

**HOPE FOR HEP-C PATIENTS:**  
**PATIENTS SUCCEED IN OVERTURNING**  
**FIRST EVER PRODUCT PATENT ON MEDICINE IN INDIA**

**2 November 2012, New Delhi.**

In a landmark victory for patients' groups fighting against patents to ensure access to medicines, the Intellectual Property Appellate Board (IPAB) has revoked a patent granted in India to F. Hoffmann-La Roche AG (Roche) for pegylated interferon alfa-2a (Pegasys, a medicine used to treat Hepatitis C) as well as held that a patients' group can challenge the validity of granted patents.

Mr. Eldred Tellis, Director of Sankalp Rehabilitation Trust, who had challenged the patent, said, "We hope that the absence of patent barrier will spur generic competition to bring down the price of this much-needed drug for those suffering from Hepatitis C. We also hope that the Government will now take concrete steps to start providing access to this medicine. It is unacceptable that people are dying due to Hepatitis C because they cannot afford to buy the medicine."

As may be recalled, this patent granted to Roche in 2006 was the first product patent on a medicine in India under the new TRIPS-mandated product patent regime for medicines. The patent granted a monopoly to Roche to market pegylated interferon alfa2a. Patients with chronic Hepatitis C, who need a six-month course of treatment of Roche's pegylated interferon alfa2a, have to purchase it at a cost of approximately INR 4,36,000 [USD 8,752.38] (available at a discounted price of INR 3,14,496 or USD 6,313.28). Again, it has to be taken in combination with ribavirin, which alone costs INR 47,160 [USD 946.70].

Concerned about the impact of this patent on access to medicines, Sankalp—an organisation that provides treatment and rehabilitation support for injecting drug users—filed a post-grant opposition challenging the grant of the patent with technical and legal aid from Lawyers Collective HIV/AIDS Unit.

Mr Anand Grover, senior counsel and Director of Lawyers Collective HIV/AIDS Unit, who appeared for Sankalp in this matter, said, "This victory will facilitate early entry of generics which is likely to lower the prices. If this happens, millions suffering from Hepatitis C, both in India and globally, will benefit. It is also historic because this was the first ever product patent granted on a medicine in India since 1970."

Hepatitis C represents a huge public health problem in India and globally. An estimated 10–12 million people in India, including 50% of IDUs nationally and 90% of IDUs in the northeast, are infected with the Hepatitis C virus (HCV). Left untreated, Hepatitis C can lead to liver cirrhosis, liver cancer or liver failure. Hepatitis C is especially of concern for those co-infected with HIV, as several studies have shown that HIV-HCV co-infection leads to increased rates of disease progression. Injecting drug users are especially vulnerable to HIV-HCV co-infection with HIV-HCV co-infection rates as high as 93% among IDUs in Manipur. However, unlike both first- and second-line HIV treatment, which is available to all people living with HIV who need it, Hepatitis

C treatment is not available in government hospitals largely due to its high cost and treatment programmes do not even bother to screen patients for HCV due to the unavailability of treatment.

Despite Sankalp's case that Roche's claims did not satisfy the patentability requirements under Indian law, in 2009, the Patent Office rejected the post-grant oppositions filed by Sankalp and an Indian company and upheld the validity of Roche's patent. Sankalp then filed an appeal before the IPAB challenging this decision.

Before the IPAB, Roche also challenged Sankalp's standing to file the post-grant opposition as well as the appeal. Roche argued that because Sankalp was not a business competitor or a researcher in the sector, it could not have challenged its patent at all. Sankalp argued that its members were directly affected by Hepatitis C as well as that it represented a community of drug users who are particularly at risk to Hepatitis C. The IPAB observed that "public interest is a persistent presence in intellectual property law" and also held that it was against public interest to "allow unworthy patents to be on the Register". Holding that "the appellant who works for the community which needs the medicine, is definitely 'a person interested'", the IPAB noted that a successful challenge would "break the monopoly" and "bring the drug within reach of the community for whom it works, not only by reduction in cost, but also because of increase in supply".

Mr. Grover said, "We are happy that the IPAB has recognised the element of public interest in setting aside undeserving patents and held that patients' groups, who are directly impacted by patents on medicines, can challenge granted patents. This will be of import as concerned patients' groups will now have better clarity in challenging patents on medicines for HIV, cancer and other diseases."

Setting aside the patent, the IPAB held that Roche's pegylated interferon was obvious to a person skilled in the art. It also found that Roche has not provided any evidence, in the specification or even otherwise, to prove that pegylated interferon has enhanced efficacy. The IPAB, however, held that Roche's claims were novel.

Welcoming the findings on obviousness and section 3(d), Mr. Grover said, "The IPAB has rightly observed that the patentee used conventional methods to pegylate interferon and obtained predictable results, thereby rendering it obvious to a person skilled in the art. It also correctly held that the patentee has failed to satisfy the requirement of section 3(d) of showing enhanced efficacy. We hope that the Patent Offices too follow these standards while deciding pre- and post-grant oppositions."

The text of the order can be accessed at the website of the IPAB. We will upload a copy of the official certified copy on our website as soon as we receive it.

In solidarity,

**Lawyers Collective HIV/AIDS Unit and Sankalp Rehabilitation Trust, India**