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Inside Views
The Judgment In Novartis v. India: What The Supreme Court Of India Said

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Intellectual Property Watch

By Frederick M. Abbott

As part of a series of amendments to the India Patents Act that took effect on January 1, 2005, the Parliament of India adopted Section 3(d). This statutory provision has been in force for more than seven years. A challenge brought by Novartis to the constitutionality of the provision and to its compatibility with the WTO TRIPS Agreement (World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights) was rejected by the High Court at Madras in 2007. That judgment was not appealed. On 1 April 2013, the Supreme Court of India rendered judgment [pdf] on an appeal by Novartis against rejection by the India Patent Office of a product patent application for a specific compound, the beta crystalline form of imatinib mesylate. Imatinib mesylate is used to treat chronic myeloid leukemia and is marketed by Novartis as “Glivec” or “Gleevec”. Affirming the rejection, the Supreme Court confirmed that the beta crystalline form of imatinib mesylate failed the test of Section 3(d). The Court clarified that efficacy as contemplated under Section 3(d) is therapeutic efficacy.

This judgment has attracted worldwide press coverage. It has received severe criticism from a number of originator pharmaceutical companies, including Novartis, and from the US Chamber of Commerce, to the effect the judgment of the Indian Supreme Court has dealt a harsh blow against the future of innovation, particularly in India. It is somewhat difficult to know why this decision interpreting Section 3(d) should come as a major surprise to anyone. Perhaps more important, it is difficult to understand what it is about the Supreme Court judgment that might so offend the sensibility of patent lawyers or government policymakers. The judgment is well-crafted, with close attention to the facts presented, and appears to take a balanced view of the matters brought before the Court. What did the Supreme Court of India say?

The case involves a substantial number of fairly complex technical issues, including some fairly complex legal issues. Without intending an injustice to that complexity, the main points made by the Court are these:

1. The express terms of the Patents Act as amended in 2005 reflect the considered judgment and will of the Indian Parliament as found in the legislative record. Section 3(d) was proposed by the Government with the stated purpose of addressing concerns raised by members of Parliament that the introduction of pharmaceutical product patent protection would substantially inhibit the availability of medicines for the population of India and developing countries more generally. Parliament sought to limit practices that might result in the grant of patents for insubstantial technological contributions. Parliament adopted in the Section 3(d) amendment, including the explanation, a requirement that patents for new forms of known substances should only be granted on the showing of a significant enhancement in known efficacy.

2. International legal rules accepted by India, in particular the WTO TRIPS Agreement, provide sufficient leeway or flexibility in the adoption of patenting standards to allow the approach adopted by the Indian Parliament.

3. The facts of this case involve certain transitional arrangements between the former pre-2005 Indian patent system which did not allow patents for pharmaceutical products, and the post-2005 regime under which such patents are permitted. For patent applications filed (with priority date) before 1 January 1995, a patent could not be secured in India for a pharmaceutical product. From 1995 to 2005, pharmaceutical product patent applications could be filed and held in a “mailbox”. A patent could be granted and become effective after 1 January 2005, based on a “mailbox application”.

4. In 1992, Novartis filed an initial patent application in the United States covering the drug “imatinib”, which patent application also covered pharmaceutically acceptable salts. It was subsequently granted a patent. Novartis applied for and received US Food and Drug Administration (FDA) approval for the marketing of a salt form of that drug called “imatinib mesylate”. The drug was placed on the market in that form in 2001.

5. In 1997, Novartis filed a patent application for a specific variation of the imatinib mesylate salt, the “beta crystalline” form. An examiner in the United States rejected this patent application, but the examiner was overruled by a Patent Office appeal board because the new crystalline form of the mesylate salt of imatinib involved a sufficient “manipulative step” under US patent law. The patent was granted for the United States.

6. In 1998, Novartis filed an application in India for this beta crystalline form. The application did not disclose any improvement in efficacy. However, when India adopted section 3(d) in 2005, Novartis undertook some studies to meet the statutory requirement to show enhanced efficacy.

