India's Trouncing of Big Pharma Is a Victory for the World's Poor

by Ramtanu Maitra

April 7—On April 1, big multinational pharmaceuticals with big money and clout got a black eye in India, when that country's highest court turned down an appeal from the Swiss pharmaceutical company Novartis to patent an updated version of its cancer drug, Gleevec (known as Glivec in the United States). Novartis was denied a patent by the Indian authorities on the grounds that the new version was insignificantly different from the old. The Supreme Court cited Section 3(d) of the Indian Patents Act of 2005, which allows new forms of existing drug formulations to be patented *only if they result in increased efficacy.*

Furthermore, last month the Intellectual Property Appellate Board (IPAB) upheld the decision to award compulsory license[1] to Natco, an Indian generic drug manufacturer, to manufacture the German multinational pharmaceutical company Bayer's cancer drug Nexavar at a significantly reduced price. The decision was taken following an appeal filed by Bayer Corporation against the Union of India, the Controller of Patents, and Natco, against the exclusive license issued to the generic drug manufacturer in March 2012.

The decision has global significance: Médecins Sans Frontières (MSF)/Doctors without Borders, which relies on India to supply 80% of the generic HIV drugs it distributes in developing countries, describes India as the "pharmacy of the developing world," according to an April 1 statement on its website.

Big Pharma's Muscle-Flexing Resisted

These decisions have been welcomed widely within India, where millions of poor and middle-class families will now have access to these life-saving drugs. For instance, in India, one version of generic Gleevec is available under the name of Imatib, manufactured and marketed by a leading Indian company, Cipla. Its retail price is only Rs300 (about US$6) for each 400 mg tablet; Novartis's Gleevec 400 mg tablets cost Rs3,000 (about US$60), about 10 times as much.

The decision by the Indian Supreme Court on Gleevec was hailed as a landmark victory, since it provides patients of weaker financial means access to affordable medicines throughout the developing countries.

"This is a huge relief for the millions of patients and doctors in developing countries who depend on affordable medicines from India, and for treatment providers like MSF," said Dr. Unni Karunakara, MSF International President. "The Supreme Court's decision now makes patents on the medicines that we desperately need less likely. This marks the strongest possible signal to Novartis and other multinational pharmaceutical companies that they should stop seeking to attack the Indian patent law."

The Court's decision was also welcomed by Y.K. Sapru of Cancer Patients Aid Association (CPAA), which had opposed Novartis's patent application. Sapru said, "We are very happy that the Apex Court has recognized the right of patients to access affordable medicines over profits for big pharmaceutical companies through patents. Our access to affordable treatment will not be possible if the medicines are patented. It is a huge victory for human rights."

Loon Gangte of the Delhi Network of Positive People (DNP+) was quoted on Pharmabiz.com April 3: "We are extremely pleased and relieved that the Supreme Court has recognized the public health importance of Section 3(d)."

1. Section 84 of the Indian Patent Act says that at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds:

1. that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or,

2. that the patented invention is not available to the public at a reasonably affordable price, or,

3. that the patented invention is not worked in the territory of India.

The IPAB ruled that Bayer had violated the second and third terms of Section 84.

India's High Court decision will mean that hundreds of millions of poor people will receive the drugs they need. Here, a pharmacy in Ranikhet, India dispenses medications.

Importantly, the Court's decision also drew the guarded support of Brian Druker, director, Knight Cancer Institute at Oregon Health and Sciences University, the man who invented the molecule imatinib, the precursor to Gleevec, as a promising anti-cancer compound in the 1990s. "This patent decision clearly makes more affordable drugs available immediately and this is good for patients in the short term," Druker said in an e-mail response to the Indian daily *Business Standard.* "I have consistently spoken out about what I view as the high price of drugs, but if we too severely restrict the price of medications, we may lose the ability to invest in new drugs," he added.

Over the decades, India has developed a strong drug-manufacturing base, which has developed the ability to manufacture cheaper drugs. Although Brazil, Canada, China, Singapore, and South Africa also manufacture generic drugs, India is by far the biggest producer. Indian pharmaceutical companies also make generic versions of the raw ingredients and chemicals used in the drugs' manufacture. India exports two-thirds of its pharmaceutical output to developing countries, according to the World Health Organization (WHO). Generic competition fueled by Indian drugs has been largely responsible for reducing the prices of antiretroviral drugs used to treat AIDS, in some cases by as much as 98%.

