S.S.RANA & CO.
ADVOCATES

How to analyze section 3(d) of Indian Patent Act?

Introduction:

Section 3(d) of the Indian Patent Act was first introduced in the year 2005, 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 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 reactant".

For example: salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The idea for introducing such an amendment was to prevent **'Ever-greening'** of patents. Federation of Indian Chambers of Commerce and Industry (FICCI) on 29 march, 2010 addressed that removal of section 3(d) would result in ever-greening.

Ever-greening- Ever-greening is any of various legal, business and technological strategies by which producers extend their patents over products that are about to expire, in order to retain royalties from them, by either taking out new patents (for example over associated delivery systems, or new pharmaceutical mixtures), or by buying out, or frustrating competitors, for longer periods of time than would normally be permissible under the law. Further explaining that: "Ever-greening, is referred to the practice whereby pharmaceutical firms extend the patent life of a drug by obtaining additional 20-year patents for minor reformulations or other iterations of the drug, without necessarily increasing the therapeutic efficacy."

US raised Opposition to Section 3(d) of the Indian Patent Act

Section 3(d) of the Indian Patent Act 1970 (amended in 2005) does not allow patent to be granted to inventions involving new forms of a known substance unless it differs significantly in properties with regards to therapeutic efficacy. Thus, the Indian Patent Act does not allow ever-greening of patents. This is a cause of concern to the US pharma companies.

Thus, on 30th April, 2014, USA brought out a special 301 report, which includes some flagged issues. These issues were:

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- Issues of inter-alia, concerns over the provision of section 3(d) of the Patent Act which relates to non-patentability of inventions involving chemical forms that do not show increased efficacy;
- Issues of Compulsory License by the Controller General of Patent, Designs and Trademarks under section 84 of the Patents Act; and
- Inclusion of a statement relating to Compulsory License for green technologies in India's National Manufacturing Policy and challenges relating to enforcement of IP Rights.

This special report 301 is a unilateral measure taken by the United States under their Trade Act, 1974 to create pressure on countries to increase Intellectual Property Rights (IPR) protection beyond the TRIPS Agreement.

India has a well-established legislative, administrative and judicial framework to safeguard Intellectual Property Rights which meets its obligations under the Agreement on Trade Related Intellectual Property Rights (TRIPS) while utilizing the flexibilities provided in the international regime to address its developmental concerns.

Case studies: For more clear projection of the section 3(d) we are discussing a landmark case "Novartis Ag v. Union of India". This is a landmark case concerning whether Novartis should be granted the right to patent Glivec® or Gleevec, which is an anti-leukemia drug.

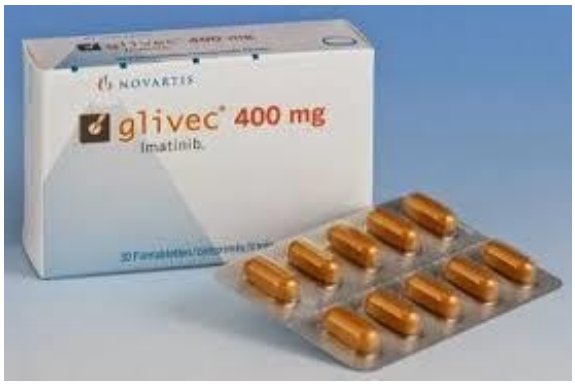

Image source: Internet

Background: The facts of the case have been summarized as:

- **On 17th July, 1998,** Novartis filed Indian patent application for the beta-crystalline form of **Imatinib Mesylate**. Imatinib Mesylate, which was in a product form had been accepted for product patent applications as per "mail box" process and the same was contemplated to be examined post January 1, 2005 once India introduced product patent regime. This

was in compliance with the requirements of TRIPS. The application was kept in mailbox as required under TRIPS and the Act till 1st January, 2005.

- In between **2002-2003,** Novartis applied for and was granted exclusive marketing rights (EMR) in relation to Product under the then existing Section 24A of the Act.
- On **1st January, 2005**, India introduced product patent regime and simultaneously amended Section 3(d) of the Act. Section 3(d) disallows patenting of a new variant of an already known substance unless such new form has significant efficacy over the older version. This was introduced with a view to prevent ever-greening of patents.
- In the year **2005** only, Novartis patent application attracted five pre-grant oppositions even before the application was taken up for the examination. These oppositions were filed by Cancer Patients Aid Association, NATCO Pharma, Cipla, Ranbaxy Laboratories and Hetro Drugs.
- On **25th January, 2006**, Assistant Controller of Patents upheld the pre-grant oppositions and rejected Novartis' patent application on Controller order. Grounds of rejection were-
  - application lacked novelty,
  - was obvious, and
  - was not an invention in view of section 3(d) of the Act.

  Controller held that the Product was a new version of an older molecule that Novartis first patented in 1993 and the increment in efficacy is not substantial enough to receive the grant of a patent.
- In **May, 2006**, Novartis filed writ petitions before the Madras High Court against the Union of India, the Controller General of Patents & Designs, Opponents, before the establishment of the appellate authority Intellectual Property Appellate Board (IPAB).
- **Novartis contended that:**

  (i) the Controller erred in interpreting the enhanced efficacy standard imbibed in Section 3(d) with regard to Product; (ii) Section 3(d) was vague, ambiguous and contrary to the requirements of TRIPs and that it violated Article 14 (right to equality) of the Constitution of India; and

  (iii) the Controller disregarded the in-house laboratory test performed by Novartis' scientists on rats to show that a 30% increase in bioavailability between Imatinib and Imatinib Mesylate was adequate to meet up the "enhanced efficacy" benchmark of section 3(d).
- In **April, 2007**, the Central Government issued a notification under Section 117G of the Act whereby all appeals from the order of Controller, pending before the High Court, were transferred to the IPAB set up in Madras. Therefore, the Madras High Court transferred the appeal from the Controller's order rejecting patent to the IPAB. However, the Madras High

Court, reserved the right to pronounce its judgment on the issue of the constitutional validity of Section 3(d) of the Act.

- On **6th August, 2007**, Madras High Court held that Section 3(d) does not violate Article 14 (right to equality) of the Constitution of India. This order was not appealed further by Novartis.
- On **26th June, 2009**, IPAB reversed the decision of the Assistant Controller on the issues of anticipation and obviousness. However, the IPAB held that the subject matter of the patent application was barred from patentability under Section 3(d) of the Act and therefore rejected the patent. However, it allowed the process patent for the Product.
- On **11th August, 2009**, Novartis filed a special leave petition (SLP) under Article 136 of the Indian Constitution in the Indian Supreme Court, against the order of the IPAB.
- On **1st April, 2013,** Supreme Court passed the Final order against Novartis.

Held by Supreme Court: Novartis had provided *no evidence* that the beta crystalline form of Imatinib improved the therapeutic effect of the drug. The Court never said that a change in bioavailability may never result in enhanced efficacy. The Court said that the patent applicant needed to demonstrate that there was a resulting enhancement in efficacy. The Court said that it appeared that Novartis was in fact marketing an older form of the drug and not the beta crystalline version. The Court said that it appeared that Novartis may have been trying to use a patent in India to cover a drug that it was not actually selling. The Supreme Court affirmed that India has adopted a standard of pharmaceutical patenting that is stricter than that followed by the US or the EU.

Conclusion: It is concluded that Section 3(d) does not violate the TRIPS mandate rather prevents frivolous patenting without neglecting valuable incremental innovations in pharmaceuticals and is very well compatible with TRIPS agreement.