Novartis case: background and update - Supreme Court of India to recommence hearing

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Tomorrow, a Division Bench of the Supreme Court of India, comprising Justice Dalveer Bhandari and Justice Deepak Verma, will re-commence the hearing of Novartis AG's (Novartis) challenge to the order of the Intellectual Property Appellate Board (IPAB) rejecting its patent application for *Gleevec* (beta crystalline form of imatinib mesylate), an anti-cancer drug used to treat chronic myeloid leukemia.

The outcome of this case will affect not only the patenting of this particular anti-cancer drug, but will also determine the position in India on patenting of new forms of already known drugs. Novartis has challenged the IPAB's interpretation of section 3(d) of India's patent law and its application to Novartis' patent application for the beta-crystalline form of an already known substance, imatinib mesylate.

Section 3(d) of the Patents Act is the public health safeguard in the Indian patent law that, amongst others, disallows patenting of new forms of known substances, unless the new form exhibits a significant enhancement in efficacy. It is one of the safeguards introduced by Parliament of India in 2005 to prevent evergreening. Evergreening is the practice of pharmaceutical companies to obtain patents on frivolous or minor changes to known drugs and thereby establish or extend their monopoly over a drug.

Due to the keen interest both domestically and internationally on this case, Lawyers Collective HIV/AIDS Unit, representing Cancer Patients Aid Association (CPAA) in these matters, will provide daily updates on the progress of the case. The reports will be factual updates without any comments as that is not permissible under Indian law relating to contempt. This initial posting will provide a brief factual and legal background leading up to the case.

Brief background

In 1997, Novartis AG, a pharmaceutical company based in Switzerland, filed a patent application in the Chennai (Madras) Patent Controller?s office for the beta-crystalline of imatinib mesylate, brand name *Glivec* (*Gleevec*) on the ground that it invented the beta crystalline salt form (imatinib mesylate) of the free base, imatinib.

Novartis' patent application was kept in the mail-box and not opened until 2005 as the TRIPS Agreement permitted developing countries such as India that did not provide product patent protection to pharmaceuticals and agrochemicals to introduce such product patent protection from 1 January 2005.

In the meantime, Novartis had obtained Exclusive Marketing Rights (EMR) for marketing *Gleevec* in India. On the basis of this, it obtained orders preventing some of the generic manufacturers from manufacturing and selling generic versions of the medicine. At that time, Novartis was selling * Gleevec* at USD 2666 per patient per month. Generic companies were selling their generic versions at USD 177 to 266 per patient per month.

In 2005, India amended its patent law to comply with its obligations under the TRIPS Agreement to provide process and product patent protection in all fields of technology, including pharmaceuticals and agrochemicals. Cognisant of patenting practices, Parliament introduced a significant and important provision to prevent evergreening and granting of frivolous patents' section 3(d).

After the 2005 amendment to the patent law, CPAA and other generic companies filed pre-grant oppositions against Novartis' patent application for imatinib mesylate, claiming, among other things, that Novartis' alleged "invention" lacked novelty, was obvious to a person skilled in the art, and that it was merely a "new form" of a 'known substance' that did not enhance the substance's efficacy, and was thus not patentable under section 3(d). These arguments were based on the fact that Novartis had already been granted a patent in 1993 in the United States and other jurisdictions for the active molecule, imatinib, and that the present application only concerned a specific crystalline form of the salt form of that compound.

CPAA and the generic companies contended that the 1993 patent effectively disclosed both the free base, imatinib, and the acid-addition salt, imatinib mesylate. Further, CPAA and generic companies argued that different crystalline forms of imatinib mesylate did not differ in properties with respect to efficacy, and thus the various forms of imatinib mesylate must be considered the 'same substance' under section 3(d).

Novartis' patent application rejected by Patent Controller [January 2006]

In January 2006, the Patent Controller in Chennai, in a landmark decision, refused to grant Novartis a patent, agreeing, amongst others, with the contentions of the CPAA and generic companies that the subject application lacked novelty, was obvious, and was not patentable under section 3(d).