Last year, when the Indian patent office allowed generic drug-maker Natco Pharma to sell generic Nexavar, the cost for a month's treatment at the time was Rs8,800 (about $176)—a fraction of Bayer's price of Rs280,000 (about $5,600). It is likely that in the coming months and years, more Indian generic firms will manufacture by Nexavar, bringing down the price even further. This trend is already evident.

For instance, Cipla, one of the biggest Indian pharmaceutical companies, today announced that it has reduced the price of the generic drug Soranib (used for the treatment of primary kidney cancer and advanced primary liver cancer), from Rs28,000 (about $560) to Rs6,840 (about $137), a decrease of almost 80%. Cipla also slashed the price of its lung cancer drug Gestinib by almost 60%.

It also cut the price of the brain tumor drug Temozolamide for all three strengths in which it is produced. While the price of the 20 mg 5-capsule pack has been cut from Rs1,875 (about $33.50) to Rs480 (about $9.60), the price of the 100 mg strength has been brought down from Rs8,900 (about $178) to Rs2,400 (about $48). The price of the 250 mg 5-capsule Temozolamide has been reduced to Rs5,000 (about $100), from a high of Rs20,250 (about $405). Cipla added that it might slash the prices of other cancer drugs as well. In March, Swiss pharma giant Roche announced that it intended to sell cut-price versions of two of its major cancer drugs in India.

Should the Poor Be Allowed To Live?

Big pharma people are upset, and so are a few others. Some have expressed concerns that the multinational pharmaceuticals will shun India in the future and set up their R&D facilities elsewhere. But these individuals are in the minority. By protesting against the Court's decision, what the proponents of Big Pharma's rights are contesting is Section 3(d) of the modified Indian Patent Law of 2005.

The Novartis lawsuit is the first legal challenge to the most controversial safeguard, a provision against

The Swiss Pharma-giant Novartis was slapped down by the Indian Supreme Court in its attempt to patent an updated version of its cancer drug Gleevec. Instead, generics, such as the Indian drug manufacturer Cipla can continue to produce and sell its vastly cheaper generic Imatib to the poor of India and other developing countries.

"ever-greening"—which targets attempts to patent minor improvements to old drugs and thus slap on a much higher price. Section 3(d) intervenes in that effort, and forbids the patenting of derivative forms of known substances (e.g., salts, polymorphs, metabolites, and isomers), unless they are substantially more effective than the known substance. Novartis had asked the Chennai High Court in 2006 to strike down this section as inconsistent with the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which requires that patentable inventions be new and involve an "inventive step."

Section 3(d) states that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process, machine, or apparatus unless such process results in a new product or employs at least one new reactant, is not a valid reason for a patent.

In that context, the Court decision of 2006 was very specific. It said efficacy is a pharmacological idea associated with the ability of a drug to produce a desired therapeutic effect independent of potency, i.e., "healing of disease." And, the IPAB Board had noted, with respect to enhanced efficacy, that "it is not possible to quantify this term by any general formula," and that an assessment would "vary from case to case." In revisiting these readings, the Supreme Court also had the views of Shamnad Basheer (as an intervenor-cum-amicus) and Anand Grover (counsel for the Cancer Patients Aid Association). The latter had argued for a strict reading of 3(d) which would see efficacy entirely in pharmacological terms.

While Basheer agreed that all advantageous properties may not qualify under 3(d), he held that increased safety and reduced toxicity should be seen favorably. As Dwijen Rangnekar wrote in *The Hindu* April 3, even as the Supreme Court recalled the concerns that led to the adoption of 3(d)—thus, urging a "strict and narrow reading" for medicines—it preferred to delay definitive pronouncement and allow for jurisprudence to develop on this matter. Yet, it is firm in noting that enhancements in the "physical properties" of a product would render a patent application in violation of 3(d).

Will the U.S. Learn a Lesson?

IPAB's decision to allow exclusive licensing of Nexavar has caused an international uproar. Eric S. Langer, in his article, "Understanding India's New Patent Laws: Did the 2005 Patents Act Engender a Western Intellectual Property Rights Culture in the Country?," published April 1, 2008, in *BioPharm International*, wrote that exclusive licensing is a tool that strikes at the heart of the patent system. It is an effective measure to restrict patent exclusivity; it strikes a balance between health concerns and access to life-saving drugs, and financial concerns based on the claim that restricting patents will suppress innovation. The article states:

"The recent fight over the revised Act in India brought compulsory licensing to the forefront, and the country fought for the provision to remain in effect. The generics industry has been strong for years now. Whether or not the provision is much used, the strategic compromise allowing it to remain in the revised Act, even with the restrictions, is crucial for both sides to claim success. World health bodies are assured their supply of cheaper drugs will not dry up. Industry is content because increased patent protection is anticipated to bring foreign investment to India, regardless of the existence of the compulsory licensing provision.

