

India revokes cancer drug patent in fresh industry blow

August 2 2013, by Penelope Macrae

India has revoked a local patent granted to Britain's GlaxoSmithKline for a breast cancer drug in the latest blow to global companies seeking a bigger presence in the country's \$13 billion medicine market.

Tykerb, one of the most widely prescribed [breast cancer](#) treatments in India used to treat advanced forms of the disease, is a newer version of GlaxoSmithKline's (GSK) original anti-[breast cancer drug lapatinib](#).

The Indian patent board revoked the patent for Tykerb, calling it an incremental improvement of the original compound and not sufficiently innovative to warrant a patent.

The ruling underscores Indian authorities' tough stance against what is called "evergreening" or minor changes to a drug to extend its patent shelf life, said lawyer Dominic Alvares, part of the team which challenged GSK's Tykerb patent.

"India has some of the toughest patent laws—and they are based on public interest," Alvares, of S. Majumdar and Co, told AFP.

Once drugs go off patent, they can be sold more cheaply. India is known as the "pharmacy to the world" for its huge generics industry that turns out cheaper copycat versions of life-saving branded drugs for poor patients in developing nations.

The Tykerb ruling comes after the Supreme Court in April struck down

a patent for an updated version of Swiss giant Novartis's blockbuster drug Glivec used to treat a deadly form of leukaemia.

Novartis had argued the compound was a significant improvement because it was more easily absorbed by the body but the court said it did not pass the test of innovation.

Experts then said the Novartis court ruling could pave the way for a rush of similar Indian decisions.

The latest ruling only affects GSK's newer patent, not the original patent for the main active ingredient in the drug, lapatinib, which expires in 2019.

For the first time, the patent board acted on a complaint filed by another international [pharmaceutical firm](#) rather a local Indian company.

The challenge to GSK's patent was launched by an Indian subsidiary of German health group Fresenius. It had disputed the patents both for the original molecule and Tykerb.

"We are pleased that the Intellectual Property Appellate Board in India has upheld our basic patent for the lapatinib compound, the active ingredient in Tykerb," said a GSK official who did not wish to be named.

"We are, however, disappointed that the board has revoked our later expiring [patent](#) (in 2021) for the lapatinib ditosylate salt," the official said, adding GSK was considering an appeal.

Western drug-makers are seeking to win a larger part of India's rapidly expanding drugs market, valued at around \$13 billion, to compensate for slowing sales in advanced markets.

But they say that India fails to respect intellectual property rights.

"Intellectual property protection is an important aspect in ensuring innovation is encouraged and appropriately rewarded," the GSK official said.

India earlier did not grant drug patents but resumed awarding them in 2005 as part of a World Trade Organization agreement.

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