The patent rejection meant that generic companies could manufacture and market their generic versions of the drug, both in India and abroad, and make available the generic imatinib mesylate priced at less than one-tenth of Novartis' price.

In June 2006, Novartis AG and its Indian subsidiary, Novartis India, filed a series of writ petitions against the Government of India, CPAA, and four Indian generic manufacturers (Natco, Cipla, Hetero and Ranbaxy), before the Madras High Court. These writ petitions challenged the decision of the Patent Controller to refuse to grant Novartis a patent for the beta-crystalline form of its anticancer drug, imatinib mesylate, as well as the validity of section 3(d) that provided one of several grounds for rejecting its patent application.

Over a period of time, the writ petitions challenging the decision of the Patent Controller were converted into statutory appeals. In April 2007, the Government of India notified the IPAB to hear appeals relating to patents. Consequently, Novartis' appeals were transferred to the IPAB, a specialist tribunal on matters relating to intellectual property.

Constitutional validity of section 3(d) upheld by Madras High Court [August 2007]

Meanwhile, in August 2007, the Madras High Court issued its decision rejecting Novartis' writ petitions challenging the validity of section 3(d). The Madras High Court refused to examine whether section 3(d) was in compliance with the TRIPS Agreement.

Novartis' primary contention in its challenge to the constitutional validity of section 3(d) was that the use of the term 'efficacy' in section 3(d) is vague and ambiguous, and therefore violates the equality provision (Article 14) of the Indian Constitution.

During the arguments, while conceding that the meaning of the term 'efficacy' is known, Novartis contended that because there was no clarity as to what constituted 'enhancement of efficacy' and 'significant enhancement of efficacy' as required by section 3(d), the law was vague and lent itself to arbitrary decisions by the Patent Controller. The Government of India, CPAA and generic companies argued that section 3(d) is not in violation of the equality provision of the Indian Constitution as the concept of efficacy is well-known to persons in the pharmaceutical industry and it is impossible to lay down a 'one size fits all' standard to determine what constitutes a significant enhancement of efficacy. Dismissing the petition, the Madras High Court held that section 3(d) was not vague or arbitrary and therefore did not violate the Indian Constitution. It held that the term 'efficacy' was known in the pharmaceutical field to mean 'therapeutic efficacy'.

While dismissing Novartis' writ petitions, the Madras High Court held: 'We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to it's citizens.'

Novartis AG did not challenge the judgment of the Madras High Court upholding the constitutional validity of section 3(d).

Appeal on merits rejected on the ground of section 3(d) [June 2009]

The next round of litigation then commenced before the IPAB. After a series of litigation in which Novartis contested the constitution of the IPAB, Novartis' appeal challenging the Patent Controller's order was finally heard by a specially constituted Bench of the IPAB, comprising Justice Negi (Chairperson) and Dr PC Chakraborty (Technical Member) in November and December 2008.

In its decision issued in June 2009, the IPAB overturned the Patent Controller's findings on novelty and inventive step and held that the beta-crystalline form of imatinib mesylate was new and involved an inventive step.

However, the IPAB held that Novartis' alleged invention did not satisfy the test of section 3(d) in as much as Novartis did not provide data to show that the beta-crystalline form of imatinib mesylate exhibited significantly enhanced therapeutic efficacy over imatinib mesylate, the known substance.

Primarily on the basis of this finding, the IPAB rejected Novartis' appeal and refused to grant it a patent for the beta-crystalline form of imatinib mesylate.

*Proceedings before the Supreme Court *

Challenging the IPAB's order, Novartis approached the Supreme Court directly by filing a special leave petition challenging the IPAB's interpretation and application of section 3(d) to its patent application. Subsequently, CPAA and Natco filed cross-petitions challenging the IPAB's findings on other issues including novelty and inventive step.

