

Patent issue dogs pharma MNCs

Panel looking beyond cancer treatments to evaluate drugs for local firms to copy

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MUMBAI: Pharmaceutical companies from Merck to Bristol-Myers Squibb face fresh threats to protecting their patents in India as a government-appointed panel prepares to evaluate more drugs for local makers to copy.

The panel is looking beyond the cancer treatments it studied last year to areas such as HIV and diabetes, according to two people with knowledge of the matter, who asked not to be identified because the discussions are private.

It plans to study more than 20 drugs and recommend the government assign about three so-called compulsory licenses to allow local firms to make low-priced copies in India, they said.

The heightened scrutiny illustrates how emerging markets are becoming harder to navigate for global drugmakers including Pfizer and Novartis, which have struggled to defend their rights on blockbuster therapies in India. The drugmakers are facing a rising threat to their patents as India's government seeks to make treatments cheaper locally, said Ajit Mahadevan, leader of the life sciences consulting group at Ernst & Young in Mumbai. "Moves by policy-makers like compulsory licensing result in the feeling that you're not very comfortable investing," Mahadevan said. You can't build predictability, and big pharma doesn't like that. Indian generic drug makers gained in Mumbai trading on Wednesday.

Hyderabad-based Natco Pharma, which was awarded the nation's first com-



Drugs under scrutiny	Drugs received compulsory licenses
Merck (MRK) Sitagliptin medication: Januvia HIV drug: Raltegravir	Merck (MRK) Chronic myeloid leukemia drug: Sprycel
Bristol-Myers Squibb (BMY) Saxagliptin drug: Onglyza Arthritis drug: Abatacept	Natco Pharma To copy Bayer's Nexavar cancer drug

pulsory license in March 2012, gained as much as 4.4 per cent before closing 1.7 per cent higher. Cipla added 1.3 per cent and Lupin gained 2.1 per cent. The smaller Indian players, focused more on the Indian market, will benefit, if more compulsory licenses are awarded, said Nitin Agarwal, an analyst at IDFC Securities in Mumbai. Their success depends on whether they're first mover, and how many players the government allows in the market.

Compulsory licensing occurs when a government allows someone else to produce a patented product without the consent of the patent owner, who still owns the rights and receives payment for its use, according to the World Trade Organisation.

Such licenses can therefore put pressure on brand-name manufacturers to cut prices in response to cheaper generics. R.K. Jain, additional secretary at the min-

istry of health and family welfare, didn't immediately respond to a call and an e-mail seeking comment on compulsory licenses.

Among the therapies the committee is preparing to study or had an early look at are two diabetes drugs, Merck's sitagliptin medication, Januvia, and Bristol-Myers saxagliptin drug called Onglyza; Merck's HIV drug raltegravir, sold under the brand name Isentress; and Bristol-Myers arthritis drug abatacept, sold as Orencia, according to the people.

The panel is also considering other drugs and it still isn't clear which ones will be shortlisted, the people said. Patents provide Merck with the incentive to assume the risks associated with drug discovery, the Whitehouse Station, New Jersey-based company said in an e-mailed response to questions.

"We encourage the government of India to reassure investors that India

respects and values innovation and the protection of intellectual property," Bristol-Myers in an e-mailed statement said it is deeply concerned with the deteriorating protections for patented innovative medicines in India and will continue to act to protect its intellectual property rights. Any recommendations will still need the government's approval. The panel's proposals will be submitted to the department of industrial policy and promotion, which will make a decision on whether compulsory licenses can be awarded. India's Controller General of Patents, Designs and Trademarks will then need to sign off on the compulsory licenses.

Following that, a generic drugmaker could require the patent holder to grant it a license to make a copy in India. Besides boosting the domestic generic drug industry, cheaper copies of blockbuster medicines

would help India meet the needs of low-income citizens. Diabetes afflicts 65 million Indians, according to the International Diabetes Federation.

The country has an estimated 2.1 million people living with HIV, according to the Joint United Nations Programme on HIV/AIDS. The committee recommended compulsory licensing for dasatinib, a Bristol-Myers therapy for chronic myeloid leukemia sold under the brand Sprycel, last year, the people said.

"Any award of compulsory licenses will take time because the process is fraught with bureaucracy," said Leena Menghaney, a patient advocate at Doctors Without Borders in New Delhi.

"India also is worried about its international image," she said. The US International Trade Commission said in August that it would investigate Indian policies that discriminate against US trade and investment at the request of the House Committee on Ways and Means and the Senate Committee on Finance.

"What the Indian government is really worried about is the court cases that will follow from drug companies," Menghaney said. "It's worried about the international criticism it will face from developed country governments who back their pharmaceutical companies, and the impact it will have on the India-US relationship."

Roche decided not to pursue Indian patents for its breast cancer medicine Herceptin because of the Indian intellectual property environment, the company said in an e-mail.

Patents