Compulsory Licensing of Pharmaceutical Patents

It is scandalous that India is yet to issue a single compulsory licence for a drug after the 2005 amendment.

Five years have gone by since the reintroduction of the product patent regime for pharmaceuticals and it is time public policy reckoned with the implications of local firms being debarred from producing and selling a patented drug even if they develop the processes of manufacturing the same, unless they are granted a compulsory licence (CL). The latter is a right granted by the government that allows parties other than the patent holder to produce and sell a patented product or use a patented process, without the consent of the patent holder. Even the Government of the United Kingdom, where neoliberalism was first conceived, takes advantage of CLs in order to reduce costs in the National Health Service, but the Government of India, which can also avail of CLs for non-commercial purposes, for example, to authorise the production of patented medicines for free or subsidised distribution in government hospitals, has not done so. The interests of the transnational pharmaceutical companies holding the patents seem more important than the public interest.

Indeed, in the aftermath of the "Doha Declaration on the TRIPS [Trade-Related Aspects of Intellectual Property Rights] Agreement and Public Health" of November 2001, a number of countries have issued CLs, some of them in the context of the HIV/AIDS crisis. For instance, Brazil, Ecuador, Kenya, Malaysia, South Africa, and Thailand have issued CLs for anti-HIV/AIDS drugs. India has around 25 lakh persons suffering from HIV/AIDS, but only 12% of them are being treated. The first generation drugs are now less effective, and it is time they are all administered the second and third generation drugs. The National AIDS Control Organisation can distribute these patented drugs to many more of those affected if the government takes advantage of CLs for non-commercial use. (Of course, a CL can also be granted for commercial purposes upon a potential licensee not being able to obtain a voluntary licence on reasonable terms and within a definite time frame.)

Surprisingly, it is still not sufficiently clear, though there should have been no ambiguity on this count after the Doha Declaration (mentioned above), that "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". The government now seems to be waking up to the implications of this Section 5(b) of the Doha Declaration and has put up a Discussion Paper on "Compulsory Licensing of Patents" on the web site of the Department of Industrial Policy and Promotion of the Ministry of Commerce and Industry, soliciting views/suggestions of the public by 30 September 2010. The paper highlights the fact that "No CLs have been issued in India under the amended Patents Act", this despite the fact that "65% of the Indian population still lacks access to essential medicines".

The paper draws the attention of the readers to two significant cross-border acquisitions –Ranbaxy Laboratories by the Japanese transnational Daiichi Sankyo and Piramal Health Care by the US transnational Abbot Laboratories, both of which are in the list of the top 10 pharmaceutical companies operating in India. The authors of the paper are concerned that "If large Indian generic companies with the capability to manufacture drugs based upon a CL ... are themselves taken over, then the regime of cheap and effective drugs may be threatened..." The paper goes on to discuss what it calls the "flexibilities" incorporated in the Patents Act, 1970 as amended in 2005 in its Chapter XVI entitled "Working of Patents, Compulsory Licences and Revocation", which deals with the issue of CLs. We need not go over this ground, but a few comments are called for. Why cannot the government put in place a CL system which is simple and easy to administer and implement? Has the government really taken full advantage of all the "flexibilities" that the TRIPS Agreement post-the-Doha-Declaration provides? What are of practical importance are the grounds for grant of a CL and the procedure. The grounds of "reasonable requirements of the public" or "reasonably affordable price" can be legally challenged and such a process can be lengthy and its outcome uncertain. So such grounds need to be clearly and unambiguously elaborated upon. As regards the question of a "reasonably affordable price", the discussion paper has some suggestions, among which are the very reasonable guidelines of the Japanese Patent Office.

What then seems to be holding back the government from taking advantage of the instrument of the CL in the public interest? Frankly, the government seems more bothered about the interests of the large transnational pharmaceutical companies. We are reminded of the top priority the then Indian Prime Minister Atal Behari Vajpayee gave to resolving the issue of "data exclusivity"

– about which the transnational pharmaceutical corporations were highly agitated at the time – immediately after his return from the US in November 2001. On such matters, has the present incumbent been any different? So, it is not merely the question of a liberal specification of the grounds and procedure for the grant of CLs to non-patentees to produce and sell patented products, it is essentially the de facto precedence that the government accords to the rights of the patent holder over the basic human right to health.