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Supreme Court to hear Novartis case on Section-3(d) of Indian patent law on Nov 29

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The next hearing of Novartis vs Union of India case in Supreme Court regarding interpretation on Section-3(d) of the Indian patent law will be held on November 29, 2011. The court will be hearing the arguments on maintainability of Novartis' petition to Supreme Court.

The case was actually scheduled to be held on 17 January 2012, but it has been moved to an earlier date and will now be held on November 29.

The case is the final act in a legal battle over the patentability of the salt form of the anti-cancer drug imatinib and section 3(d) of the Indian patent law that stretches back over five years. In 2006, the Indian patents office ruled that Novartis did not deserve a patent for imatinib mesylate, a salt form of a life-saving cancer drug, on the grounds that the application claimed a new form of a drug too old to be patentable in India.

The company then embarked on a series of lawsuits against the Indian government including the one that is currently pending before the Supreme Court. In this case Novartis is challenging a part of India's patent law - Section 3(d) - which read with other provisions of the patent law and the Madras High Court decision says that a new form of a known medicine can only be patented if it is not obvious and shows significantly improved therapeutic efficacy over the known substance.

Section 3(d) of India's Patents Act prohibits 'evergreening' - the practice of multinational pharmaceutical companies to extend their patent terms by making small, trivial changes to existing medicines and thereby preventing access to generic affordable drugs. Under Section 3(d), patents will not be granted for new uses or new forms of existing medicines. However, some new forms of existing medicines may get patents if the company can demonstrate a significant increase in efficacy.

In 2006, when the Indian patent office ruled that Novartis did not deserve a patent for imatinib mesylate (Gleevec) on the grounds that the application claimed a new form of an old drug, the company embarked on a series of lawsuits. In 2007 in its constitutional challenge against Section 3(d) before the Madras High Court, Novartis also argued that increased bioavailability of the salt form of imatinib meant increased efficacy, entitling it to a patent on imatinib mesylate. But at the time, Madras High Court clarified efficacy to mean "therapeutic effect in healing a disease".

The Indian Patent Appellate Board (IPAB) – where appeals for unsuccessful patent applications are heard subsequently applied this interpretation, and held that the salt form of imatinib mesylate did not meet the test of therapeutic efficacy, and therefore confirmed the rejection of Novartis's patent application. Unhappy with this standard, Novartis is now before the Supreme Court to argue against the interpretation of efficacy by the Madras High Court and IPAB.

If Novartis succeeds, India may end up granting far more patents than required under international trade rules or envisioned by India's lawmakers, with huge ramifications on generic production and the availability of affordable medicines for people across the developing world, according to International humanitarian medical organisation Médecins Sans Frontières (MSF).