Novartis's Appeal for Glivec Patent Dismissed

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Section 3-d continues to rule as India's Premier Court Rejects Novartis's Appeal

In what would be touted as the landmark judgment in all the years to come and for the Pharma Industry as well as the Indian Patenting System, the Supreme Court of India has rejected Novartis's plea on its blood cancer drug Glivec and denied patent to it. The drug was not considered to be patentable as per the provisions of Section 3(d) that draws a distinction between "ever-greening" and incremental innovation.

The Supreme Court rejected the claims of Swiss pharma giant stating that the drug had failed to qualify for a patent according to Indian law. The Court also held that patents could be granted only in the case of genuine inventions. It is worth mentioning that Gleevec is approved in more than 90 countries including the US, EU, and Japan for the treatment of all phases of Ph+ CML.

Novartis had been fighting since 2006 to get the patent for Glivec, which as claimed by oncologists is major advance in treating chronic myeloid leukaemia. It had been continuously pushing for the patent arguing that if the rights of investors are not upheld then it will hit research and development of new drugs. In a country where generic medicines accounts for more than 90 percent of the drug sales, the judgment for sure will raise many eyebrows among the global drug makers.

What is non-patentable under Section 3(d):

(d) 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 or the mere discovery of any new property or new use for a known substance or 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 reactant.

The underlying assumption of section 3 (d) is that derivative, such as salt forms, polymorphs, isomers etc that are structurally similar to known pharmaceutical substances are likely to be functional equivalent as well, and if this is not the case and the new form of an existing substance works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim to a patent.

The Glivec History

- In 1993, Novartis filed patent for the drug Imatinib, used for the treatment of chronic myelogenous leukemia (CML). Further research resulted in Imatinib Mesylate (IM), where it was discovered that beta crystalline (BC) polymorph of imatinib mesylate was most stable form and resulted in formulation of pharmaceutically useful drug **"Glivec".**

- In 1998 Novartis filed **patent application** for the said polymorph with Chennai Patent Office. Latter in 2002, Novartis also applied for exclusive marketing right (EMR) and was granted the same on November 2003. Consequently, on the basis of EMR Novartis sued generic drug makers before the High Court of Madras and Bombay.

- The Madras High Court maintained EMR and restrained the generic drug producers on the ground that Glivec is available to patients free of cost under a company donation scheme Glivec International Patients Assistance Program (GIPAP).

- However Bombay High Court disagreed with the ruling of Madras High Court. Besides this the validity of EMR was challenged by defendants.

- Cancer Patients Aid Association, Natco, Cipla, Ranbaxy, and Hetro Drugs Limited, India filed representations by way of pre- grant oppositions. The Assistant Controller of Patents and Designs passed five orders dated January 25, 2006 refusing to proceed with the application for patent.

- Novartis filed Writ Petitions on 17 May 2006 before the High Court of Madras challenging the validity of Section 3(d) of the Patens Act on the ground of the section being unconstitutional alleging that it violated Article 14 (Fundamental Rights) of the Constitution of India. It further contended that the section was not in compliance of Article 27 of TRIPS. The High Court by its order dated February 23, 2007 converted the said Writ Petitions into appeals.

- During the pendency of the Writ Petitions, the Central Government brought into force the provisions whereby which appeals against the order or decision of the Controller could be filed with the Intellectual Property Appellate Board (April 2, 2007).

- The Madras High Court by order dated April 4, 2007 transferred the said writ petitions to this Appellate Board. Incidentally this was the first case in India that was transferred to the Appellate Board.

- IPAB though held that although the beta crystalline (BC) version of IM (Imatinib Mesylate) was both novel and inventive, it failed the test under Section 3(d), which requires demonstration of *"significantly enhanced efficacy"*;

- Novartis then approached the Supreme Court challenging IPAB's order.

The Apex Court's decision will be welcomed not only by the generic drug makers but also by the social organizations and public health aid groups in India. Undoubtedly the decision would lead to lowering of drug prices of the patented drug and/or better availability. It is worth mentioning that in 2010-11, 30% of the total patent applications were filed in the field of chemical, drug and biotechnology (11934 out of 39400 applications filed with Indian Patent Office).

The Apex body's decision may therefore prove to be a major setback for the drug discovery and development programs in India and abroad and as a deterrent factor for innovators and MNCs that are contemplating investment in R&D and intellectual property in India.

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