

Manufacture of patented drugs for export under study

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Opposition from patent owner will be heard before decision is taken

Hearing scheduled in the Delhi Patent Office late next week

Natco has sought compulsory licences overriding patents on 2 anti-cancer drugs

CHENNAI: The government is to consider whether or not it should allow its drugs companies to manufacture patented medicines for export to poor countries at a hearing scheduled in the Delhi Patent Office late next week.

But, in an unusual step, it will hear opposition from the patent owner before it takes its decision.

The hearing is a response to India's first ever application for a manufacture-for-export licence under its 2005 Patent (Amendment) Act.

Hyderabad-based Natco Pharma has requested compulsory licences overriding patents owned by the Swiss company Roche on erlotinib and the U.S. company Pfizer on sunitinib — both are anti-cancer drugs. If the government agrees, it will be the second time an export licence has been granted for public health reasons since WTO members agreed on the trade provision in August 2003. The first was issued by Canada for the production of an HIV/AIDS drug for export to Rwanda.

"The Nepal government issued us an import licence and based on that we applied," M. Adinarayana told *The Hindu* on Saturday. Natco, which intends to produce 30,000 tablets of erlotinib and 15,000 of sunitinib, has offered the patent holders a 5 per cent royalty, in line with the WTO requirement to provide remuneration.

A test case

"The hearing is a test case for India" he said referring to S.92A of the Patent Act, which states that a licence will be issued to supply medicines to "any country having insufficient or no manufacturing capacity ... to address public health problems," but under terms specified by the Patent Controller.

The Patent office has done something unusual, he explains. For compulsory licenses, the government is empowered to take decisions based on the strength of the application alone.

"I intend to ask the patent office why it is allowing representation from the patent holder," he said. "And," he continued, "I also want to know what options there are for redress."

"These are the first compulsory licences under review in India and the outcome of these will decide how the mechanism operates," said Leena Menghaney of Medecins Sans Frontiers, who believes that the decision could improve the availability of many low-cost drugs for many diseases to distribute to the world's poorest countries.

"Compulsory licences," she said, "should be available for all essential drugs that are unaffordable and unavailable."

Because Natco has applied under S92A (for export only), if a compulsory licence were to be granted, Indians would not be able to buy the low-cost version produced by its industry.

In the case of erlotinib however, this could change.

The Delhi High Court is expected to rule soon on a case brought by Roche against Cipla for patent infringement after Cipla brought out its version of the drug in January.

But the patent on the drug may not be relevant if the drug is considered a derivative of gefitinib, licensed to Astra Zeneca, which does not qualify for an Indian patent because it was developed before India

agreed to introduce product patents in 1995. A compulsory licence would only be necessary if the patent stands.

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