pharmaceutical and agricultural chemical products â€œmight have the effect of putting life-saving medicines beyond the reach of a very large section of people.â€• It examined the legislative history of the Indian Patents Act, including the impact of the TRIPS agreement and the subsequent Doha Declaration.

The Court noted that after patents for pharmaceutical and chemical substances were barred in India, Indiaâ€™s pharmaceutical industry grew dramatically and became â€œthe major supplier of drugs at cheap prices to a number of developing and under-developed countries.â€• The Court therefore noted that the reintroduction of product patents in India, including for pharmaceutical and chemical substances, was a cause of great alarm for those concerned with ensuring continued access to affordable medicine in India and abroad. To this end, the Court reproduced letters from the World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS) expressing concern about the potential impact that Indiaâ€™s forthcoming modifications to

its patent system could have on access to affordable medicines throughout the world, particularly for HIV treatment.

The Court concluded that:
â€œ[T]he Indian legislature attempted to address [these concerns] and, while harmonizing the patent law in the country with the provisions of the TRIPS Agreement, strove to balance its obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own people but in many other parts of the world (particularly in the Developing Countries and the Least Developed Countries).â€• After examining the parliamentary debates surrounding the enactment of the Act, the Court held that section 3(d) was undoubtedly meant to address chemical substances, and pharmaceutical products in particular, and that it clearly established a â€œsecond tier of qualifying standardsâ€• for pharmaceutical products meant to â€œleav 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.â€•

The Court next held that imatinib mesylate was a â€œknown substanceâ€• because it had previously been patented and sold in the United States and thus did not qualify as an â€œinventionâ€• in terms of clauses (j) and (ja) of sectio 2(1) of the Act. The Court then considered arguments on both sides as to whether the beta-crystalline form of imatinib mesylate enhanced the â€œknown efficacyâ€• of a â€œknown substanceâ€• pursuant to section 3(d) of the Novartis argued that the physiochemical properties of new forms of old medicines should be considered in determining whether efficacy has been enhanced pursuant to section 3(d) of the Act. In particular, it contended that the physiochemical properties of its polymorph form of the imatinib molecule, including better flow properties, better thermodynamic stability and lower hygroscopicity, resulted in improved efficacy. It argued that these properties made the product â€œnewâ€• because it â€œstores betterâ€• and is â€œeasier to proc Court rejected this contention and held that, for medicines, efficacy means â€œtherapeutic efficacy.â€• The Court declared that this standard must be interpreted â€œstrictly and narrowlyâ€• and that while improvements in physicochemical properties may be beneficial to some patient, they do not meet the standard for â€œtherapeutic efficacyâ€• under section 3(d).

Novartis also argued that increased bioavailabilityâ€”the degree and rate at which a drug is absorbed into a living system or is made available at the site of physiological activityâ€”constituted enhanced efficacy under section 3(d). The Court rejected this argument as well. It held that â€œincreased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy.â€• Rather, whether an increase in bioavailability led to an enhancement of therapeutic efficacy â€œmust be specifically claimed and established by research data.â€• Further, the Court did not accept that the crystal form of imatinib mesylate was more bioavailable than free base, as no in vivo animal studies had been conducted. The Court held that there was â€œabsolutely nothing,â€• save the submissions of counsel, to show that Novartis had enhanced the efficacy of its product through increased bioavailability. Such a "bald assertion" did not meet the standards required by section 3(d).

**Decision Excerpts**

"In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) 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) of the Act, since these properties have nothing to do with therapeutic efficacy." Para. 187.

"Thus, even if Mr. Groverâ€™s submission is not taken into consideration on the question of bioavailability, the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model." Para. 189.

"We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment." Para. 191.