Patents (Amendment) Bill 2005: A Critique

EPW, April 9, 2005

Only one more amendment was required, technically speaking, to make Indian law finally compliant with the TRIPS Agreement, i e, the introduction of product patents for pharmaceutical inventions. However, the Patents Bill made 74 amendments to the Patents Act of 1970, thus taking it much beyond the requirements of TRIPS. While Parliament has modified some of these amendments, it has chosen not to incorporate all the flexibilities that are available within TRIPS to safeguard public interest. As the bill now stands, unless the president were to return it to Parliament for consideraton, it fails to protect the public from the aggressive monopolies that patents confer on the right holders.

K M Gopakumar, Tahir Amin

The Patents (Amendment) Bill 2005 was finally voted in by the Rajya Sabha on March 23. Unless the president exercises his powers under Article 111 of the Constitution so as to return the bill to Parliament for its reconsideration, it will be passed into law.

The justification for the Patent (Amendment) Bill is to meet India's World Trade Organisation (WTO) obligations under the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). The TRIPS provided three deadlines for developing countries like India to comply with the multilateral patent regime. The first deadline was in 1995, to introduce mailbox protection and exclusive marketing rights (EMRs). The second was in 2000 to comply with TRIPS provisions on the duration of patent protection. India amended the Patents Act in 1999 and 2002, well beyond the WTO's required dead lines. The third and final deadline was to introduce product patent protection for pharmaceuticals and agrochemicals by January 1, 2005. To meet this deadline, the government issued an ordinance on December 26, 2004, to amend

its Patents Act 1970. Technically speaking, only one further amendment was required under TRIPS, i e, the introduction of product patents for pharmaceutical inventions. However, the ordinance carried out a further 74 amendments to the Patents Act, thus taking it much beyond the TRIPS requirements. In effect these set of amendments took India into a 'TRIPS plus' regime.

The final round of amendments effected by the government has raised protests from all corners of the world, including multilateral organisations such as the World Health Organisation and UNAIDS, who described the implications of the patent ordinance as 'potentially devastating' to developing and least developed countries who are dependent on Indian generic drugs. Responding to the widespread criticism, the government withdrew or re-drafted certain amendments to the ordinance and Parliament gave its approval to the bill with those amendments. The key amendments which could have lasting effects on the accessibility to medicines in India and other developing countries which import inexpensive drugs from India pertain to the scope of patentability, immunity to generic manufacturers, pre-grant opposition, compulsory licence provisions and compulsory licences for exports. However, a thorough reading of the text shows that some of the key amendments are still inadequate to the extent that they are riddled with loopholes and ambiguities, thereby failing to really address the concerns raised. This analysis and critique brings attention to the main shortcomings of the bill.

Scope of Patentability

It is common in the pharmaceutical sector to file patent applications for already known molecules by claiming trivial improvements. This naturally extends their monopoly even after the expiry of the original patent. This process is often referred to as 'evergreening'. Patents are obtained for formulations, pharmaceutical salts, isomers, polymorphs, combinations, new uses of such forms, and manufacturing processes. According to a report of the US National Institute of Healthcare and Medicines (NIHCM)

Drug manufacturers patent a wide range of inventions connected with incremental modifications of their products, including minor features such as inert ingredients and the form, colour and scoring of tablets. In some cases these patents may discourage generic

companies from trying to develop a competitive product. In others the generic company may be able to design around the new features.

Thus, the subsequent patent often extends the monopoly and blocks the introduction of generic products which can be sold at very low prices. In the light of such practices it was absolutely necessary for developing countries like India to limit the scope of patentability only to new chemical entities so as to ensure the accessibility, availability and affordability of medicines.

The obligation under TRIPS is to provide product patent protection for inventions in pharmaceutical and agrochemical sectors. However, TRIPS is silent on the subsequent patenting of known substances. As a result implementing countries have the option of limiting patent protection to new chemical entities only. According to the minister of state for commerce and industry, there were 4,792 patent applications1 pending in the mailbox of the Indian Patent Office.2 However, during this period, only 297 new chemical entities received marketing approval from the US FDA between 1995 and 2004.3 The disparity between the number of applications and new chemical entities entering the market raises a very serious question whether the applications in the mailbox are intended to patent products with frivolous or marginal changes. If the answer is in the affirmative then such drugs with 'evergreened' patents will increase the number of monopoly drugs in the market, prevent the entry of generics and keep prices of these drugs at high levels.

