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# Supreme Court of India Denies Novartis Patent Application

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In a landmark judgment delivered on April 1, 2013, the Supreme Court of India dismissed an appeal by Novartis AG, a Swiss pharmaceutical giant, to win patent protection in India for its cancer drug Glivec. The polarizing decision has been hailed by activists as a step in the right direction for affordable healthcare, and as being detrimental to innovation and investment by the international business community.

**Background**

Prior to 2005, Indian patent law only provided for process patents. In 2005, the Patents Act, 1970 (the "Act") was amended retrospectively to allow for product patents so that India could meet its obligations under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"). The Act was welcomed by multinational companies as a measure to curb Indian generic drug companies that were manufacturing low-cost versions of drugs patented by the multinationals.

In 1997, Novartis filed an application for a patent for Glivec - the application was taken into consideration in 2005, under a "mailbox" scheme, after the change in the patent regime. In 2006, the Indian Patent Office ruled that the drug was not substantially different from one for which patents had already been given in the U.S. and Europe and that the active ingredient, imatinib myselate, was a known compound before the development of Glivec, and therefore it did not pass the requisite novelty test to obtain a patent. Novartis contended that it had developed a newer beta-crystalline form of imatinib myselate, which was patentable. On appeal, the decision by the Patent Office to deny Novartis a patent was upheld by the Intellectual Property Appellate Board in 2009. Novartis filed an appeal before the Supreme Court of India.

**Factors considered by the Court**

In its 112-page judgment, the Court considered a variety of factors that led to its decision, including:

- The need to strike a balance between promoting research and development in science and technology and keeping private monopoly at a minimum;
- The particular context in which patent law developed in India, with an aim to minimize the abuse of patent monopoly;
- A comparison of the high growth rate of the domestic pharmaceutical industry with that of the multinational companies in India, prior to the changes in patent law in 2005;
- India's reputation as the "pharmacy of the world" - a low cost producer of high quality bulk drugs;
- The provisions of the TRIPS Agreement;
- The Doha Declaration on TRIPS and Public Health of 2001, which took into account the effect of intellectual property protection on prices and public health concerns caused by it and enabled member states to control patent rights for public health reasons;

- Concerns voiced by the WHO and by the international community on the effect of the TRIPS Agreement on the supply of affordable drugs from India, particularly to countries in Africa and South East Asia;
- The Parliamentary debate in India over the changes in patent law in 2005;
- The technical details relating to Glivec, provided by Novartis in its patent application;
- The labeling on packages of Glivec;
- The price of the drug marketed by Novartis – Rs. 120,000 (approximately $1,700) and the price of the generic drug in the market (Rs. 5,000 to Rs. 9000, approximately $ 200).

**Interpretation of the Act**

In deciding Novartis's appeal, the Court was primarily required to interpret Section 3(d) of the Act, which states that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not an invention for the purposes of the Act. The provision also explains that derivatives of a known substance are to be considered the same substance, unless they differ significantly in properties with regard to efficacy. The Act defines "invention" as a new product or process involving an inventive step and capable of industrial application. "Inventive step" is defined to mean a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

Section 3(d) aims at preventing "evergreening", i.e., prolonging the life of a patent by making minor incremental changes that do not necessarily alter the utility and features of the original patented product. The Court was of the opinion that Section 3(d) applied particularly to pharmaceuticals and that there was a higher requirement for the granting of patents in India; what was patentable in other countries may not be patentable in India.

While discussing the meaning of "efficacy", the Court laid down that the test of efficacy, in the context of Section 3(d), for a medicine that claims to cure a disease could only be "therapeutic efficacy", which must be judged strictly and narrowly. It was found that the physico-chemical properties of beta crystalline form of imatinib mesylate that distinguished it from imatinib mesylate had nothing to do with therapeutic efficacy.

The Court also considered whether a patent granted previously in the U.S. (the "Zimmerman Patent") also included imatinib mesylate, which would make it a known substance. The Court rejected Novartis's contention that imatinib mesylate was a new product and the outcome of an invention beyond the Zimmermann patent. It held that imatinib mesylate was a known substance from the Zimmermann patent itself, and was therefore not an 'invention' for the purposes of the Act. Further, it was held that the beta-crystalline form of imatinib myselate did not have any pharmacological properties that were not possessed in the free base of imatinib, and therefore, both the compounds were known substances with known efficacy.

The Court recognized that the Indian legislature had to balance its obligations under the TRIPS Agreement with its duty to protect and promote public health measures in India. It was clarified that its decision applied narrowly to the case at hand and that Section 3(d) does not bar patent protection for all incremental inventions of chemical and pharmaceutical

substances. In dismissing the appeal by Novartis with costs, the Court found that the beta crystalline form of imatinib mesylate, failed in both the tests of invention and patentability as provided under the Act.

**Conclusion**

The decision of the Supreme Court is likely to have implications for several Western pharmaceutical companies involved in intellectual property cases in India. Many multinational pharmaceutical companies have expressed their frustration at the way the Indian Patent Office and courts have interpreted the Act to restrict patent protection for their drugs in favor of domestic generic drug companies. The decision will raise questions about the ability of multinational companies to obtain patents in India for newer versions of existing drugs and the commitment of the government to attracting foreign investment in the pharmaceutical sector. In 2012, the Indian Patent Office granted a compulsory license to Indian drugmaker, Natco, to manufacture Bayer's patented cancer drug, Nexavar.

The perceived lack of protection for intellectual property rights in India may also have long-term effects on innovation in drug-making. Without patent protection, there will be fewer incentives for multinationals to invest in research and development for new treatments. Novartis has warned that it will be cautious about investing in India, especially over introducing new drugs, and seek patent protection before launching any new products. It will also continue to refrain from research and development activities in the country.

The decision is also a wake-up call to the Indian government to introduce reforms in the healthcare, insurance and drug-pricing sectors in India. India's health care system is poorly funded and the lack of extensive insurance coverage means that individuals bear the brunt of medical costs. There is a need to introduce negotiated tiered drug-pricing that allows access to expensive medicines. Given the recent slowdown in the Indian economy and the need to attract foreign investment, it is crucial that the Indian government restores confidence in the Indian market among foreign investors.