The New York Times

April 1, 2013

Patent's Defeat in India Is Key Victory for Generic Drugs

By GARDINER HARRIS

NEW DELHI — India's Supreme Court rejected a patent application by Novartis for a major cancer drug on Monday, in a landmark ruling that will permit poor patients continued access to many of the world's best medicines, at least for a while.

The ruling allows Indian makers of generic drugs to continue making copycat versions of the drug Gleevec — also spelled Glivec in Europe and elsewhere — which provides such an effective treatment for some forms of leukemia that the Food and Drug Administration approved the medicine in the United States in 2001 in record time.

But the ruling's effect will be felt well beyond the limited number of leukemia patients in India who need Gleevec, made by Switzerland-based Novartis. On the one hand, it will help maintain India's role as the world's most important provider of cheap medicines, which is critical in the global fight against HIV/AIDS and other diseases. Gleevec can cost up $70,000 per year, while Indian generic versions cost about $2,500 a year.

"India, being the pharmacy capital of the world, can continue to produce affordable, high-quality medicines without the threat of patents for minor modifications of known medicines," Dr. Yusuf K. Hamied, chairman of Cipla, an Indian generic drug giant, wrote in an e-mail.

On the other hand, the ruling could cost lives in the future. Drug company executives and others argue that India's failure to grant patents for critical medicines – and Gleevec is widely recognized as one of the most important medical discoveries in decades – is a shortsighted strategy that undermines a vital system for funding new discoveries.

In a televised interview, Ranjit Shahani, vice chairman of Novartis's Indian subsidiary, said that companies like Novartis would invest less money in research in India as a result of the ruling. "We hope that the ecosystem for intellectual property in the country improves," he said.

The case grapples with the contention that rich nations, increasingly reliant on the creation of idea-based products like computer programs and medicines, require poorer countries to pay for their ideas. Some countries – particularly India, Brazil and China – have begun to challenge the price they must pay, especially when the idea-based products are lifesaving medicines that their people

desperately need.

The question is how to pay for ideas in ways that maximize their use while encouraging their creation, two sometimes contradictory goals. Poor countries have tended to focus on the immediate issue of access while tending to ignore the more uncertain and far-off issue of innovation, while the United States has long emphasized the need to finance new discoveries rather than provide access to medicines for all.

India exports about $10 billion worth of generic medicine every year, more than any other country. India and China together produce more than 80 percent of the active ingredients of all drugs used in the United States.

In Monday's decision, India's Supreme Court ruled that the patent that Novartis sought for Gleevec did not represent a true invention. The ruling is something of a historic anomaly. Passed under international pressure, India's 2005 patent law for the first time allowed for patents on medicines, but only for drugs discovered after 1995. In 1993, Novartis patented a version of Gleevec that it later abandoned in development, but the Indian judges ruled that the early and later versions were not different enough for the later one to merit a separate patent.

Leena Menghaney, a patient advocate at Doctors Without Borders, said that the ruling is a reprieve from more expensive medicines, but only for a while.

"The great thing about this ruling is that we don't have to worry about the drugs we're currently using," Ms. Menghaney said. "But the million-dollar question is what is going to happen for new drugs that have not yet come out."

Anand Grover, a lawyer who argued the case on behalf of Cancer Patients Aid Association in India, said the ruling had a sweeping effect since it confirmed that India has a very high bar for approving patents on medicines.

"What is happening in the United States is that a lot of money is being wasted on new forms of old drugs," Mr. Grover said. Because of Monday's ruling, "that will not happen in India."

Indeed, the vast majority of drug patents given in the United States are for tiny changes that often provide patients few meaningful benefits but allow drug companies to continue charging high prices for years beyond the original patent life.

In a classic example, AstraZeneca extended for years its franchise around the huge-selling heartburn pill, Prilosec, by performing a bit of chemical wizardry and renaming the medicine Nexium. Amgen has won so many patents on its hugely expensive erythropoietin-stimulating drugs that the company has maintained exclusive sales rights for 24 years, double the usual period.

One result is that the United States pays the highest drug prices in the world, prices that only a tiny fraction could afford in India, where more than two-thirds of the population lives on less than $2 a day. While advocates for the pharmaceutical industry argue that fairly liberal rules on patents spur innovation, academics are far from united in sharing that view.

But as the economies of emerging markets grow, their refusal to pay higher premiums for newer drugs could significantly reduce the money needed for innovation. The drug industry makes nearly two-thirds of its profits in the United States, a dependence that many in the industry fear is unsustainable. And even minor improvements in medicines – making a pill once-a-day instead of twice-a-day – can have significant impacts on patient wellness, industry executives say.

The United States government has become increasingly insistent in recent years that other countries adopt far more stringent patent protection rules, with the result that poorer patients often lose access to cheap generic copies of medicines when their governments undertake trade agreements with the United States.

Drug companies have relied on the American government to lobby on the issue because they have few tools to punish India and other countries. If the companies decide not to introduce high-priced drugs in India, the country could legalize generic copies under international law. And with major drug makers cutting back on research budgets anyway, large investments in research infrastructure may be unlikely even if countries adopt patent laws more amenable to the industry.

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