

# Novartis Fights Patent Rejection In Indian Court

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In a case that could affect India's role as drug provider to the developing world, the Supreme Court began hearing arguments Tuesday over whether the government had the right to deny a patent to Swiss drugmaker Novartis AG for its lifesaving cancer treatment Gleevec.

A victory for the company, aid groups warned, could open the door to patenting dozens of other generic medicines made by India's \$20 billion drug industry and sold to needy nations at far lower costs than those charged by Western drug manufacturers.

"There will be nothing left to defend if we lose," said Leena Menghaney of Mediciens Sans Frontieres, or MSF. "The generic industry is just going to pack up and leave."

The case, launched soon after India passed its Patent Act in 2005, revolves around a legal provision aimed at preventing companies from seeking patents or extensions based on minor changes to existing treatments — a practice known as "evergreening" that is common in Europe and the United States.

The provision has allowed India to reject patents for a range of older drugs for cancer, AIDS, tuberculosis, malaria and other illnesses that are made by India's generics industry.

It also led to the rejection of Novartis' application for Gleevec, in which it argued a newer, more easily absorbed version qualified for a patent because it was demonstrably more effective. The blockbuster drug keeps chronic myeloid leukemia and some other cancers in remission. Its earlier version was ineligible for an Indian patent because the country gives no protection to drugs invented before 1995.

Novartis insisted the revamped Gleevec, marketed outside the United States as Glivec, represents a unique breakthrough rather than just a tweak to the old formula, and that the Indian law "intended as a hurdle for 'evergreening' is not applicable at all," the company said in a statement.

But Indian patent officers and an appellate court said the change only amounted to an obvious development on an existing treatment. It's not known when the Supreme Court might rule.

Novartis now is arguing for a wider understanding of the provision requiring innovation toward improved drug efficacy, hoping to set a legal precedent it says is key to preserving financial incentives for companies to develop new drugs.

"We believe there are important issues to be addressed that are essential to the future of intellectual property law in India and the viability of the innovative pharmaceutical business in this country," the company statement said.

Lawyer Anand Grover for the Cancer Patients Aid Association, which has joined the government to defend the patent rejection, said Novartis' stance represents "a very dangerous argument" to India's effort to prevent patent abuse.

The case is just one of many challenges to India's generics industry, which has frustrated multinational pharmaceuticals since 1972 when India decided not to recognize patents on drug products and began churning out low-cost copies of branded medicines.

Current trade talks with the European Union have snagged on the issue of intellectual property, with EU officials wanting stricter provisions that activists say would also kill the generics industry.

India now makes one-fifth of the world's generics, sending about half abroad.

Given India's own enduring poverty — with more than 800 million people living on less than \$2 a day — many argue the limits still make sense domestically, particularly as Indian patients bear at least 80 percent of their own medical costs.

Branded and patented drugs are often 10-40 times pricier than generics, said Dr. Amit Sengupta of the People's Health Movement. In the case of Gleevec's generic equivalent, a monthly treatment in India costs about 8,000 rupees, or \$175 — one-fifteenth the \$2,600 price charged by Novartis in the country.

"That is really the margin between life and death," Sengupta said, particularly if the verdict leads to more drug patents on older products relied on globally. In treating HIV, for example, the medical charity MSF says it buys 80 percent of its medicines from India.

The pharmaceuticals "don't even care if people live or die so long as they make their money," said AIDS activist Loon Gangte of the Delhi Network of Positive People. "We can't let them win."

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