Novartis AG v. Union of India & Others
(Supreme Court of India, 1 April 2013)

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Summary

On 1 April 2013, the Supreme Court of India confirmed the rejection by the Indian Patent Office of a patent application filed by Swiss drug maker Novartis on the anti-cancer medicament "Glivec". The Supreme Court (hereinafter "the Court") considered that Glivec did not qualify as a patentable "invention" under Section 3 (d) of the Indian Patents Act.

The facts

Glivec is based on the original drug "imatinib". In 1992, Novartis filed a patent application for "imatinib", which also covered pharmaceutically acceptable salt forms of "imatinib". This patent was granted by the US Patent and Trademark Office (USPTO). Novartis received US Food and Drug Administration (FDA) approval for one salt form of imatinib, i.e. "imatinib mesylate", in 2001. As opposed to the original ("free base") substance imitanib, the salt form (i.e. mesylate) is soluble in the human body.

In 1997, Novartis filed a US patent application for a specific variation of imatinib mesylate, i.e. its "beta crystalline form", for which the USPTO eventually granted a patent. The beta crystalline form enables oral administration of imatinib mesylate.

In 1998, Novartis also applied for product patent protection for the beta crystalline form of imatinib mesylate in India. The Indian Patent Office rejected this application in 2006, based *inter alia* on the failure by Novartis to show "significantly enhanced efficacy" of the beta crystalline form over its original salt, i.e. imatinib mesylate, as required under Section 3(d) of the Indian Patents Act. This consideration was confirmed by the Indian Intellectual Property Appellate Board (IPAB) on 26 June 2009. Novartis appealed to the Supreme Court.

In order to meet the statutory requirement of enhanced efficacy under Section 3(d), Novartis in 2005 conducted studies to show *inter alia* a 30% increase in bioavailability of beta crystalline imatinib mesylate over the original substance imatinib.

The legal issues:

Novartis claimed that the subject matter of its patent application, i.e. beta crystalline imatinib mesylate, was based on two separate patentable inventions:

- The selection of the imatinib mesylate salt from the original substance imitanib;
- The development of the specific beta crystalline form of imatinib mesylate.

Imatinib mesylate

The Court came to the conclusion that imatinib mesylate lacked novelty, as it was already included in the claims to the original substance imatinib.[1] The Court based its opinion on a number of scientific articles that describe not only the free base, i.e.

[1] See especially paras 124, 125, 131, 132 of the judgment.

imatinib, but also its salt form, i.e. imatinib mesylate, and its anti-tumoral properties. In addition, Novartis, in patent infringement proceedings in Europe, had argued that the imatinib patent encompassed claims to the salt mesylate. According to the Court, a patent holder cannot claim a wide scope of an existing patent in infringement litigation but then claim a narrow scope of the same patent in the context of examining novelty of a salt derivative.[2] The scope of the original patent claims thus defines the teachings that are pertinent for the novelty test.

The beta crystalline form of imatinib mesylate

The Court accepted the IPAB's view that the original patent claims to imatinib did not encompass the claims to the beta crystalline form of imatinib mesalyte.[3] While the beta crystalline form could thus be considered novel, the Court decided that it did not meet the requirement of enhanced efficacy under Section 3(d) of the Patents Act and therefore constituted no patentable "invention" (i.e. rejection on subject matter grounds).

The Court interpreted "efficacy" in Section 3(d) as referring to **therapeutic** efficacy.[4] In this context, the Court observed that Novartis should have shown enhanced therapeutic efficacy of the beta crystalline form over the immediately preceding substance, i.e. imatinib mesylate. Instead, Novartis only compared the beta crystalline form to the free base substance, i.e. imatinib.[5] The Court considered that the particular **physico-chemical properties** of the beta crystalline form such as more beneficial flow properties, better thermodynamic stability and lower hygroscopicity were meaningless for the efficacy examination, as these properties "have nothing to do with therapeutic efficacy".[6]

Thus, the remaining and crucial issue before the Court was whether increased **bioavailability** of the beta crystalline form constituted enhanced therapeutic efficacy. The Court clarified that increased bioavailability alone does not always result in higher therapeutic efficacy, no matter whether the latter is understood in a narrow or a broader sense. The patent applicant needs to show, through the submission of clinical trials data, that in the particular case, higher bioavailability does result in increased therapeutic efficacy.[7] This may be explained by the fact that bioavailability as such only indicates the extent to which a drug reaches its site of action. This does not necessarily say anything about the actual effect the drug generates on the body. In this case, the Court emphasized that Novartis had failed to submit any evidence to show that increased bioavailability of the beta crystalline form actually increased the therapeutic effect of the substance on the human body.[8] Therefore the Court decided that the patent application had failed to clear the hurdle of Section 3(d) and that the decision of the Patent Office was correct.

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[2] See in particular para 143 of the Court's decision: "[…] It is, of course, a fundamental principle that the construction of a claim is the same whether validity [i.e. regarding novelty] or infringement [i.e. regarding scope of claims] is to be considered; **no patentee is entitled to the luxury of an 'elastic' claim which has a narrow meaning in the former but a wide meaning in the latter**. […]" (emphasis by the Court).

[3] See paras 124 and 158 of the decision.

[4] Para. 180.

[5] Paras 165, 171.

[6] Para. 187.

[7] Para. 189.

[8] Ibid.

The Court in the end clarified that its decision did not imply a general rejection of patentability of incremental inventions in the areas of chemical and pharmaceutical substances.[9] The Court did not say that increased bioavailability may never result in enhanced therapeutic efficacy. And it left open the exact definition of "therapeutic efficacy", which could be applied narrowly to only cover curative effect, or more broadly to encompass increased safety and less toxicity.[10]

Points of significance

- Provisions like Section 3(d) of the Indian Patens Act provide an operational tool for judges to prevent the patenting of incremental changes of existing products.
- Efficacy may be used as a criterion for examining the notion of "invention"/"patentable subject matter". Alternatively, it may also be used in the context of the novelty or inventive step examination.[11]
- In the absence of an express provision comparable to Section 3(d) of the Indian Patents Act, judges may nevertheless have recourse to the criterion of efficacy. In the case of product derivatives, similar chemical structures of the original and the derivative product will usually set a presumption of obviousness, which may only be rebutted by showing surprising effects of the derivative such as enhanced efficacy.
- The interpretation of the term "efficacy" will be decisive in this context. TRIPS leaves Members free to define efficacy in a broader sense (including non-therapeutic/physical efficacy, such as improved methods of drug administration) or in a narrow sense, as applied by the Indian Supreme Court (limiting the definition to therapeutic efficacy). Many drug derivatives will pass a broad test of physical efficacy, while failing a test of therapeutic efficacy.
- Improved bioavailability does not necessarily result in improved therapeutic efficacy.
- If the claims of an existing patent are interpreted widely to extend the scope of the patent to the greatest possible extent (e.g. in infringement litigation), this wide scope may be used by competitors to challenge the patentability of follow-on patents on derivatives of the patented product.

Key words

Section 3(d), efficacy, therapeutic efficacy, bioavailability, patentable subject matter, patentability, invention, novelty, inventive step, new forms, salts, derivatives, incremental innovation.

Available at: https://main.sci.gov.in/jonew/judis/40212.pdf

[9] Para. 191.

[10] See Frederick M. Abbott, « The Judgement In Novartis v. India: What The Supreme Court Of India Said", Intellectual Property Watch of 4 April 2013 (http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/?utm_source=post&utm_medium=email&utm_campaign=alerts).

[11] Para. 190 : « Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of 'patentability' or as an extension of the definition of 'invention', […]"