On 9 August 2011, the Supreme Court of India commenced final hearing of these matters.
Relying on the IPAB's findings that Novartis' patent application satisfied the tests of novelty and inventive step, Novartis is now challenging the IPAB's finding on section 3(d). Its argument is that section 3(d) that relates to 'discoveries' is inapplicable to its patent application which, having satisfied the criteria of novelty, inventive step and industrial application, is an 'invention' under the Indian patent law. [Section

2(1)(j) of the Patents Act defines 'invention' to mean 'a new product or process involving an inventive step and capable of industrial application'.]

Appearing for Novartis, Mr. Tehmtan R. Andhyarujina, Senior Counsel, urged that once it was established that the beta-crystalline form of imatimib mesylate was an 'invention', section 3(d) could not have been applied by the IPAB to reject Novartis' patent application. He said that the IPAB's holding indicated a complete non-application of mind in as much it held the beta-crystalline form of imatinib mesylate to be an invention and then applied section 3(d) 'a provision relating to discoveries' to refuse to grant
a patent to Novartis 'invention'.

Disputing the IPAB's holding that the term 'efficacy' in section 3(d) means therapeutic efficacy, Mr. Andhyarujina argued that the IPAB erroneously relied on the Madras High Court's interpretation of the term 'efficacy' to mean therapeutic efficacy in the pharmaceutical field. Referring to the IPAB's finding that the term 'efficacy' meant therapeutic effect in the pharmaceutical field and improved power of producing an effect in other fields, he urged that one term in the statute could not have two different meanings. In any event, he argued that neither imatinib nor imatinib mesylate had therapeutic effect and that it was only the beta-crystalline form of imatinib mesylate that had therapeutic effect. Reiterating Novartis' pleadings before the IPAB on the interpretation of the term 'efficacy', he argued that improved bioavailability and thermodynamic stability are properties that improved efficacy and that the beta-crystalline form of imatinib mesylate exhibited both these properties.

Continuing the arguments for Novartis, Mr. Gopal Subramaniam, Senior Counsel, reiterated Novartis' proposition distinguishing inventions and discoveries. He argued that the intention of the patent law was to provide patents to inventions. Once a patent applicant had satisfied the Patent Office that its patent application related to an invention as defined by section 2(1)(j) of the Patents Act by satisfying the tests of novelty, inventive step and industrial application, section 3(d) could not be interpreted or applied in a manner to destroy the primary purpose of patent law. He urged that pharmacological innovations must be given utmost protection because they are needed for humanity. Alluding to the patents granted to Novartis in numerous other jurisdictions for the exact same application, he argued that using section 3(d) to disallow patents for inventions would sound the death knell for patents and affect research and development for the entire sector.

Referring to the terms ‘discovery’ and ‘invention’ used in section 3, Gopal Subramaniam relied on several documents to establish the difference between ‘discovery’ (bringing to light something that existed before but was not known) and ‘invention’ (creation of something that did not exist). He then argued that section 3(d) could apply only where the substance was already in existence and was subsequently discovered, but not to inventions of new substances, as in the case of *Gleevec*.

Pointing out that section 3(d) required a comparison of known efficacies of the known substance and the new form of the known substance, Mr. Gopal Subramaniam argued that section 3(d) could only be applied if the efficacy of the known substance (imatinib) was already known. Referring to the IPAB’s finding that efficacy means therapeutic effect / efficacy, he said that clinical trials were necessary to establish therapeutic effect / efficacy. He urged that given that such efficacy had never been established for imatinib, it was not possible to demonstrate enhanced efficacy of the beta-crystalline form of imatinib mesylate over the efficacy of imatinib. In such a situation, he argued that section 3(d) could not have been relied upon to reject Novartis’ patent application.

On 11 August 2011, after hearing the arguments till forenoon, the Supreme Court adjourned the matters to 6 September 2011 for further hearing.

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