

Indian Patent Office sets aside patent granted to Roche for valganciclovir

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In a significant decision, the Indian Patent Office at Chennai, in its decision on April 30, 2010, has set aside the 'patent' granted to Roche for valganciclovir. The Patent Office rejected the 'patent' primarily on the grounds that the claimed invention—valganciclovir, an ester prodrug of ganciclovir (a known compound)—lacked inventive step and did not satisfy the requirement of showing increased therapeutic efficacy as required under section 3(d) of the patent law.

In June 2007, Roche was granted a patent for valganciclovir in India, but the Chennai Patent Office took this decision without hearing the arguments of public interest groups, including the Indian Network for People Living with HIV/AIDS (INP+) and the Tamil Nadu Networking People with HIV/AIDS (TNNP+), that opposed the granting of the patent.

In December 2008, the Madras High Court in Chennai therefore decided to set aside Roche's patent until these arguments could be heard. The Chennai Patent Office, during the course of this hearing, refused to hear all the arguments made by the oppositionists and rejected the pre-grant opposition, after which the public interest groups approached India's Supreme Court.

The Supreme Court directed the groups to join the post-grant opposition proceedings that were already taking place through oppositions filed by generic companies and the Delhi Network of Positive People (DNP+). At this stage Roche challenged the legal standing of DNP+ to oppose the patent after it had been granted, claiming an ambiguity in India's patent law.

Having heard the arguments of all the public interest groups and the generic companies, the Indian Patent Office has now determined that Roche's claims for a product patent on valganciclovir were invalid and recognised only the validity of one of the process claims made by Roche. It has also held that patients groups can file post-grant oppositions.

Valganciclovir is an important drug for the treatment of active cytomegalovirus retinitis (CMV) infection that people living with HIV are susceptible to. If left untreated, the infection can lead to blindness without treatment. It is also an important drug for post operative treatment for patients who have received an organ transplant. CMV can be effectively treated with oral doses of valganciclovir consisting usually of 264 tablets given over four months.

Roche's price for valganciclovir is Rs 1040 per 450mg tablet and approximately Rs 2,74,560 per patient. The exorbitant prices of the drug and the grant of a patent to a new form of an old drug led DNP+ to challenge the patent by way of a post grant opposition. The challenge was based on several grounds including that valganciclovir lacked novelty, inventive step and that, being a new form of an old drug, it did not satisfy the requirement of increased therapeutic efficacy as required under Indian law.