

US' Gilead appeals against patent rejection of AIDS drug Viread

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NEW DELHI: US drug company Gilead Sciences has filed an appeal in the Indian [Intellectual Property](#) Appellate Board (IPAB) to challenge a recent order by an Indian Patent Office that rejected two patent claims for its best seller drug Viread (tenofovir disoproxil fumarate). In August, the Indian Patent Office in Delhi shot down two patents sought by the US firm for Viread after patient groups and Indian company Cipla challenged its patentability.

After India ushered in the new patent regime in 2005, the government provides 20-year [marketing](#) exclusivity for patented products. A patent rejection allows generic companies to market their low-cost version in the country.

“In August 2009, the Indian Patent Office issued unfavourable decisions in two opposition proceedings on two key patent applications that claim the invention of Viread, the first nucleotide to be developed and licensed as a treatment for HIV/[AIDS](#). The same claims have been issued by other patent offices worldwide, including the US, which confirmed the patentability of Viread after a rigorous re-examination process that concluded last year,” Polly Fields, an executive at Gilead Sciences, public affairs, said.

Viread is one of the world's most widely prescribed antiretroviral medications and raked in \$4 billion in 2008. Gilead has entered into licensing collaborations with 13 Indian companies allowing them to sell their generic drugs in India and 94 other countries by paying a 5% royalty, till Viread's patent expires in 2017. More than 80% of the world's 33 million people living with HIV live within these licensed territories.

In return, the Indian companies did not challenge Gilead's patent claim for Viread. The rejection of its patent means, Gilead will not get the royalty fees. But Mumbai-based Cipla refused to enter into the alliance and instead launched its drug at the risk of patent infringement before the patent order came. This means, if the patent order had gone in Gilead's favour, Cipla would have to pay damages to Gilead.

Gregg Alton, executive VP, corporate and [medical](#) affairs, Gilead, said its licensing model enhances patient access to medications, besides providing incentives for medical innovation. But an Indian industry executive said the Gilead model is a case of renting a house it does not own. Brazilian AIDS advocacy group Brazilian Interdisciplinary AIDS Association and Delhi Network of Positive People, are among those who have opposed Viread's patent in India.

Viread drug is a pre-95 molecule and, hence, cannot be patented under Indian laws. Its patent has also been rejected in Brazil. Access to the drug has been restricted due to licensing agreement and patient groups will challenge the appeal, said MSF's Access Campaign head for India Lenna Menghaney.