"The United States can learn from India's compromise. The U.S. pharmaceutical industry is slowly becoming less efficient in its product development—spending more but producing drugs that are not much more effective. Consumer frustration with high prices of prescription drugs continues to increase. Compulsory licensing would increase competition through lowering barriers to entry in the market. Increased competition could lead to lower prices, as in India where the generics market is strong. More substitutes would decrease the informational problems between consumers, physicians, and manufacturers.

"Most importantly, a compulsory licensing provision in the United States would raise consumer confidence in the patent system, bridging the gap between consumer access and industry innovation. It adds an element of transparency that promotes cooperation between industry and consumers. Industry representatives in India are confident about future prospects due to increased patent protection and do not anticipate the compulsory licensing provision eliminating its chance of success. The United States should also adopt the view that a compulsory licensing provision will not destroy pharmaceutical industry profitability but will promote competition and increase consumer confidence in the entire system."

Accommodating to the WTO

Despite these two landmark decisions, which would provide the poor greater access to cheaper drugs and strengthen India's generic drug-manufacturing base, India's patent laws have been heavily compromised in recent years to accommodate the diktat of the WTO. Analysts point out that the muscle that the Indian pharmaceutical industry has acquired was primarily a result of the Indian Patents Act of 1970, which came into force in 1972.

That Act was part of a wider set of policies of the Government of India at the time, to develop a "self-reliant" pharmaceutical industry; the impulse behind it was the commitment to national sovereignty, and the determination to aid the billions of poor in developing nations. That commitment is now weakened by the shift India made in 2005 to obeisance to the WTO globalizers. The 1970 Act provided for product patents for all inventions, except for food, medicine, drugs, and substances produced by chemical processes. For the latter category, only the process patent was granted. The patent term was also reduced from 16 years to 5 years from the date of patent approval, or 7 years from the date of application, whichever was earlier.

The 1970 Patent Law was a point of contention for the Big Pharma companies. They endlessly bickered, and applied their money-muscle, using the WTO and other international institutions dominated by the West, charging that countries like India use exclusive licensing to enhance commercial interests through increased exports, under the pretext of improving public health. Others pointed out that, although India's market did profit from exports, in reality, the government was committed to people's health interests. India's National Pharmaceutical Pricing Authority (NPPA) was created in 1986 to control the prices of a list of drugs—again, to allow access by the poor.

But, that was then, before New Delhi came under the spell of globalizers and reformers; now it is dancing to the tune of international Mammon-worshipping institutions. When the 1970 Patent Law took effect, India had a slow rate of economic growth, but had developed its economic base, such as in food self-sufficiency, to ensure some protection to the poor.

With the advent of "reformers" and globalizers,

such as the present Prime Minister, Manmohan Singh, and his handful of henchmen, it is evident that all those measures will come under attack, and the reformers and globalizers will continue to weaken that infrastructure until the product satisfies the wheelers and dealers of various international institutions.

The most notable amendment in the Patents (Amendment) Act of 2005 is the deletion of Section 5 of the 1970 Act, which granted process patents to the innovators of new food, medicine, drugs, and substances produced by chemical process. The new Act also provides protection for 20 years for all categories of inventions, except those excluded under Section 3, the one that allows patents only for new forms of existing drug formulations, if they result in increased efficacy. The Act further affirms that the sellers of already approved generic drugs in India will now have to pay licensing fees. Under the new regime, local drug makers will have to apply for a license to manufacture patented drugs after paying a "reasonable" royalty to patent holders, if they had been making them after January 1995.

As a result of the 2005 Act, a number of Indian drug companies have begun to attach themselves to Big Pharma, and because of the maturity of India's drug-manufacturing infrastructure, and low wages, some of these pharmaceuticals are surely heading towards producing drugs for Big Pharma at much higher prices. The international patent laws allow countries to issue exclusive licenses to make or buy generics during a national health emergency.

What worries at least one Indian bio-scientist, and rightly so, is that if India were to declare a national health emergency in the future, there would be few domestic firms left to make generics in sufficient amounts, as happened a few years ago in the U.S. with influenza anti-virals.

A discussion paper by India's Commerce Ministry, in November 2010, cautioned, "There is a concern that their [Indian drug firms'] take-over by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them. This may weaken competition leading to headroom for increase in domestic drug prices."