

Novartis case hearing against Indian patent office on Sept 11

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Bangalore: The Supreme Court will take up the landmark case involving swiss drugmaker Novartis and India's patent office on September 11, 2011. The case was due to come up for hearing on August 22.

The swiss pharma major has filed a case against the patent office of India after it refused to grant a patent to Novartis on its cancer drug Glivec on the grounds that it is not a new medicine but an amended version of a known compound.

The Novartis website states that the decision on the life-saving drug was challenged because "we strongly believe (that) safeguarding incentives for innovation through the granting of patents leads to better medicines for patients". The company website also states that "working through the judicial system is a legitimate approach to gaining clarity on the unique aspects of India's patent law".

Patent attorneys and analysts have been closely following this case because of the impact it can have on the Indian pharma industry. Dr Ajay Kumar Sharma, associate director, Pharma & Biotech, Healthcare Practice, Frost & Sullivan, South Asia & Middle East, opines, "The fight is not about just Glivec (Gleevec in the US) actually, it is about figuring out how the Indian patent law is going to function. The outcome of the case will tell if there will be a transparency in the Indian patent laws. Any wrong decision now could be detrimental to the Indian pharma industry."

Irrespective of the decision, molecular generics of Glivec which are being made before 2005 will still be in the market. The bone of contention in this matter is whether India will accept Novartis' claim to patent. Dr Ajay Kumar added that the result of the case will have a huge bearing on the company's initiatives in India in the future. He said, "Actually, the Glivec story is done. The case is now more about understanding how the Indian patent system is going to react to such claims and if it will rightfully support innovation."The decision of the patent court,however could take a few more months to be fully comprehended," he added.

The patent would have been a blow to the domestic generic manufacturers of the drug even though generics launched before 2005 would stay in the market. (Read [Generics challenge pharma drug pricing regime](#))

The case hearing comes months after the [Nexavar compulsory licensing decision](#) by the Indian court that dealt a heavy blow to Bayer. The German firm was stripped of its exclusive right to sell Nexavar in India due to its high prices. Bayer AG has, however, demanded a withdrawal of the compulsory licence. Indian firm Cipla, which sells the drug in the country, has reduced its price by three-fourth. The case is presently before the Intellectual Property Appellate Board in Chennai and the next hearing is scheduled for September 3, 2012. The ruling has attracted wide spread criticism from the Western world, while at the same time, drawn appreciation from other countries such as China.

The Novartis case is important in the wake of the fact that India is an emerging market for drug companies from the West, while the country is also one of the biggest exporters of generic drugs. The ruling in the case could thus impact the introduction of new drugs into the Indian market by MNC drug companies.