Drug Makers Decry Indian Patent Law

By GEETA ANAND

MUMBAI—Multinational drug companies have pushed big-time into India in recent years after the country agreed to respect intellectual property rights for pharmaceutical products.

But India's patent office and courts have repeatedly declined to defend patents widely accepted in many other countries on some of the world's best-selling medicines. As a result, multinational pharmaceutical firms have been thrown a curve ball as they seek to expand in one of the world's fastest-growing markets.

In the latest example, Bayer AG failed this week to persuade the Delhi High Court to direct India's chief drug regulator to not give marketing approval to a competitor's copy of its cancer medicine Nexavar.

Top-selling, life-saving medicines, including the anticancer treatment Glivec from Novartis SA; anticancer drug Tarceva from Roche SA; and HIV medicine Viread from Gilead Sciences Inc. all have failed to win protection from India's patent office or the judicial system.

The Drug Controller General of India is the equivalent of the U.S. Food and Drug Administration. But the Indian agency has a higher bar for issuing patents, and doesn't automatically refuse to approve copies of patented medicines while any outstanding patent issues are being resolved in court, as the FDA does.

Indian Patent Woes

The pharmaceutical giants selling these blockbuster drugs have been unable to secure intellectual property protections for them in India

Manufacturer	Drug*	Action on Patent
Novartis	Glivec	Patent Office denies application; appealed to Supreme Court
Roche	Tarceva	Patent granted but courts refuse to issue injunctions stopping generic versions
Bayer	Nexavar	Patent granted but court won't stop drug regulator from reviewing generic application
Gilead	Viread	Patent denied and appealed to appellate board

*Brand name

Without the regulator holding off on approvals, companies that get patents in India frequently are left to pursue copycats in court—where they also have run into unfavorable decisions.

Executives at multinational drug companies say India will suffer if it fails to recognize patents that are widely accepted elsewhere or protect patent holders from copycat competitors.

"If this science and innovation can't be patented, it is sending a very strong message about how limited India's patent protections are," says Gregg Alton, executive vice-president of corporate and medical affairs at Gilead Sciences.

Until 2005, Indian law recognized only process patents for making pharmaceutical products—and not the actual products. Indian companies were well-known for selling lower-cost copies of some of the most expensive, branded medicines in the world.

This made Indian companies such as Cipla Ltd. the champion of HIV patients in Africa, where poor people needed access to life-saving medicines, but a problem for the multinational drug industry, which relies on intellectual property protection of innovation to fund the high cost of research.

As a member of the World Trade Organization, India faced increasing pressure to enact legislation recognizing intellectual property laws on medicines. But the trade organization rules allowed countries some flexibility on the nature of the laws passed.

When India finally adopted its expanded patent law, it was widely hailed and multinational firms began expanding with gusto. They now sell their latest branded medicines here, expecting the burgeoning middle class and slowly growing health insurance system will pay for them. Pharmaceutical manufacturing has boomed, as has the clinical trial industry.

But little noticed at the time was that the new law sets a higher bar than Europe and the U.S. for approving patents, says D.G. Shah, head of the Indian Pharmaceutical Alliance, a Mumbai-based industry group.

Among the tougher provisions is one that says patents be will granted only when products are more efficacious—a provision the Indian patent office has used to deny several patents, he says.

In court and in interviews, Indian officials and companies contend the Indian system is fair and that, by contrast, international patent offices grant patents where there isn't significant innovation or benefit. They say it is India's duty to grant patents only when there has been significant innovation, and to foster a competitive environment that keeps prices low so the country's vast and mostly poor population can afford medicines.

"The U.S. would grant a patent to a piece of toilet paper," says Amar Lulla, chief executive of Cipla, the Indian generics drugmaker. "Just because the U.S. granted a patent, doesn't mean it should be valid."

In its Tuesday decision to dismiss Bayer's appeal, the Delhi High Court made a blistering attack on the company's efforts to block copies of its cancer medicine Nexavar. Calling the appeal "a speculative foray," the court added that "the petitioner, no doubt, is possessed of vast resources and can engage in such pursuits."

The court ordered Bayer to pay the expenses of the Indian government as well as those of Cipla, which wants to market a copy of Nexavar.

Mr. Shah, the industry group head, said the patent law gives India a way to deny patents when needed to protect its poorer population against high prices. Nexavar is sold in India for about $2,000 a month, he said, compared to Cipla's planned $200 price for its generic version. Bayer and Cipla said the prices in general were accurate.

In response, the U.S. government has lobbied the World Intellectual Property Organization, a United Nations group, to require member countries to adopt a common patent law that can be widely applied. That proposal hasn't received much traction, says Jamie Love, director of Knowledge Economy International, a Washington-based research and advocacy organization.

In denying Novartis's patent application for Glivec last year, the Indian patent office said the company didn't demonstrate improved efficacy for the patentable form of the medicine over an earlier version.

Novartis filed an appeal of the decision to the Indian Intellectual Property Appellate Board, where it was denied. The Swiss drug maker has since appealed to the Supreme Court.

A Novartis spokeswoman said the drug sells for about $2,500 a month in India, far more than locally made copies, but that 99% of Indian patients get the medicine free or for a steeply reduced price through an access program.

The Indian Patent Office approved a Roche patent on its cancer drug Tarceva, but the company has lost legal efforts stop copycat versions of the drug being sold in the market. The Delhi High Court and the Supreme Court last year both declined to issue injunctions to restrict the sale of the copies.

Commenting on the Supreme Court decision, a Roche spokesman said in an interview Wednesday that "any research based company will need to consider carefully what this ruling means for future investments in this country."

Also last year, the Indian Patent Office rejected patent applications from Gilead on Viread, a widely patented and prescribed antiretroviral medicine for HIV. The patent office dismissed the innovations as obvious.

The patent had been challenged by Cipla, which was already selling its own version, as well as by patient groups worrying the Viread price would be too high.

Gilead said it had been trying to find ways to make lower-cost versions available in India. Gilead licensed the Viread patent to 13 companies in the country in exchange for a 5% royalty on finished product sales. Some of those companies sell the medicine for as little as $8.50 a month in parts of India; the same supply costs about $400 in the U.S., according to Gilead officials.

—Arlene Chang, John W. Miller and Alicia Mundy contributed to this article.

Write to Geeta Anand at geeta.anand@wsj.com