

Supreme Court rules against Novartis in Glivec case

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According to news reports just in, the Supreme Court has ruled against Novartis in the Glivec case and has rejected its plea for the grant of the patent for the drug molecule. Novartis had applied for a patent for the beta-crystalline version of the drug, on the basis of increased safety due to the modifications in the chemical entity. For more background see [here](#) and [here](#).

Mr. Ranjit Shahani, CMD, Novartis India has said that, "We fought this case because we strongly believe patents safeguard innovation and encourage medical progress, particularly for unmet medical needs. This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options."

Novartis maintained that even though 95% of patients receive Glivec through the Glivec Patient Access Program (GPAP), they still pursued the case to gain a clarity into the Indian patent system. An official statement from Novartis claimed that "The Supreme Court denial of Glivec patent clarifies limited intellectual property protection and discourages future innovation in India." Mr. Ranjit Shahani however added that the "GPAP would continue regardless of the judgement".

This has been hailed by NGOs and patient advocacy groups as a win over the notorious practice of evergreening. Section 3d of the Indian Patents Act, has special provisions against it. Leena Menghaney, India manager for MSF's Access Campaign said, "Patent offices in India should consider this a clear signal that the law should be strictly applied, and frivolous patent applications should be rejected".

According to TV reports, while reading out the judgement, the honourable judge in this case said, "the claim does not mean any standards of novelty and inventiveness". Also it has been said that the new patent cannot be granted, since it is not a major modification.

NGO's have called the decision as landmark one for affordable medicines for the general public. Dr. Unni Karunakara, MSF International president added, "Instead of seeking to abuse the patent system by bending the rules and claiming ever longer patent protection on older medicines, the pharmaceutical industry should focus on real innovation, and governments should

develop a framework that allows for medicines to be developed in a way that also allows for affordable access. This is a dialogue that needs to happen. We invite Novartis to be a part of the solution, instead of being part of the problem."

Cipla, one of the largest generic firms in the world, also produces the generic version of Glivec at less than 10 times its innovator price. Dr.Y.K.Hameid, non -executive chairman,Cipla commented,"The judgement in the Novartis case is a victory for patients both in India and around the world. We are pleased with the judgement which prevents the use of frivolous patents to deny access to medicines for patients. India, being the 'Pharmacy Capital of the World' can continue to produce affordable, high quality medicines without the threat of patents for minor modifications of known medicines. This judgement will not only benefit patients in India, but patients around the world."

Legally, Novartis can apply for a review petition, but experts claim that it will not have much impact on course of the decision.Novartis said that they had no comments on the same.

The Novartis Glivec case had gained mythic proportions during the last few years, in intellectual property circles, because of the anticipated effect on how big pharma would view India. In a press briefing after the judgement, Mr.Shahani himself commented that over the years, "Glivec (had)got a larger than life perspective."

The SC verdict comes close on the heels of a number of decisions going against the interests of the innovator pharma industry, such as revocation of patents and the grant of compulsory licenses. It remains to be seen, if the industry's popular claim that such an environment would hamper innovation and discourage big pharma from investing in India would hold true. Mr. Shahani too added,"I don't think anyone would want to invest given the current atmosphere."