

Roche drops India patent for breast-cancer drug (Update)

August 17 2013, by Penelope Macrae

Swiss pharmaceutical giant Roche says it is abandoning a patent for top-selling breast cancer drug Herceptin in the Indian market, paving the way for local drugmakers to make a cheaper generic version.

The decision comes after an Indian health ministry committee earlier this year urged the government to issue a "compulsory licence" that would have obliged Roche to license a domestic generic firm to make a much cheaper copy.

"Roche has come to the conclusion not to pursue" the patent, the company said in an emailed statement to AFP late Friday.

Roche said its decision to relinquish its patent took "into account the strength of the particular rights and the IP (intellectual property) environment in India in general".

India's patent laws are tougher than in many other countries as part of attempts to make medicines more affordable to its vast poor population.

This has led to a string of patent setbacks in India for Western drugmakers which have been engaged in a series of intellectual property battles.

Indian patient rights groups accuse Western pharmaceutical firms of greedy pricing that denies impoverished patients in India and across the world access to vital medicines.

India, known as the "pharmacy to the world", has a huge generic drug industry that turns out cheaper copycat versions of life-saving branded medicines.

The active ingredient of Herceptin, used to treat an extremely aggressive form of breast cancer, was discovered before 1995 when India did not recognise patents.

To join the World Trade Organization, India had to change its law but it did not start recognising drug patents until 2005. Even then, it gave patent protection only to drugs discovered after 1995.

Roche obtained an Indian patent for Herceptin six years ago that involved a different composition of the drug.

But that patent was challenged by India's Cancer Patients' Aid Association as insufficiently innovative.

Indian law refuses patents for tweaks to drugs—so-called "evergreening".

"They (Roche) had seen the writing on the wall, they knew the Herceptin patent had been granted on very shaky legal grounds," Kalyani Menon Sen, a leading campaigner for affordable medicines, told AFP.

Earlier this year, India said in a ruling on Novartis's leukaemia drug Glivec that no new patent for a reformulations of an old medicine could be granted unless they displayed a "significant therapeutic improvement".

Like Roche's Herceptin, Glivec's main ingredient was discovered before 1995.

Roche did not disclose its price for Trastuzumab, sold under the brand name Herceptin, but said it had a "local pricing policy".

Patient rights groups said the drug cost 92,000 rupees (\$1,490) for a single dose, and called the price "exorbitant" in a country like India.

"More than a million women (in India) have been diagnosed (with aggressive HE2+ breast cancer) in the six years that this patent has been in force—with less than 10 percent able to access the drug," Sen said.

Roche said Herceptin would remain on sale in India. It has global patents on Herceptin running through 2019.

It noted there were "no approved bio-similars (copies) of Herceptin in India" yet but Sen said two Indian firms are working on generic equivalents.

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