7. The first issue before the Supreme Court was whether the mesylate salt form of imatinib had been disclosed, and was therefore publicly known, prior to 1997. On the basis of the documents, the Supreme Court found that it was. The mesylate salt was the form in which the drug was marketed. To satisfy the requirement of “enhanced efficacy” in section 3(d), comparison of the beta crystalline form had to be made with the already known mesylate salt. In light of this, the Indian Supreme Court found the efficacy studies reported by Novartis very odd. Novartis alleged that the beta crystalline form showed a 30% increase in “bioavailability” (based on tests in rats). But this 30% increase in bioavailability was not in comparison to the known and previously marketed mesylate salt form of the drug, which would ordinarily be soluble, but rather in comparison to the “free base” form of the imatinib drug that was not marketed because it was not soluble. So, Novartis did not compare its “new” form of salt to its “old” marketed form of salt, but rather to what it knew would be a much less bioavailable form. There was no evidence in the record as to how the new salt compared to the old salt even in terms of bioavailability.

8. The Supreme Court interpreted the meaning of “efficacy” in Section 3(d). It said that the new form of a drug must demonstrate an improvement in its therapeutic effect or curative property as compared to the old form in order to secure a patent. Novartis offered evidence that the beta crystalline form differed regarding certain properties relating to production and storage (e.g., heat stability). The Court held that these properties may be important from storage point of view, but would not be relevant to showing “enhanced therapeutic efficacy”.

9. As previously noted, Novartis also presented evidence regarding increased “bioavailability”. The Court observed that “bioavailability” measures the level at which the drug is made available in the human body. The level of bioavailability may or may not have an influence on the therapeutic or curative effect of the drug. In this case, the Court held that such effect was not demonstrated.

10. The Court discussed at some length the meaning of therapeutic efficacy in respect to pharmaceutical products, and observed that there are different possible meanings. The definition may be limited only to action resulting in a curative effect, or it might be more broadly extended to cover improved safety or reduced toxicity. The Court decided to leave open what is the appropriate definition of enhanced (therapeutic) efficacy – the narrower or broader interpretation – because it did not need to reach that question in this case. Novartis had provided *no evidence* that the beta crystalline form of imatinib improved the therapeutic effect of the drug. There was *nothing to measure*. The Court did *not* say that a change in bioavailability may never result in enhanced efficacy. It said that the patent applicant needed to demonstrate that there was a resulting enhancement in efficacy.

11. At the very end of the decision, in requiring Novartis to pay the costs of the challengers, the Court said that it appeared that Novartis was in fact marketing an older form of the drug and not the beta crystalline version, and 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. It suggested that this showed Novartis "in rather poor light".

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. For India, a patent applicant must not only show that a new form of known compound is different than an old form, but that the modification will result in an improvement in the treatment of the patient. There is in fact nothing new about such a standard. This was the approach followed by the US Patent Office up until a case decided by the Court of Appeals for the Federal Circuit, *In re Brana*, in 1995. Today, the Patent Office and Federal Circuit will approve patents for very minor modifications, supporting the practice known as "evergreening". This is a very expensive proposition for US consumers because it allows the manufacturers to market and sell higher-priced patent-protected versions of their popular drugs.

The Federal Circuit rationalizes this practice, saying that allowing patenting without demonstration of significant therapeutic effect encourages the development of new compounds, therefore encouraging innovation. But, this is just a theory about the best time along a continuum for granting a patent. It may well be that granting patents after researchers have demonstrated that drugs will accomplish something significant in terms of curative effect will encourage researchers to concentrate on achieving desirable end results, rather than winning marketing games. The race will not be won by the first person who creates a new compound, but the first person who creates a new compound and shows that it is therapeutically significant.

The Indian Parliament, supported by the Supreme Court, has decided that Indian consumers should only pay for expensive patented products when those products represent a genuine advance over older versions. It is important to note what the Supreme Court did not say. It did *not* say that a new form of known compound may never be patented. It did *not* say that improving the bioavailability characteristics of the drug may never result in enhanced efficacy. It left open the question whether enhanced efficacy refers narrowly to curative effect, or more broadly to improved safety profile and reduced toxicity.

From a patent law standpoint, it is rather difficult to discern what about the Supreme Court's decision strikes the US Chamber of Commerce, Pfizer or Novartis as some great threat to innovation or the long-term welfare of patients. It may put a damper on the profits of Pfizer or Novartis as they are less able to extend the life of patents by minor modifications that result in patients and public health systems paying more for drugs. But, one should be very careful of confusing the interests of the shareholders of Pfizer and Novartis with the interest of patients in the United States, Europe, India or Kenya. One might also be skeptical of claims from the industry that it will withdraw from the Indian market. Where there are profits to be made, the industry will be participating.

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