

# Grant of Patent Will Not Lead to Any Increase in Sovaldi Pricing: Alton

Exec vice-president (corp) says a thorough and appropriate review of co's IP has occurred

ET Q&A

The recent decision of the Indian Patent

Office to grant patent to US drug maker Gilead for its blockbuster drug Sovaldi, after rejecting it last year, has come after a thorough and appropriate review, says company's executive vice president, corporate and medical affairs **Gregg Alton**. Brushing aside criticism from some experts, Alton tells **Vikas Dandekar** that the grant of the patent will not lead to an increase in the price of the drug. Edited excerpts:

**How would you respond to those who have criticised decision of the Indian Patent Office to grant the metabolite patent for Gilead's hepatitis C compound sofosbuvir?**

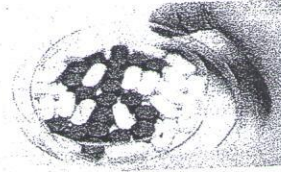
The original decision of the Patent Office in 2015 actually stated that the compounds covered in the application were both novel and inventive - a point that has been missed. In addition, this was not an appeal. The patent application was initially rejected by the Indian Patent Office and returned for further review by the Delhi High Court on a point of process. That restarted the application review and gave us the opportunity to formally address the pre-grant oppositions submitted, in hearings with all concerned parties conducted by the

Patent Office in February 2016. Regarding this decision, the Patent Office wrote that claimed invention is novel, non-obvious, and that Section 3(d) does not apply. A thorough and appropriate review of our IP, regardless of geography, is all we can ask for and we feel that this is what occurred.

This patent application has also been granted in 18 other countries including China, the Philippines, Russia and South Africa.

**What sort of gains do you expect following the grant of such a patent? Do you foresee an increase in prices of the medicines?**

This patent approval will have no impact on the pricing of Gilead's branded medicines. In addition, our licensees have been free to set whatever prices they wish for the generic versions they produce. This will continue. The competition generated between the 11 Indian manufacturers in our programme has already brought the price of generic sofosbuvir down to \$120 per bottle. Our aim is to make our medicines available to as many people as possible, as quickly as possible. The most commonly cited criticism of IP as a barrier to access is that patents allegedly prevent generic competition and enable



## TREATMENT FOR ALL

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**GREGG ALTON**

Gilead executive vice president, corporate and medical affairs

higher pricing than is affordable. Gilead believes that if used responsibly IP does not hinder access, and has supported a sustainable model of voluntary generic licensing for more than a decade.

Regardless of IP, we provide developing countries with significant discounts on branded hepatitis C medicines and access to generic versions through our programme of voluntary generic licensing.

**Is it true as some say that only Gilead has gained from the market competition while other companies have gained less than expected from sofosbuvir due to the intense competition?**

Our licensed manufacturing partners are all starting on a level playing field and creating competition between them to help drive down prices for the benefit of patients is the focus of the programme. However, improving access to treatment is not just about increasing availability of affordable drugs. Lack of affordable and reliable diagnostics is also a big issue.

Ultimately, to underpin the availability of these medicines, we need to support governments in adopting a public health approach to hepatitis C by creating a comprehensive awareness, prevention, screening and treatment strategy, so a robust marketplace can exist.

This will take time. If only individuals that are willing to pay out of pocket for medicines can access treatment, it will not support our goals of reaching as many patients as possible, or provide good returns to generic manufacturers. We have read that the Indian government is already looking at implementing a national programme - as have many other countries - and we welcome such proactivity.

Pricing