# India's rejection of drug patent could reverberate

April 1 2013, by Linda A. Johnson


A cameraman films the head office of Novartis India Limited in Mumbai, India, Monday, April 1, 2013. India's Supreme Court on Monday rejected drug maker Novartis AG's attempt to patent a new version of a cancer drug Glivec, in a landmark decision that healthcare activists say ensures poor patients around the world will get continued access to cheap versions of lifesaving medicines. (AP Photo/Rafiq Maqbool)

The India Supreme Court's rejection of a patent for an improved version of a costly cancer drug by Novartis AG could have big implications for the world's largest drugmakers.

The ruling, which was handed down on Monday, signals the latest shift in the world of drug development in emerging markets such as India and Brazil, where drugmakers have been looking for growth.

Western governments routinely grant patents for slightly improved versions of medicines whose patents are about to expire. That enables drugmakers to get many patients to upgrade to their new, generally more expensive versions rather than the cheaper, generic knockoffs even though some doctors and patients argue that the improvements don't justify the high cost.

But India, Indonesia and some other developing countries have been bucking that trend. They've been shooting down Western patents and licensing local pharmaceutical companies to make cheap generic versions of medicines that most of their residents otherwise could not afford.

Major drugmakers such as Pfizer and Bayer AG on Monday declined to say what they might do regarding the ruling and other recent decisions by poor countries to let local drugmakers sell cheap generic versions for medicines that have monopolies under patents in Western countries. But some industry insiders—including a Novartis executive—predict that multinational drugmakers will decide against doing drug research and development in India.

"Novartis will not invest in drug research in India. Not only Novartis, I don't think any global company is planning to research in India," Ranjit Shahani, the vice chairman and managing director of Novartis India, said after the ruling.

Erik Gordon, a professor and analyst at University of Michigan's Ross

School of Business, agrees. He said the ruling means that there's "no reason to do research and development in India" because of its "national policy of hostility toward medicine patents."

One thing is clear, though: Emerging markets are not the gold mine that optimistic pharmaceutical executives have been making them out to be.

India's move casts significant doubt on the companies' predictions that within a few years, emerging markets will generate one-quarter or even one-third of their global revenue. They've been counting on governments and a rising middle class in emerging markets to spend more on their brand-name medicines rather than the locally made drugs that may be counterfeit.


A dove flies near the logo of Novartis India Limited at their head office in Mumbai, India, Monday, April 1, 2013. India's Supreme Court on Monday rejected drug maker Novartis AG's attempt to patent a new version of a cancer drug Glivec, in a landmark decision that healthcare activists say ensures poor patients around the world will get continued access to cheap versions of lifesaving medicines. (AP Photo/Rafiq Maqbool)

"Less patent protection in huge, developing markets means less revenue, and growth stories that are going to look like fantasies," Gordon said.

That's a big problem for drugmakers that already squeezed on all sides.

Government and private health plans in industrialized countries, particularly in deficit-laden Europe, have been pushing for lower drug prices and occasionally even refusing to cover very-expensive drugs. Consumer health spending has been constrained by severe recessions across the globe. Research is ever more expensive. And virtually every drugmaker has been hurt in the last few years by expirations of patents for popular drugs that once made billions every year.

Countries such as Indonesia and Brazil for several years have been licensing local pharmaceutical companies to make cheap generic versions of medicines, usually drugs for HIV, the deadly virus that causes AIDS.

But recently, India has overturned patents for several cancer drugs, including Bayer AG's Nexavar, AstraZeneca PLC's Iressa, Pfizer Inc.'s Sutent and Bristol-Myers Squibb Co's Sprycel, according to Mark Grayson, spokesman for the big drugmakers' trade group, Pharmaceutical Research and Manufacturers of America.

"Certainly companies will take this into account in deciding ... whether India's a good market," he said.

Grayson noted India has granted patents for very few medicines. He and the trade group's members say that without patents to protect sales of their drugs, drug companies won't have the billions they need to develop innovative new drugs.

"This is really about the future and coming up with medicines for unmet medical needs," he said.

Meanwhile, last month Pfizer's chief intellectual property lawyer, Roy F. Waldron, testified before a House trade subcommittee hearing on U.S.-India trade relations that India's stance makes it extremely difficult to get and keep a medicine patent there.

"We have seen several countries adopt policies similar to India's, which are leading to a worldwide deteriorating trend" that weakens the competitiveness of U.S. drugmakers and threatens U.S. economic growth and future medical advances, Waldron said.

But some say ending research in India would backfire, or that operating in India is so cheap a pullout wouldn't make sense.

"That would just be cutting off their nose to spite their face," said analyst Steve Brozak of WBB Securities, adding, "It's still much cheaper to put whole lab in India," as opposed to hiring a postdoctoral student to do research in the U.S.

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