

US Court rules Ranbaxy's generic valganciclovir does not infringe Roche's Valcyte patent

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In a verdict on the patent litigation between Roche Palo Alto and the Daiichi-Ranbaxy on the former's patent rights with crystalline valganciclovir, the active ingredient in anti-viral drug Valcyte, the District Court of New Jersey has ruled that Ranbaxy's generic version does not infringe the patent even as Roche's patent on the product is valid.

The verdict is on a complaint filed by Roche alleging Ranbaxy of patent infringement of the former's US Patent No 6,083,953, following an Abbreviated New Drug Application filed by Ranbaxy on amorphous form of valganciclovir with the US Food and Drug Administration (FDA) in 2006. Roche argued that the amorphous form of valganciclovir would change to the crystalline form and thus will infringe the '953 patent.

In its verdict issued of late, the Judge refused to agree with the argument stating that Roche failed to prove the spontaneous change of form in the generic product and that Ranbaxy's product contained crystalline form of valganciclovir. However, the court also stated that the patent '953 form crystalline form of the active ingredient is valid as Ranbaxy failed to prove that the patent is given on a known substance. The '953 patent is valid till 2015.

With the Court concluding that the generic version did not infringe original patent, whether Ranbaxy will go ahead with seeking marketing approval from the US drug regulator is yet to be known. "We welcome the positive judgement," said the Ranbaxy spokesperson and refused to comment on the future marketing plans.

Meanwhile, the verdict will give Ranbaxy room to seek marketing approval from the US FDA, unless Roche approach the senior court challenging the verdict, feels a patent expert. "It is almost sure that either Roche or Ranbaxy would approach the higher court with appeal. Otherwise, Ranbaxy has two options, either to approach the US FDA for approval, where they might need to submit additional data to prove that how the amorphous form is different from crystalline form, or have to wait for the expiry of the said patent. But we cannot predict which way the issue will move in future," said Dr Gopakumar G Nair, a renowned patent expert and CEO of Gopakumar Nair Associates.

In June 2008, Ranbaxy has received a tentative approval from the US drug regulator to make and market 450 mg tablets of valganciclovir hydrochloride, which prevents unnecessary cases of blindness. The first-to-file status on this is expected give Ranbaxy a potential 180 days marketing exclusivity once the patent expires in 2015.

However, the verdict will not have any impact on the on-going patent litigations between

Roche and Indian companies and patient group networks, said Dr Nair. Valcyte is known as the most effective antiviral treatment cytomegalovirus retinitis among HIV patients and in India, Roche is facing several patent litigations, mainly from Cipla Ltd, Ranbaxy Laboratories Ltd, Matrix Laboratories Ltd and patient groups Network for People Living with HIV-AIDS and Tamil Nadu Networking People with HIV-AIDS.

According to IMS, the global market research agency, the total annual market sales for valganciclovir HCl tablets for March 2008 was US\$ 239 million. The drug is also indicated for preventing cytomegalovirus (CMV) disease in kidney, heart and kidney-pancreas transplant patients at high risk (donor CMV seropositive/recipient CMV seronegative).