Alert 413 - India – more good news for the generics industry as Supreme Court rejects Novartis appeal

When the Supreme Court handed down its decision on 1 April, a long running battle over the validity of Novartis's Glivec patent finally came to an end. Although the Court decided that Novartis's drug was not patentable, which is good news for the generics industry; it also gave some comfort to innovator companies and acknowledged the importance of patents in fostering research and the development of new medicines.

Background

Novartis's patent application (1602/MAS/1998) for β crystalline form of Imatinib mesylate, marketed under the brand name Glivec, was filed as long ago as 1998. Because at that time, India's Patent Law did not allow the patenting of pharmaceutical products, the application did not proceed, and Novartis obtained an Exclusive Marketing Right (EMR) pending the introduction into the Patents Act of provisions for the patenting of pharmaceuticals. When these provisions were introduced in 2005, and Novartis's application considered, five Pre Grant Oppositions were filed: one by an NGO, Cancer Patients Aid Association (CPAA), and four by generic companies. In January 2006, the Controller rejected the application, ruling in favour of the opponents.

As the Intellectual Property Appellate Board (IPAB) had not yet been established, Novartis appealed to the Madras High Court. The Court clarified the meaning of the term 'efficacy' and 'therapeutic effect', but because by then the IPAB had been established, it referred the case to the IPAB for decision. IPAB ruled that the invention claimed was not patentable as it fell within the provisions of section 3(d) of the Patents Act which provides, essentially, that a new form of a known substance will not be patentable unless it results in increased efficacy

Having failed in a challenge to the constitutional validity of Section 3(d) before the division bench of the Madras High Court, Novartis obtained special leave to appeal to the Supreme Court against IPAB's order.

The Supreme Court (SC) Judgment

The Court's ruling hinged on interpretation of Section 3(d). The Court noted that *'efficacy' is the ability to produce a desired or intended result. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under*

Consideration, Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy". Also noting that '*just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy and whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data.* The Court did not rule on the exact scope of 'therapeutic efficacy', leaving that to be determined by future courts.

In determining the additional bar to patentability introduced by Section 3 (d), the Court considered the jurisprudence and evolution of the section, which had been an attempt to meet both the obligations of TRIPS and the public health care needs of India. It also analyzed the sequence of events that led to discovery of the beta form of imatinib mesylate, and revisited the prosecution history of corresponding patent applications in the US to determine whether the claimed molecule was novel and not anticipated by existing prior art. It found that, for the purposes of Section 3(d), 'imatinib mesylate' (not imatinib free base, as had been argued by Novartis' counsel) was the 'known form'; 'imatnib mesylate' had been disclosed in the prior US Zimmerman Patent as example 21 in the patent specification. It was on this basis that the Court ultimately rejected Novartis's application to patent the beta crystalline form of imatinib mesylate.

Implications for Industry

Although the Court's decision favours the generics industry, it is soundly based on India's *Patent Law,* and leaves room for innovator companies in the future to satisfy the 'efficacy' requirements of Section 3(d) by reference to safety, bioavailability and toxicity factors. Importantly, the Court acknowledged the importance of patents in fostering research to develop new medicines and noted that Section 3(d) does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances.

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