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Big Pharma's profiteering protests

The war against the Indian patent regime is little more than multinationals' chagrin at their inability to exercise monopolies

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The US Chamber of Commerce has recently asked the Barack Obama Administration to designate India a Priority Foreign Country. This is the worst classification given to foreign countries that "deny adequate and effective" protection of intellectual property rights. The US industry trade group Pharmaceutical Research and Manufacturers of America (PhRMA) has expressed a similar view. Last year, the chamber wrote to Obama urging him to hold detailed discussions with the Indian prime minister on the issue.

According to US lobbyists, India has failed to recognise international intellectual property rights, which is deterring investments in the country. During a hearing, "A tangle of trade barriers"' before the US Energy and Commerce Committee in June 2013, the Chief Intellectual Property Officer of Pfizer Inc criticised developments in India's intellectual property regime. Some critics have gone to the extent of stating that there is potential cause for a World Trade Organisation (WTO) complaint against India for violating intellectual property treaties.

The pressure from the US lobby is not unexpected. In the history of Indian patent law, 2013 will be best remembered for the Supreme Court judgment in the Novartis AG case, in which the patent for the cancer drug Glivec was rejected. In the same year: (a) the Intellectual Property Appellate Board (IPAB) rejected a patent application for GSK Pharma's popular breast cancer drug Tykerb; (b) Swiss pharma major Roche Holding AG decided not to pursue the secondary patent for its breast cancer drug Herceptin in India; and (c) IPAB upheld the grant of a compulsory licence (CL) to Natco Pharma on Bayer's cancer drug Nexavar.

The decisions have made western pharma players apprehensive over the extent of monopoly that they can enjoy in India within the current patent regime.

The Indian patent regime has always been a thorny issue among western companies. The original Patent Act of 1970 did not allow any patent on a pharmaceutical product. Only process patents were allowed. As a result, any Indian company could manufacture a product as long as the process for manufacturing it was not under patent. This "reverse engineering" allowed the domestic pharma industry to grow tremendously. It also kept the prices of drugs reasonable. In 2001, Ciprofloxacin, a popular wide-spectrum antibiotic, was being sold exclusively by Bayer in the US at $0.95 a tablet. In India, multiple competitors kept the price down to $0.04.

However, once the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) came into effect from January 1, 1995, India was bound to align its patent regime with TRIPS. India's reluctance to amend its law resulted in adverse rulings from the WTO Dispute Settlement Body on complaints filed by the US and the European Community. As a result, India was forced to amend the patent law in 1999, with retrospective effect from 1995 and allowed exclusive marketing rights for pharmaceutical substances for which a claim could be made under the amended Act.

The Act was amended again in 2002 and reflected a fine balancing act. The amendment expanded the definition of "invention" to include micro-organisms. At the same time, the provisions relating to CL and revocation of patent were strengthened. The Indian law still did not grant patent for pharmaceutical products.

By a rough estimate, medicines that currently generate $133 billion in US sales alone will face generic competition. Big Pharma is trying its best to ensure that its dominance continues

Around the same time, as a result of pressure by several developing countries, the "Declaration on TRIPs and Public Health" was adopted at the WTO Ministerial Conference in 2001 at Doha. The Doha Declaration acknowledged that public health problems in many countries were, in part, a result of the intellectual property regime under TRIPS. This was followed by a decision of the TRIPS Council in 2003 to allow an exporting country to grant CL to meet public health requirements in the importing country.

Against this backdrop, the Indian law was further amended in 2005, to make India fully complaint with TRIPS within 10 years of the latter coming into effect. The 2005 amendment allowed patents for pharmaceutical products. The most significant amendment was to Section 3 (d), as a result of which unless "a new form of a known substance" does not result in "enhancement of the known efficacy of that substance", it would not amount to "invention". The purpose of Section 3 (d) is to prevent the "evergreening" of patents. The objective is to disallow patents for trivial changes made to an existing product and claiming it as a new invention.

The judgment in Novartis related to the interpretation of Section 3 (d). The Supreme Court noted the shift in Novartis' stand during the patent application process. Initially, Novartis had claimed that the modified version of imatinib (the chemical in question) had better physical properties than the original family of compounds — as a powder, its grains flowed more easily over one another, it decayed more slowly and absorbed less moisture from the atmosphere. However, in the amended filings, it was stated that the modified version of imatinib had higher "bioavailability," a measure of how much of any given dose of a drug reaches its target issue.

Likewise, IPAB revoked Glaxo's patent for Tykerb because it was found to lack enhanced efficacy over its original form. It was held that Tykerb was only the salt form of labatinib, the original compound, and was not an invention since there was no proof of enhanced therapeutic efficacy.

On the other hand, a CL was granted on Bayer's cancer drug Nexavar since it had failed to work the invention in India. Not only was the drug available at an exorbitant price of ₹2,80,000 a month, Bayer had not imported the drug till 2008 and done so only in small quantities in 2009 and 2010. At the same time, IPAB increased the amount of royalty payable by Natco to seven per cent.

Thus seen, no significant change has been made to the Indian law in 2013. The law is the same as it was enacted in 2005. The current regime is in sync with India's international obligations.

The Indian legal system has also worked fairly. This is clear when a CL application filed by BDR Pharma against Dasatinb, an anticancer drug patented by BMS, was rejected. News reports say the government may grant a CL for only one anti-cancer drug as against three sought by the health ministry. The developments cannot in any way be treated as a concerted attempt to thwart global pharma companies in India.

The lobbying against the Indian regime has been made to appear as though no patent would be granted at all under Indian law. Merely because Big Pharma has not been allowed to indulge in unconscionable profiteering cannot be a reason for changing the regime.

In this context, it is significant that patents for some of the big selling drugs will continue through 2016. By a rough estimate, medicines that currently generate $133 billion in US sales alone will face generic competition.

Big Pharma is trying its best to ensure that its dominance continues. The injunction sought by Roche from the Delhi High Court against Biocon–Mylan, from launching a bio-similar drug to herceptin for breast cancer treatment, even though the patent has expired, is part of the same strategy.

The current lobbying by US pharma companies should not be seen in isolation. If the Indian government succumbs to its demands, it would be seen as ignoring the domestic industry as well as the general public. It would also have global ramifications. India needs to show the way globally, as it has done so far, by enforcing provisions that take into account the interests of various stakeholders.

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