

## India generics giant wins cancer drug patent case

## September 8 2012

Indian generics giant Cipla says it has scored a "landmark" court win in a patent challenge launched by Switzerland's Roche Holding over the Mumbai firm's version of a lung-cancer drug.

Delhi High Court Justice Manmohan Singh on Friday ruled that Cipla's drug, Erlocip, did not violate the Roche patent on its anti-<u>lung cancer</u> medication Tarceva due to its different molecular make-up.

"It's a landmark judgment in a patent case," Pratibha Singh, a patent lawyer who represented Cipla, told Mint newspaper. "The court has taken all efforts to analyse claims of both parties in terms of legality and scientific evidence."

No further details of the judgment were available.

The Cipla court case was being watched worldwide as it involved interpretation of stricter drug patent protection rules introduced by India in 2005 to comply with <u>World Trade Organization</u> regulations.

India is the world's leading exporter and manufacturer of non-branded medicines and medical charities have expressed concern that compliance with WTO trade rules could reduce the country's role as a supplier of cheap medicines.

Roche's Tarceva is priced at 140,000 rupees (\$2,533) for a month's supply, though it has discount schemes to make the drug more



affordable for poorer people, the newspaper said, while Cipla's version is priced at 25,000 rupees.

It was not immediately known whether Roche would appeal the ruling.

The decision could act as a precedent for a string of other Indian generic firms also facing patent challenges from Roche over their versions of Tarceva.

The Delhi ruling came ahead of a high-profile battle expected to start Tuesday in India's Supreme Court over a bid from Swiss firm Novartis for <u>patent protection</u> for its top-selling <u>cancer treatment</u> drug Glivec.

The Novartis case could have significant implications for multinational drug firms, determining how much protection they will receive under India's <u>patent law</u> from cheaper generic rivals.

Novartis filed in 2006 a <u>patent application</u> in India for Glivec, used to treat blood and gastrointestinal cancer but a lower court rejected the request, saying the drug was a new formulation of an existing product.

The Novartis' challenge goes to the heart of India's patent act, which says a patent cannot be granted for an old drug unless changes make it significantly more effective.

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