

LIFE, OR SOMETHING LIKE THAT

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The new patent regime might consolidate the drug industry in the hands of a few players. India must find answers to where protectionism begins and public interest ends

By Yoga Rangatia

Insight

The Pioneer

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The world looks up to India for making good quality cheap drugs, even for dreaded infections like HIV/AIDS. But the countdown to January 1, 2005, and the Government's obligation to align with a global patent regime, could change the situation. The question everyone is asking, and no one seems to have an answer to, is the impact this new system will have on drug availability and affordability.

The crux of the Indian success story was the ability to "reverse engineer" chemical molecules that were found effective in treating illnesses. And marketing drugs in the rest of the developing world which does not have a strong pharmaceutical industry. The Indian companies themselves did not invent new molecules, thereby cutting costs that it would have otherwise incurred on research and clinical trials.

The gain was at the cost of pharmaceutical companies that were heavily investing in research for newer chemical entities. In 1995, India had promised that it will switch to product patent system, which will further strengthen the innovator's right to market the new product, profit from which will recover the investment made on research. The domestic industry would not be allowed to "copy" the product for about 15 years. The Government also agreed that a "mailbox" facility will be setup for patent application after that period and this will be opened for consideration on

January 1, 2005.

In the meantime, the Centre was expected to make changes to its Patent Act, 1970, enforcing these provisions in India. The previous Governments have undertaken some amendments to this effect, but contentious provisions have not yet taken shape.

Take for instance the provision to leave a window period for registering protest with the patent office before a patent is granted, called "pre-grant opposition". Experts say, the provision avoids expensive litigation in courts after the patent is granted. The provision exists in the present patent system and, more importantly, the Trade Related matters of Intellectual Property Rights (TRIPS) does not require India to do away with this flexibility.

What worries consumers and the domestic industry more is the kind of patents that will be granted in the new regime. Will minor modification to an existing molecule be eligible for patents? Or a newer way of taking the drug (say injectibles in place of oral pill) be eligible for the patent? Those against the provision say that if the law is ambiguous, it can be easily misused by companies to extend their market monopoly beyond say 15 to 20 years and profit from lack of competition. Domestic industry is against granting patents on isomers, polymorphs and metabolites of already existing patents. Both these provisions will have an immediate bearing on about 4,000 patent applications that are said to have accumulated in the mailbox since 1995.

Surely, all of these cannot be new chemicals, but improvisation by companies to make the most of the change in patent regime. If not remedied in the new Amendment Bill, critics warn, a situation may arise where some drugs will have to be recalled by domestic manufacturers, shooting up their prices immediately. Experts argue that while putting in place a newer system, India must include measures to prevent patent system misuse.

The Doha Declaration of the WTO Ministerial round allowed Governments "compulsory licensing" of drugs, should a situation of national emergency arise. Other arguments are in favour of a price control mechanism super-imposed on the product patent regime. Canada, for instance, had switched to the product patent regime. But its Government clamps price control if manufacturers make unreasonable profits. Even the US Government buys drugs from its neighbour, where they are cheaper. India should also keep the "stick" handy, should one need it.

While looking at the issue afresh, the Manmohan Singh Government will be drawing the fine line between encouraging innovation and discouraging restrictive monopoly. The Government has responded with setting up a group of Ministers, led by Defence Minister Pranab Mukherjee, to look into the issue. Both the ally Left and the Opposition NDA have not revealed their cards on whether they will vote for the Bill if introduced in the Parliament. They are probably still watching the Government's next move.

The manner in which successive Governments have responded to the issue of such vital importance to public health is disappointing. The whole process

of policymaking is shrouded in secrecy, lending suspicion that the Government is yielding to powerful pressure groups. Take for instance the manner in which the Commerce Ministry moved a hush-hush Cabinet note order in July 2004 to pass an Ordinance in the third amendment. It was only after the matter was referred to the GoM that the Chemicals and Health Ministry came into the picture. Even now, there is no saying whether the Bill will be introduced in the Parliament this winter session, in time for the January 2005 deadline. Commerce Minister Kamal Nath might be tempted to take the Ordinance route.

The no-show by the Health Ministry on the issue is also appalling. The Government has not conducted any in-depth study on what impact a tougher patent regime on drugs can have on availability and affordability. The babus of Nirman Bhavan have opined that since most drugs that are ordinarily consumed are already off-patent, there will be no immediate price rise. There are no answers to the long term impact of the new system. Only recently, the Ministry setup a WTO cell but whether their views are sought before the GoM meet is not known.

Lawmakers must also share the blame for not having studied the issue. The impact of the TRIPS agreement has not figured in Parliamentary discussion thus far. The Lok Sabha hardly takes up these issues. The Parliament committees have also not scored well. The powerful Standing Committee on Commerce has also not taken up the matter for discussion, yet.

Will the new patent regime consolidate the drugs industry in the hands of a few multinational players? After 2005, will there be sufficient competition in the market to push drug prices down? These are some question India must find answers to.

As the world economy integrates, there are serious posers. One needs to ask where protectionism begins and public interest ends.

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The terrorist mission of Jesus stated in the Christian bible:

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"Think not that I am come to send peace on earth: I came not so send peace, but a sword.

"For I am come to set a man at variance against his father, and the daughter against her mother, and the daughter in law against her mother in law.

"And a man's foes shall be they of his own household.

– Matthew 10:34–36.

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