INDIA ADOPTS A NEW PATENT ACT

Apprehension on Drug Prices Unfounded

The Patent (Amendment) Bill 2005 has been passed by the Indian Parliament. The new law provides for product patent in drugs, agricultural products and embedded software while patentability of plants remains outside its purview.

Indian Commerce and Industry Minister, Kamal Nath, said that the issue of patentability of new chemical entities and micro-organisms would be referred to an expert committee, which will look into further amendments.

He said that apprehension about drug prices rising once the product patent regime was in force were unfounded as enough safeguards were built into the legislation. He asserted that the provisions "were not multinational-driven but nationally driven."

India's obligation to the WTO is to put in place a product patent regime from January 1, 2005. The Minister said that India could not renege on its international obligations. Moreover, the patent legislation is a tribute to Indian scientists as they were not merely lending their knowledge and intellect but also were able to create intellectual capital abroad and patent them successfully.

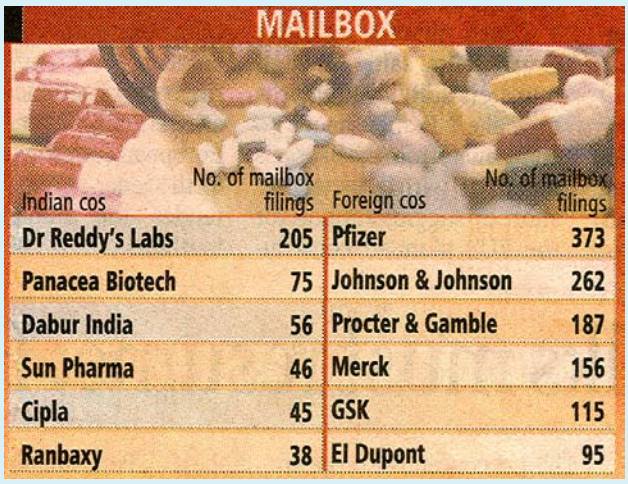
(BL, 23.03.05)

Amendments in the Patent Act

- Definition of patentability modified to prevent evergreening of patents
- Pre-grant opposition strengthened; Patent Controller to hear the opposition and dispose off the representation within a period of time
- The time for filling pre-grant opposition has been increased from three to six months
- Any person making an opposition representation would have the right of becoming party to any proceedings
- Least Developing Countries would be allowed importation of patented pharmaceutical products from India
- Even after the Mail Box is opened, companies already manufacturing the patented products would be allowed to do so after paying a reasonable royalty to the patent holder. No infringement proceedings could be instituted against such enterprises
- Compulsory licensing norms eased to allow exports, curb anticompetitive behaviour
- Patentability of software related to inventions omitted

Patent Mailbox Opened

US-based Pfizer has emerged as the biggest pharmaceutical patent applicant in India. Patents Office of India has opened the mailbox of patent pleas for pharmaceutical and agro-chemical inventions for 1995-2005. Mailbox applications are meant to recognise inventions as India switches to a product patent regime. Among Indian companies, Dr. Reddy's Laboratories has been the most aggressive patent seeker.



Indian cos	No. of mailbox filings	Foreign cos	No. of mailbox filings
Dr Reddy's Labs	205	Pfizer	373
Panacea Biotech	75	Johnson & Johnson	262
Dabur India	56	Procter & Gamble	187
Sun Pharma	46	Merck	156
Cipla	45	GSK	115
Ranbaxy	38	EI Dupont	95

Of a total of 8,926 patent pleas in the mailbox, a majority of 7,520 belong to foreign entities. Expectedly, the US, home to a host of leading pharmaceutical multinationals, took a considerable lead over other countries including hosts India, which was in the second slot.

However, India's second position does not truly reflect its patenting prowess as opposed to other countries. India is expected to lose out heavily on the patent controller's priority scale for examination of the pleas. This is because foreign applicants have used the Patent Cooperation Treaty (PCT) route for patent filings in India than India itself. This will give automatic precedence over corresponding Indian filings, if any. Date of PCT filing with a relevant international bureau will be reckoned as the date of filing in India too, even if the Indian plea was actually made earlier.

The moot point is that the seemingly huge number of patent filings is no guarantee to a commensurate patent grant spree. A vast majority of these are likely to be either frivolous or preventive pleas. *(FE, 21.03.05)*

Surrender to Multinationals

– Arvind Panagariya*

Representing the interests of its ultra-powerful pharmaceutical multinationals, the US had pushed for a very high level of patent protection for medicines during the Uruguay Round (UR) negotiations. India, which had witnessed its poor benefit from the low-cost generic drugs industry that grew around its relatively weak patent regime for medicines, had led the fight against this US push. In the end, though the US was largely successful in achieving its objectives, India managed to push a set of flexibilities into the UR Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) that could be used to protect the interests of the consumers against those of the multinationals.

