PHARMACEUTICALS

India spurns cancer patents

Nation seeks to cap high cost of drugs to treat non-infectious diseases.

BY ERIKA CHECK HAYDEN

Once the scourge of the developing world, infectious diseases such as malaria, tuberculosis and AIDS can now be fought with cheap drugs. But as people in poorer nations live longer and adopt Western habits, non-communicable diseases such as heart disease, diabetes and cancer have become the main killers — and paying for their treatment has become a thorny problem.

India may now be drawing a line in the sand. In the past three weeks, officials there have refused patents on two breast cancer drugs — the latest in a series of decisions to limit patents on pricey brand-name medications. These moves reflect a tension: India now surpasses the United States in terms of annual cancer deaths, and wants to find ways to treat the disease cheaply. But this desire runs counter to the goals of drug makers, who see middle-income nations as central to their growth plans.

The first of the recent rejections occurred on 27 July, when an Indian federal board of patent officials revoked a patent on a slightly modified version of the breast cancer drug lapatinib, sold as Tykerb by London-based pharmaceutical firm GlaxoSmithKline. Then, on 4 August, Swiss drug company Roche reported that a patent office in the city of Kolkata, a hub of the national patent system, would not grant patents on a version of the company's drug trastuzumab, sold as Herceptin. Indian officials allowed other patents that will protect both drugs from generic competition until 2019. But the rulings will stop the companies from extending their patent protection beyond that date, opening a window for manufacturers of generic drugs to then step in.

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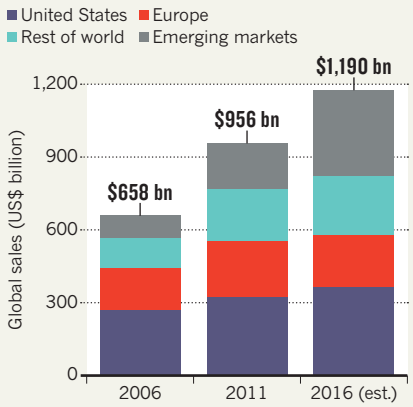
The fight echoes one in the late 1990s and early 2000s over drugs for treating infections such as HIV. That dispute was largely resolved when drug makers allowed developing-world companies to create cheap generic medicines. Today, antiretroviral treatments can be bought for less than US$100 a year, compared with more than $10,000 a year in 2000, according to international aid organization Doctors Without Borders (Médecins Sans Frontières), based in Geneva, Switzerland.

DRUG MONEY

By 2016, drug makers could be earning as much from emerging markets, such as China, Brazil and India, as they do from selling in the United States.



Emerging markets: China, Brazil, India, Russia, Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam.

SOURCE: IMS INSTITUTE FOR HEALTHCARE INFORMATICS

But drugs for non-communicable diseases — particularly cancer — will be much trickier to negotiate. "There's no easy compromise that's going to arise around non-communicable diseases the way that we saw around HIV," says Thomas Bollyky, a lawyer with the Council on Foreign Relations in New York who fought for affordable HIV medicines in the 1990s.

In India, a $15,000 course of trastuzumab can cost more than ten times the average annual wage. And there are no older, off-patent drugs that could serve as an alternative, because none of them target the specific type of breast cancer as well as trastuzumab.

Yet drug makers are reluctant to cut prices in middle-income countries such as India, China and Brazil, which are projected to account for much of the industry's growth in the near future (see 'Drug money'). Although Africa's ability to pay for HIV drugs was never going to be high, some people in middle-income nations can afford expensive medicines. Drug makers do not want to erode that niche market through lower-cost drugs, even if the vast majority of people in need cannot pay, says James Love, director of Knowledge Ecology International, a non-governmental organization in Washington DC that advocates for social justice in access to knowledge.

A number of ideas to skirt the impasse have been floated, but none are simple. Drug makers argue that governments of middle-income nations should broaden insurance programmes and access to health care. They also argue that drugs will become more affordable as economies grow and people earn more money. By reducing support for intellectual property, India is undermining incentives for drug development and foreign investment that will allow for growth, says Amy Hariani, director and legal policy counsel for life sciences at the US–India Business Council, an industry group based in Washington DC. "The best way for the Indian economy to grow is by rewarding innovation," she says.

Another idea comes from the World Health Organization, which for the past five years has been trying to broker an international treaty that would see member states supporting the development of lower-cost medicines with prizes and research funding rather than patents. "We think the answer is to make the price of drugs really cheap, and to provide funding as a reward for innovation rather than through a monopoly on a drug," says Love.

There is also increasing pressure on drug companies to adopt pricing models that allow people in the same country to be charged different prices for drugs, depending on their ability to pay. Companies, including Roche in the case of trastuzumab, say that they already offer such differential pricing through special access programmes. Still, Roche's own figures show that it sold enough trastuzumab last year to treat only 3,700 Indian breast cancer patients — 15% of those who need it.

The battles may end up being mere skirmishes if India goes further and allows local companies to disregard Roche's trastuzumab patent altogether and manufacture a cheaper generic version, using a 'compulsory licence'. Last year, India issued such a licence on a cancer drug sold by German firm Bayer. And in January, India's ministry of health recommended compulsory licences for trastuzumab and two other cancer drugs.

Indonesia issued compulsory licences for seven drugs in 2012, and China and the Philippines have tweaked their laws to make such licences easier to issue. Prashant Yadav, director of the health-care research initiative at the University of Michigan in Ann Arbor, says that these moves portend an unsettling future. India may be the main battleground today, but the war over cancer-drug access seems likely to bleed beyond its borders unless a compromise is reached. "This requires some kind of diplomacy now," says Yadav. ■