India's top court to deliver Novartis judgment

31 March 2013, by Nirmala George

In this Jan. 29, 2007 file photo, Indian police officers block demonstrators protesting against Swiss drugmaker Novartis AG's case against the Indian government on drug patents in New Delhi, India. India's Supreme Court is to rule Monday, April 1, 2013, whether to deny a patent to Novartis AG for its cancer treatment in a landmark case that would allow Indian companies to continue producing cheaper versions of many lifesaving medicines. (AP Photo/Saurabh Das, File)

India's Supreme Court is to rule Monday on a landmark patent case involving Swiss drugmaker Novartis AG that focuses on demands by major companies that their investments be protected, against Indian companies that say they should be allowed to continue producing cheaper generic versions of many lifesaving medicines.

A decision in the seven-year legal battle is keenly awaited by the two most interested parties— big pharma companies and health aid groups—with both sides saying the outcome will set a precedent with far-reaching consequences for the future availability of the drugs.

"Across the world, people rely on India for supplies of affordable versions of expensive patented medicines," said Leena Menghaney of Doctors Without Borders. "This case will have fundamental consequences."

The case goes back to 2006 when Novartis' application for a fresh patent in India for its cancer drug imatinib mesylate was rejected by the Indian patent office.

The patent authority cited a legal provision in India's 2005 patent law aimed at preventing companies from getting fresh patents for making only minor changes to existing medicines—a practice known as "evergreening."

The drugmaker has argued that its leukemia drug Gleevec, known in Europe and India as Glivec, was a newer, more easily absorbed version that qualified for a fresh patent.

The company filed an appeal, but India's patent appeals office turned it down in 2009 on the grounds the company was unable to show significant increase in efficacy of the drug.

Novartis then approached the Supreme Court in August 2009, which heard arguments seeking to challenge the interpretation and application of India's patent law in the case.

Gleevec, used in treating chronic myeloid leukemia and some other cancers, costs a patient about $2,600 a month. Its generic version was available in India for around $175 per month.

"The difference in price was huge. The generic version makes it affordable to so many more poor people, not just in India, but across the world," said Y.K. Sapru, of the Mumbai-based Cancer Patients Aid Association.

The case once again pits big pharmaceutical companies against health activists and aid groups with both sections arguing that the judgment would

be an important milestone for the future of the pharmaceutical industry worldwide.

"The Novartis verdict is important because it will determine whether India gets to limit patents to genuine new drugs, or whether drug companies get to "evergreen" their patents until eternity, simply by re-patenting a slightly modified version of a known substance," said Ellen 't Hoen, a pharmaceutical law and policy consultant.

Western pharmaceutical companies have warned that a rejection of Novartis' application would discourage investment in research and innovation, and would hobble drugmakers' efforts to refine and improve their products.

The international drug majors have been pushing for stronger patent protection in India to regulate the country's $26 billion generic drug industry, which they say often flouts intellectual property rights.

In a statement sent to The Associated Press late last year, Novartis said patent protection was important to ensure effective protection for innovation.

"Knowing we can rely on patents in India benefits government, industry and patients because research-based organizations will know if investing in the development of better medicines for India is a viable long-term option," the company said.

Groups such as Doctors Without Borders say cheaply made Indian generics are a lifesaver for millions of patients in poor countries who cannot afford to pay Western prices to treat diseases such as cancer, malaria and HIV.

India, which has emerged as the world's pharmacy for the poor, has come under intense scrutiny from pharmaceutical giants who say India's 2005 Patent Act fails to guarantee the rights of investors who finance drug research and development.

The country's recent decision to allow a local manufacturer to produce a generic version of Bayer's patented cancer drug Nexavar, to make the drug available to the public at a reasonably affordable price, has also not gone down well with Western pharmaceutical companies.

Health and aid groups were clearly nervous before the top court rules on the Novartis case.

"Generic companies depend on the freedom to operate. If there are too many intellectual property-related challenges, then the companies very quickly withdraw from making that drug," said Menghaney.

The groups fear that a ruling in favor of Novartis would lead to a proliferation of patents—some based on a minor tweaking of formulation and dosages—on dozens of other generic medicines that Indian companies have been producing and supplying to needy nations at far lower costs than those charged by Western drug manufacturers.

And the fallout of the judgment will be felt across the world, says Menghaney. "It's not just about India."

"If generic competition on many crucial medicines ends, then prices for these medicines will increase, both in India and across the developing world. This would be devastating for millions who rely on India for affordable medicines."