Why did Supreme Court reject Novartis Cancer Drug Glivec Patent Plea

The Apex Court on 1st April 2013 pronounced a historic judgment in Novartis AG v. Union of India that settled the Indian position with respect to the grant of Patent protection to minor modified versions of life saving drug and cleared the air with respect to the scope and validity of Section 3 (d) of the Patents Act 1970 that was introduced by the Parliament by Amendment in the Act in 2005 to safeguard the access by the general public of affordable generic medicines. The Court was hearing the appeal petition of Novartis AG that was challenging the rejection appeal by the Intellectual Property Appellate Board (IPAB) of the patent petition of Novartis AG for the medicine Glivec. The Court was also hearing petition filed by Natco Pharma Ltd. and petition by Cancer Patient Aid Association seeking interpretation of Section 3 (d) of the Act and refusal of grant of patent to Novartis.

The dispute in the entire case centred on the grant of patent to beta-crystalline form of imatinib mesylate that was marketed in India by Novartis AG under the brand name of Glivec. Novartis was earlier in 2006 denied patent protection for the said medicine by the Indian Patent office on various grounds including section 3 (d) of the Patent's Act. Novartis AG was having patent protection in US for imatinib (Zimmermann patent) that was marketed under the brand name of Gleevecin the US and was now in India seeking patent protection for **beta-crystalline form of imatinib mesylate which it contended to be new product and invention outside the original patent (Zimmermann patent). The tablets of Imatinib (asmesylate) were sold as Gleevec in the US market.**

What is Patent

Patents are statutory rights granted by the State to the inventors or patent applicants for limited period of time for an invention in exchange of full discloser of invention so as to the inventions being made available for the benefit of the public at the end of the patent term. The patent holder has exclusive right to exclude others or stop others from making, using, importing or selling patented invention without his consent. The basic idea behind the grant of patent rights for inventions is that the inventor shall more likely be disclosing the invention and inventing in case the inventor is granted exclusive rights for the invention for a specified period of time. Patent are granted for inventions that are either processes and products that are new, involve an inventive step and are capable of industrial application. Here "new" refers to all those inventions that are not part of state of art that is something not known or used to/by the general public and "inventive step" refers to invention that is not known or obvious to a skilled person relating to the field.

Patents Amendment Act 2005

The Patents Amendment Act 2005 introduced the Section 3 (d) to the Patents Act that introduced the concept of product patent wherein patent or exclusive rights began to be granted for products. This section was with respect to medicines, drugs or other chemical compositions and provided for all those inventions that are not patentable. Section 3 (d) of the act provides that

mere “discovery’ of “new form” of already “known” substances are not patentable under the act unless they show “enhanced efficacy” in comparison to existing substance.

Reason behind Supreme Court Decision

The Supreme Court of India in the present case while looking into scope and interpretation of Section 3(d) observed that it was important for the court to understand “why”, “what” and “how” of the law to truly understand the essence of Law and therefore looked into history of Patents act and developments leading to the amendments in the Act.

Novartis in the Apex Court challenged the decision of IPAB and also sought a liberal interpretation of Section 3 (d). Novartis AG contended before the court that the development of beta-crystalline form of imatinib mesylate from imatinib was an invention and wasa “new” product and therefore qualified for fresh patent. Novartis AG also contended further that this form possessed pharmacological properties like better flow properties, better thermodynamic stability that showed improved efficacy and hence satisfied the test laid down by section 3 (d) of the Act.

The Apex Court rejected Novartis AG contentions and observed that the Act had provided two distinct concepts of inventions and patentability wherein the subject may satisfy the test of invention as provided by the Act but may still be not granted patent by virtue of the stipulations provided in the Act citing example of patents not being granted under the Act for inventions involving atomic energy. The Court further said that subjects in order to claim patent protection were required to therefore satisfy both the test of invention as laid down by section 2 (1) (j) and (ja) and test of patentability as provided by section 3 and 4 of the Act.

The court further said that the 2005 Amendment Act had clearly established that mere discovery of known substances or partial modification of already known molecules that donotresult in “**enhancement of known efficacy”** of the substance cannot be held as invention and cannot be patented under the Act. The court also said that here efficacy referred to **“therapeutic efficacy”** as efficacy shall depend upon the function, utility and purpose of the product that was under consideration and “**enhancement of efficacy”** as provided in explanation attached to section 3 (d) shall refer to all those properties that directly relate to “therapeutic efficacy” and held that mere change of formwith properties that are inherent to that form shall not help in qualifying “enhancement of efficacy”.

The Court relying on the above held that beta-crystalline form of imatinib mesylate was derived from imatinib and was not an invention outside the scope of original Zimmermann patent and just a mere discovery of a new form from imatinib with no proved enhanced efficacy. The court also relied on the fact that Novartis AG had sought patent in US for all beta and alpha forms of imatinib and imatinib mesylate but never sought patent for imatinib mesylate in non-crystalline as it had always maintained that imatinib mesylate was part of Zimmermann patent and never required fresh patent.

The court held that imatinib mesylate was known substance from Zimmermann patent and the development of bio-crystalline form imatinib mesylate cannot be called invention that could be

patented under Indian patent law. The court also held Novartis AG failed to show any enhanced efficacy as to the properties possessed by the beta-crystalline form of imatinib mesylate in comparison to imatinib in free base clearly failing the test laid down by section 3 (d). The court held that properties pointed by Novartis AG can be said to be properties of the imatinib in free base and did not showed any enhanced efficacy as required by the Act.

The Apex court also observed that section 3 (d) was a key public health safeguard introduced by the Parliament in the Patent Law to ensure that patents were not extended on spurious grounds especially to drug manufacturers or pharmaceutical companies who may with the grant of patent right monopolise important drug manufacture and prevent access to affordable generic medicines (cheap counterpart of branded medicines with same active ingredients as the original formulation that are sold without patent protection).

The Apex Court thus, through this judgment cleared the confusion over the interpretation of section 3 (d) of the Act and upheld the true spirit of the provision for which it was enacted. The bench comprising of Aftab Alam and Ranjana Desai observed during the course of judgment that Law of Patents in India could not be developed on artful drafting of claims by skilful lawyers or where the scope of patent was not determined by intrinsic worth of invention. The Court held that patents shall be granted only “true” and “genuine” products and not for partially modified versions which showed no improved efficacy.

The court through this judgment has also attacked prevalent industry practice of “ever-greening” where drug manufacturers seek fresh patent for minor modified versions of patented drugs so as to extend patent period just before the expiry of patent term (term during which exclusive patent rights are granted) of the original drug and to continue with the exercise of monopoly rights over the manufacture of important lifesaving drugs and prevent manufacture of these drugs by generic drug manufacturers.