It now appears, however, that India too has capitulated to pharmaceutical multinationals, both foreign and domestic. In the recent Patent (Amendment) Ordinance, 2004 that implements the TRIPs Agreement in full in India, and which must be replaced by an Act of the Parliament within six months under the Indian Constitution, India has failed to take advantage of the very flexibilities for which it had fought so hard more than ten years ago. This means cheaper generic versions of the newly patented drugs will be slower and harder to appear in the market than the TRIPs Agreement would permit.

The Economic Times

Ironically, this surrender has taken place under a government that prides itself in championing the cause of the poor and with the aid of the domestic pharmaceutical lobby that had stridently opposed the TRIPs Agreement during the UR negotiations. It has also happened relatively quietly – in contrast to the hundreds of demonstrations by hundreds of thousands of Indians during the UR negotiations, few Indians have come out to protest in New Delhi this time around.

The Ordinance fails on a number of fronts but most importantly in the area of compulsory licensing. The TRIPs Agreement allows countries to issue compulsory licenses for the manufacture of patented drugs without the patent holder's permission in case of public health emergencies. It also gives the country the sole right to determine whether a particular situation represents a public-health emergency.

The Ordinance takes no advantage of this provision. Instead, it leaves in place just the old provision for compulsory license in the Patent Act, 1970. Under that provision, the Controller of Patents must take into account such matters as the time elapsed since the issuance of the patent, efforts made by the patentee to make full use of the invention and the ability of the applicant for the compulsory license to work the invention to public advantage.

In so far as public health emergencies are concerned, India can scarcely afford the bureaucratic delays that these requirements imply. For example, they effectively give the patent holder the right to object to the compulsory license even prior to the issuance of the compulsory license. Under the TRIPs Agreement, it would be perfectly legitimate to issue a compulsory license expeditiously, postponing any representations against it till after production has begun. Can India, with the AIDS public health emergency virtually at its doorstep, afford to go slow on allowing the manufacture of generic versions of the future, more effective AIDS drugs?

Closely connected is the issue of exports of generic versions of patented drugs produced under compulsory license to third countries that lack the capacity to produce their own generic versions. The Ordinance provides for the issuance of compulsory licenses for such exports but gives the Controller of Patents the power to specify any criteria that he sees fit. Such blanket bureaucratic discretion within the Indian system can only delay the beginning of production and exports of the drugs. The WTO decision of August 30, 2003 provides a clear statement of the conditions to be satisfied for a license for exports to third countries. These conditions are relatively straightforward and there is no rationale for India to go further by placing additional conditions on the license. The exports of generics by the Indian firms have been responsible for bringing the prices of antiretroviral therapy from US$12,000 to US$140 per year and the value of such restraints on drug prices to the world's poor can be scarcely underestimated.

The Ordinance is also vague on the extension of patents beyond the normal 20-year period. There should be no room for so-called practice of "evergreening" whereby firms manage to extend patent by switching from capsule to tablet or finding new uses. The practice, endemic in the US, has been known to extend the monopoly power of the patent holder and to discourage innovations around the patent. The 20-years patent required under the TRIPs Agreement is already excessively long and there should be no room for extension under any circumstances.

Also puzzling is the weakening of the provisions for pre-grant opposition to patent applications that had existed in the original Patents Act, 1970. The TRIPs Agreement imposes no such requirement and if the interests of the public rather than multinationals are to be safeguarded, there is little excuse for this weakening. Even many developed countries such as Canada and UK, which give priority to public interest, have much tougher pre-grant-opposition provisions.

The silver lining on this otherwise bleak horizon is that India will have the opportunity to correct its mistakes when the government places the Patent (Amendment) Bill, 2005 before the Parliament to replace the Ordinance prior to June 30 as required by the Indian Constitution. If Prime Minister Manmohan Singh truly wishes to protect the interests of the public and, indeed, India as a whole, he must ensure that this Bill makes the fullest use of the flexibilities in the TRIPs Agreement that he himself probably helped negotiate as the Finance Minister of India in the first half of the 1990s. A patent law that tests the boundaries of the flexibilities even at the risk of being challenged in the WTO is a far superior option than the one that subjects India to "TRIPs plus" regime and benefits the multinationals manufacturing drugs.

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