

## FINANCIAL SCENE

# Drugs affordability and patents

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One of the urgent tasks before the new government is something that does not figure in common discourse but is still extremely important for its larger implications for Indo-U.S. economic ties. India's patent regime, which protects intellectual property rights (IPRs), has come under intense scrutiny in the United States. It is the contention of the U.S. Trade Representative (USTR) that the environment for IPR in India has deteriorated. India has been placed on the "priority watch" list of countries, whose IPR regimes will be scrutinised during the year. The saving grace is India has not been labelled a Priority Foreign Country (PFC) in the USTR's Special Report released at the end of April. The U.S. Trade

high pressure lobbying by big pharma in the U.S. is to stymie India's efforts at providing affordable medicine without in any way compromising on existing treaty agreements.

### Flexibilities

Big pharma is obviously piqued by India's decision to use the "flexibilities" that are available in the existing TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. Since 2005, when patent protection was incorporated into domestic laws, the flexibilities were used only twice. In March 2012, it issued a compulsory licence to an Indian firm for a cancer drug, whose patent holder, the German multinational Bayer, had priced it well beyond the reach of a majority of Indian patients.

Under another provision, countries have the option to deny patent to a drug that involved only incremental innovation. In April 2013, the Supreme Court upheld the 2006 decision of the Indian Patent Office denying the Swiss company Novartis' patent on a drug precisely on this ground.

Clearly, it is not just these two instances but the fear that other developing countries would emulate India that is behind the lobbying. India should be prepared to challenge any unilateral action by the U.S. before the WTO whose disputes settlement mechanism has a good record of impartiality.

The way forward is through discussions not confrontation. India needs foreign technologies and investment. Obviously, it helps alleviate any impression that India's patent regime is being diluted. Two points in India's favour are (one) patent issues are decided after a due process, never arbitrarily. Two, the very few instances of using flexibilities are indicative of the fact that India uses those safeguards selectively. Very recently, despite strong recommendations from the Health Ministry, the government refused to issue a compulsory licence for production of a copy of Bristol-Myers Squibb's cancer drug Dasatinib in India. The argument is that a case has not been made out for producing a generic version of that drug in India.

The debate should go on. There is a case for having a permanent mechanism for discussing patent-related issues, especially concerning the drug industry.

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## INDIA'S IPR REGIME IS CURRENTLY UNDER ATTACK BY THE U.S. PHARMA LOBBIES WHICH HAVE TEAMED UP WITH OTHER POWERFUL LOBBIES TO MAKE OUT A CASE AGAINST INDIA.

Representative is part of the executive office of the U.S. President empowered to develop and recommend trade policy to the U.S. government.

Any penal action against India would have cast doubts on the institutions and processes of economic diplomacy in the U.S. It would have been thoroughly ill-timed: the report was released, on schedule, two weeks before a new government took office in India.

If, indeed, the USTR had categorised India as a Priority Foreign Country, it could have led to imposition of sanctions by the U.S. on Indian trade.

Yet, while there was no downgrade, India's IP regime would be closely watched.

### Pharma lobbies

India's IPR regime is currently under attack by the U.S. pharma lobbies which have teamed up with other powerful lobbies to make out a case against India. From India's point of view, the objective of the

Patents.