

# A victory for Novartis could spell death for millions

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The Swiss pharma giant fighting in Supreme Court for patent on anti-cancer drug

A case being heard in the Supreme Court on Tuesday could signal a death sentence for Loon Gangte.

Mr. Gangte is not accused of any crime. But he — and thousands of other HIV positive people — will be avidly following the Supreme court's hearing of the Novartis vs Union of India, Cancer Patients Aid Association & others, because if the Swiss pharmaceutical giant wins its case, the drugs that keep Mr. Gangte alive could become too expensive for him.

“For us, it's about life and death,” Mr. Gangte said on the eve of the hearing. “We can't let them win.”

In the latest battle of a six-year long war, Novartis has taken the Indian government to court, challenging the legal interpretation of a critical public health safeguard in the nation's patent law — Section 3(d) — that limits the patenting of new forms of old medicines. If Novartis wins, much of the Indian generic drug industry — which acts as the pharmacy for the entire developing world — could be in trouble.

The Swiss company is fighting for a patent on a new crystalline salt form of the anti-cancer drug imatinib mesylate, which it sells under the brand name 'Gleevec'. Since the original molecule is out of patent in India, generic drug companies produce and sell Gleevec to chronic myeloid leukemia patients for about Rs.8,000 per month, while Novartis sells the drug for about Rs.1.2 lakh per month. A patent on the new form could give Novartis a 20-year monopoly on the drug, thus “ever-greening” the patent.

In 2006, the Indian patent office ruled that the new salt form did not deserve a new patent, since it did not meet the provision of “increased efficacy” required under Sec. 3(d). Novartis argued that the salt form would have higher levels of availability in the body of the patient, but the Madras High Court clarified that “efficacy” means “therapeutic efficacy in healing a disease”. Having lost its case in the lower court, Novartis is now asking the Supreme Court to interpret “efficacy” in a way that will allow its patent.

So why does a case about an anti-cancer drug matter to an HIV positive person like Mr. Gangte?

“This is the first such case to reach the Supreme Court, and it's being viewed as a test case by the industry,” says Amit Sen Gupta of the People's Health Movement. “It would open a Pandora's Box.”

Patent applications for a number of other drugs, including treatments for HIV/AIDS and tuberculosis, have been withdrawn or denied on the basis of Sec 3(d). If the provision is diluted, the cost for these treatments could shoot up by up to 40 times, making them unaffordable for the majority of patients.

“I was diagnosed in 1997, but I could not afford treatment at all until the Indian generic drugs started becoming available four years later,” says Mr. Gangte, who is secretary of the Delhi Network of Positive People. “The government started its own free HIV treatment programme in 2004, once cheaper generics were freely available.

It is not just Indian patients who are worried. “About 80 per cent of anti-AIDS drugs and 92 per cent of drugs to treat children with AIDS across the developing world comes from the Indian generic manufacturers,” says Leena Menghaney of Medecins Sans Frontieres (translated from French as Doctors Without Borders). “India is literally the lifeline of patients in the developing world, especially in the poorest parts of Africa...If Sec. 3(d) is overturned, it means any meaningful effort to make these vital medicines available will be put in jeopardy.”

“When I look through my photo albums from the early years, I can see that almost all those friends are now dead,” says Mr. Gangte. “I hope the Supreme Court does not condemn us all.”

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