CASE STUDY

NOVARTIS AG V UNION OF INDIA AND ORS

(2013) 6 SCC 1

FACTS:

Jürg Zimmermann invented a number of derivatives of N-phenyl-2- pyrimidine-amine which is in free base form (Imatinib). These derivatives including Imatinib [2], are capable of inhibiting protein kinase C and PDGF, thus have valuable anti-tumor properties and can be used in the preparation of pharmaceutical compositions for the treatment of warm-blooded animals. The N- phenyl-2-pyrimidine-amine derivatives, including Imatinib, were submitted for patent in the US. The application was made on April 28, 1994 and patent was granted on May 28, 1996 under US Patent (the Zimmermann Patent). The Zimmermann compounds (i.e., derivatives of N-phenyl-2-pyrimidine-amine) were also granted a European patent.

The appellant claims that beginning with Imatinib in free base form in a two-stage invention they first produced its methanesulfonic acid addition salt, Imatinib Mesylate, and then proceeded to develop the beta crystalline form of the salt of Imatinib. According to the appellant, starting from Imatinib free base they could reach to the beta crystal form of Imatinib Mesylate in two ways: one "by digesting another crystal form, especially the alpha crystal form, or an amorphous starting material of the methanesulfonic acid addition salt and second "by dissolving another crystal form, especially the alpha crystal form, or an amorphous starting material of the methanesulfonic acid addition salt.

It was stated in course of submissions, that for practical purposes, the best way to produce the beta form is by proceeding directly from the free base form to the beta form, by introducing a specified amount of the beta crystals at the step specified.

The appellant filed the application for grant of patent for Imatinib Mesylate in beta crystalline form at the Chennai Patent Office on July 17, 1998. In the application claimed that the invented product, the beta crystal form of Imatinib Mesylate, has-

(i) more beneficial flow properties;

(ii) better thermodynamic stability; and

(iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate.

It further claimed that the aforesaid properties make the invented product "new" as it "stores better and is easier to process"; has "better processability of the methanesulfonic acid addition salt of a compound of formula I", and has a "further advantage for processing and storing".

The Assistant Controller of Patents and Designs heard all the parties on December 15, 2005, as provided under rule 55 of the Patent Rules, 2003, and rejected the appellant's application for grant of patent to the subject product by 5 (five) separate, though similar, orders passed on January 25, 2006 on the 5 (five) opposition petitions. The Assistant Controller held that the invention claimed by the appellant was anticipated by prior publication, i.e., the Zimmermann patent; that the invention claimed by the appellant was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermann patent specifications; and further that the patentability of the alleged invention was disallowed by section 3(d) of the Act; and also that July 18, 1997, the Swiss priority date, was wrongly claimed as the priority date for the application in India and hence, the alleged invention was also anticipated by the specification made in the application submitted in Switzerland.

At that time, the appellate authority under the Act had yet to become functional. The appellant, therefore, challenged the orders passed by the Assistant Controller in writ petitions filed directly before the Madras High Court. Apart from challenging the orders of the Assistant Controller, the appellant also filed two writ petitions (one by the appellant and the other by its Indian power of attorney holder) seeking a declaration that section 3(d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with "TRIPS". After the formation of the Intellectual Property Appellate Board (IPAB), the five writ petitions challenging the five orders of the Assistant Controller were transferred from the High Court to IPAB by order dated April 4, 2007, where these cases were registered as appeals. The other two writ petitions assailing section 3(d) of the Act were finally heard by a Division Bench of the High Court and dismissed by the judgment and order dated August 6, 2007.

The appellant's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB by a long and detailed judgment dated June 26, 2009.

Though agreeing with the Assistant Controller that no product patent for the subject patent could be allowed in favor of the appellant, the IPAB held that the appellant could not be denied the process patent for preparation of Imatinib Mesylate in beta crystal form. The IPAB ordered accordingly.

Against the order of the IPAB the appellant came directly to this Court in a petition under Article 136 of the Constitution.

As this Court now proceeds to decide the case on merits, it needs to be noted that after notice was issued in the SLPs filed by Novartis AG, all the five parties who had filed pre-grant oppositions before the Controller (hereinafter referred to as the Objectors) filed their respective counter- affidavits. Two of the Objectors, namely NATCO Pharma Ltd. and M/s Cancer Patients Aid Association, additionally filed Special Leave Petition, challenging the findings recorded by the IPAB in favor of Novartis AG. Leave to appeal has also been granted in all those SLPs, and hence, all the issues are open before this Court and this Court is deciding the case unbound by any findings of the authority or the tribunal.

ISSUE:

- What is the true import of section 3(d) of the Patents Act, 1970?
- How does it interplay with clauses (j) and (ja) of section 2(1)?
- Does the product for which the appellant claims patent qualify as a "new product" which comes by through an invention that has a feature that involves technical advance over the existing knowledge and that makes the invention "not obvious" to a person skilled in the art?
- In case the appellant's product satisfies the tests and thus qualifies as "invention" within the meaning of clauses (j) and (ja) of section 2(1), can its patentability still be questioned and denied on the ground that section 3(d) puts it out of the category of "invention"?

RULE:

Supreme Court firmly rejected the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann patent. It finds that Imatinib Mesylate is a known substance from the Zimmermann patent itself. Not only is Imatinib Mesylate known as a substance in the Zimmermann patent, but its pharmacological properties are also known in the Zimmermann patent. The consequential finding, therefore, is that Imatinib Mesylate does not qualify the test of "invention" as laid down in section 2(1)(j) and section 2(1)(ja) of the Patents Act, 1970.

ANALYSIS:

Arguments were made about India's obligation to faithfully comply with its commitments under international treaties and counter arguments were made to protect India's status as "the pharmacy of the world".

The Court was also reminded that an error of judgment by it will put life- saving drugs beyond the reach of the multitude of ailing humanity not only in this country but in many developing and under-developed countries, dependent on generic drugs from India.

In fairness to the appellant, however, it should be stated that the application was made at the time when there was a different patent regime. After the application was made and before it was taken up for consideration, a number of amendments were introduced in the Indian Patents Act, 1970, which brought about fundamental changes in the patent law of the country. The appellant was, however, fully aware of these changes in the law and, in order to reinforce its claim for patent for the subject product and to bring its claim within the four corners of the changed law, it filed four (4) affidavits of certain experts, two of which stated that the beta crystal form of Imatinib Mesylate has much higher bioavailability as compared to Imatinib in free base form. .

As noted above the patent application was made on July 17, 1998, giving July 18, 1997, the date on which the appellant had applied for grant of patent for the subject product in

Switzerland, as the "priority date". On July 18, 1997, Switzerland was not one of the "Convention Countries" as defined under section 2 (1)(d) read with section 133 of the Act and it was notified as a convention country as per section 133 of the Act on November 30, 1998.

CONCLUSION:

Initially some of the respondents strongly opposed the maintainability of the petitions made directly to this Court by-passing the High Court, but in the end, all agreed that given the importance of the matter.