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# IPA welcomes Supreme Court order in Novartis case

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The Indian Pharmaceutical Alliance (IPA) has welcomed the judgement of the Supreme Court of India upholding the refusal by the Patent Office to grant a patent to Novartis for the Î²-polymorphic form of imatinib mesylate. IPA calld it a landmark judgement that will serve to set at rest the controversy that was raised regarding the scope of section 3(d) in the Patents Act, which is a crucial safeguard against the extension of patent monopolies of known drugs and the consequent delay in the availability of affordable generic versions.

In an email statement mailed to BioSpectrum, Mr D G Shah, secretary general, IPA said, "Imatinib is on the National List of Essential Medicines and is an important drug in the treatment of several cancers such as certain blood and stomach cancers. The decision of the Supreme Court will come as a relief to patients suffering from these dreadful diseases as several Indian companies including Cipla, Ranbaxy and Natco can continue marketing imatinib at a fraction of the cost of the Novartis product."

"The IPA was an intervenor in the litigation before the Supreme Court as Novartis had raised far reaching questions of patent law which could potentially impact access to affordable medicines by extension of patent monopolies to new forms of known medicines. The IPA supported the refusal by the Patent Office to grant the patent to the Î²-polymorphic form of imatinib mesylate", said the statement further.

The interpretation of section 3(d) was the crux of the controversy. Section 3(d) prohibits the grant of patents to new forms of known substances, unless the new form results in enhanced efficacy over the known substance. The purpose of the section is to ensure that patent monopolies are not extended and generic versions delayed, unless the new form results in enhanced efficacy.

The first patent for imatinib and its salts, including the mesylate salt, was applied for by Novartis in Switzerland in April 1992 and thereafter in other countries. No application could be filed in India as drugs were not patentable at that time. Over five years later, in 1997, Novartis filed its first application in Switzerland for the grant of a new crystalline form of imatinib mesylate - the Î²-polymorphic form. This application was also filed in India in 1998. By this time, India was accepting patent

applications for new medicines, in conformity with the TRIPS Agreement and these applications were to be examined for grant after 2005.

The Patent Office rejected the patent application of Novartis for the Î²-polymorphic form of imatinib mesylate on various grounds in 2006, including that a patent could not be granted for the Î²-polymorphic form under section 3(d) as it did not have any increase in efficacy over the previously known substance. Novartis appealed the rejection of the patent by the Patent Office before the Intellectual Property Appellate Board (IPAB) in 2007, but the appeal was dismissed in 2009. Aggrieved by this dismissal, Novartis went up to the Supreme Court which has now confirmed the rejection of the patent.