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Final hearing on Novartis' case on Sec 3(d) of Patents Act to begin in Supreme Court on Aug 22

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The controversial imatinib mesylate (Glivec) case between the Swiss pharma major Novartis AG and the Union of India & Others will be heard by the Supreme Court on August 22. In this long pending case, Novartis is challenging Section 3(d) of India's Patents Act which prohibits 'evergreening' - the practice of multinational pharma companies to extend their patent terms by making small and trivial changes to existing molecules and thereby preventing manufacture of generic drugs.

The Swiss pharma major moved supreme court (SLP-(C) No.20539-20549/2009) way back in 2009 after the Intellectual Property Appellate Board (IPAB) rejected its appeal for a patent on the beta-crystalline form of imatinib mesylate, an anti-cancer drug.

The case was pending in the court for quite some time. It was listed before the Supreme Court for several times since October 17, 2011. But the final argument in the case is yet to take place. After several adjournments, the case is now re-scheduled for final hearing on August 22, 2012.

The is the final act in a legal battle that stretches back to six years over India's future capacity to produce low-cost generic medicines for its people, and for patients in other developing countries. 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.