

# HC seeks Centre's reply on Gilead patent plea for Hepatitis C drug

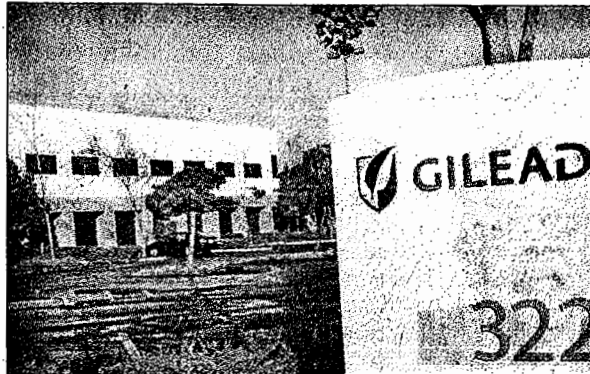
New Delhi, Jan 23

**T**HE DELHI High Court has sought the government's response on US-based pharma firm Gilead Sciences Inc's plea challenging rejection of its patent application for its Hepatitis C drug, sofosbuvir, marketed under the brand name Sovaldi. Justice Rajiv Shakdher asked the government's counsel to come with instructions on whether the matter needed to be remanded to the patent office for reconsideration or should the court hear it.

It also said the January 13 order of Deputy Controller of Patents and Designs would be subject to the final outcome of the writ petition filed by Gilead.

The court asked the government to file its reply before the next date of hearing if it wished to contest Gilead's plea. The matter has been fixed for hearing on January 30.

Hepatitis C is a viral infection affecting the liver and if left untreated, can lead to liver



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cirrhosis or liver cancer and has a high mortality rate. There are nearly 18 million Hepatitis C patients in India itself.

Gilead, represented by senior advocate Pratibha M. Singh, has challenged the January 13 order rejecting its application for patenting its expensive Hepatitis C drug, saying the decision was made

without following the procedure prescribed in the Patents Act, 1970.

As per reports, Sovaldi is priced \$84,000 for a 12-week course.

The US-company has said its patent application was rejected on the basis of documents contained in two pre-grant oppositions, filed by a pharma company and an

NGO, without issuing notice to Gilead or even hearing it.

Gilead's patent application was opposed by Natco Pharma and NGO Delhi Network of Positive People (DNP+) along with another entity Initiative for Medicines, Access and Knowledge (I-MAK) Inc. USA, the pharma company's petition said.

The rejection relates to the patent application covering the metabolites of sofosbuvir and the main patent applications covering sofosbuvir are still pending, the US pharma company said in its plea.

Gilead had last year entered into licensing agreements with seven India-based firms, including Cipla, Ranbaxy and Cadila, for the Hepatitis C drugs to make them available in 91 developing countries.

Gilead had said it planned to launch its own branded Sovaldi in India at a price of \$300 per bottle, while the Indian companies were allowed to fix their own price for the generic product they produce, paying a royalty on sales. *PTI*

*P. K. Singh*