

Indian authority withdraws patent for interferon granted to Roche

Meera Kay

Bangalore

India's Intellectual Property Appellate Board has repealed the patent granted to the drug company Roche for pegylated interferon alfa-2a (Pegasys), which is used to treat hepatitis C. The board's order represents a watershed in the history of patents in India and a victory for patients' groups fighting to widen access to drugs.

"This is India's first successful post-grant opposition case," said Eldred Tellis, director of the Sankalp Rehabilitation Trust, a non-governmental organisation that had challenged the patent. "And it is significant because the patent granted to Roche in 2006 was the first product patent on a medicine in India after the country switched to a product patent regime for medicines as mandated by TRIPS [the World Trade Organization's agreement on trade related aspects of intellectual property rights]." The Mumbai based trust provides care and support to street based drug users and seeks to prevent the spread of HIV in the city.

The order also gives hope to patients' groups wishing to challenge the validity of granted patents. The board said, "Public interest is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve. We therefore hold that the appellant who works for a community which needs the medicine is definitely a 'person interested.'"

The Sankalp Rehabilitation Trust said that because the patent gave Roche a monopoly to market the drug, it resulted in a high price for the product. Patients with chronic hepatitis C, who

need a six month course of treatment, have to buy it at a total cost of around 436 000 rupees (£5000; €6200; \$8000). Moreover, it has to be taken in combination with ribavirin, which costs 47 160 rupees.

Discussing the effect of the board's decision, Tellis said, "Virchow Biotech Private Limited, a Hyderabad based biotechnology company, was selling a biosimilar at a fifth the rate of Pegasys. Now we have to look for others who would be interested in producing a biosimilar which will be available at a lower price."

The trust said that an estimated 10 million to 12 million people in India, including 50% of injecting drug users nationally and 90% of injecting drug users in northeast India, are infected with hepatitis C virus. Hepatitis C is especially of concern in people co-infected with HIV, as several studies have shown that co-infection leads to increased rates of disease progression.

Unlike first and second line antiretroviral treatment, which is available to all people infected with HIV who need it, the hepatitis C treatment is not available in government hospitals, largely because of its cost.

The Intellectual Property Appellate Board's decision is at www.ipab.tn.nic.in/250-2012.htm.

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Pegasys patent timeline

Feb 2006—Roche was granted patent number 198952 by the Indian Patent Office for pegylated interferon alfa-2a (Pegasys)

May 2007—Sankalp Rehabilitation Trust filed its opposition to the grant

Mar 2009—Indian Patent Office rejected the trust's opposition

Late 2009—The trust filed an appeal with the Intellectual Property Appellate Board against the patent office's decision

Nov 2012—The board accepted the appeal and set aside the patent