The Indian Patent Act 1970 limited the scope of patentability by defining the term invention, patents, inventive step and industrial application. Further, the act explicitly excluded certain inventions from patentability. The provisions for determining the scope of patentability lie in the interpretation of Section 2 and Section 3 of the act. The 2005 Bill, however, introduces three new definitions in Section 2, viz, inventive step, new invention and pharmaceutical substance. The stated reasons for these definitions are to limit the scope of patentability in general and of pharmaceuticals and agrochemicals in particular. These definitions are extremely ambiguous with numerous technical loopholes, which will in fact facilitate 'evergreening' of patents. The law should have clearly defined these terms and limited the scope of interpretation to avoid the expansion of the scope of patentability.

The bill provides a new definition to the term inventive step, one of the three basic criteria for patentability. The old definition was “an inventive step – a feature that makes the invention not obvious to a person skilled in the art”. According to this definition an invention satisfies the criterion of inventive step if it is not obvious to the person skilled in the art. The new definition tries to clarify the components of an inventive step. The bill defines an inventive step, as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art”.

Hence, to meet the inventive step criterion, the patentee will either have to show that the invention includes a technical advance or has economic significance, or both. In other words, the requirement of technical advancement is compromised and diluted by the fact that a patent could be simply granted on economic significance alone. Economic significance alone should not determine the inventive step of a patentable invention. Thus the definition dilutes the requirements of an inventive step and broadens the existing provision to the benefit of patent holders. The provision should have required the applicant to comply with both requirements for an inventive step, i e, technical advance over the existing knowledge and economic significance. It should also delete the term ‘or both’.

Another entry point for broadening the scope of patentability in the bill is the definition introduced for ‘pharmaceutical substances’, which reads as “any new entity involving one or more inventive steps”. As it stands, the provision is too broad, allowing all types of pharmaceutical substances to be patented. The term ‘chemical’ should have been inserted so that the definition would be ‘any new chemical entity’. The present definition encompasses every type of pharmaceutical entity including, but not limited to, formulations, pharmaceutical salts, isomers, polymorphs and their combinations.

The bill also defines the term ‘new invention’ and introduces a new definition of a patent. A patent is now defined as “a patent for any invention granted under this act.” The definition of a patent uses the term invention, as defined in Section 2(j), as opposed to a ‘new invention’, thus creating a disconnect between the two provisions

and, therefore, a potential broadening of what a patent can be. As a result, the addition of the new definition of new invention loses its purpose.

Immunity to Ongoing Generic Production

The bill permits generic manufacturers to continue producing generic versions of new drugs which are in the mailbox and which could now be patented, on the condition that the generic manufacturer was producing and marketing the concerned product prior to January 1, 2005. However, the eventual patent holder of a mailbox application will be entitled to receive a 'reasonable royalty' from those generic manufacturers who have made a significant investment.

The question of 'significant investment' poses a threat of potential infringement suits and litigation as the patent holder may challenge the meaning of significant investment in order to extract a royalty payment. With respect to the 'reasonable royalty' it creates the problem of excessive demands from the patent holder and litigation. The reasonable royalty rate should have been fixed at a particular percentage; the accepted norm is 4-5 per cent of the drug sales. For example, in South Africa, Glaxo Smith Kline demanded a royalty of 25 per cent before the courts intervened. A higher royalty will increase the price of generic drugs and may reduce the accessibility and affordability of medicines.

Pre-grant Opposition

The amendment has restored all grounds, which were taken away through the ordinance, to oppose patent applications before its grant. The grounds for bringing an opposition remain as before and provide recourse to challenging frivolous and legally invalid patents. However, still the opposition is by way of representation and not in the form of notice to opposition. It is also not clear whether the opponent can access the documents on which the patent holder relies on the claim. Furthermore, no appeal lies against the decision of the controller of patents on the representation to oppose the patent.

The effectiveness of the opposition process depends upon the access to information on the mailbox applications. The Patent

Office in 2005 has issued a notification in its official journal that inventions either filed or claiming priority on July 30, 2003 have been deemed to be published. However, no physical publications have been available to date. This lack of publication takes away the possibility of accessing information relating to the patent application and the ability to oppose the same. Lastly the bill refers to the publication of an application, but fails make the publication of the complete specification available to the public. This will greatly hamper opposition proceedings.

Compulsory Licences

The effective and efficient issuance of compulsory licences is imperative to curb the abuse of patent rights by the patentee. According to the Commission on Intellectual Property Rights (CIPR) "developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use". The CIPR recommended that developing countries should adopt effective compulsory licensing mechanisms which include straightforward, transparent and fast procedures that do not suspend the execution of the licence. Moreover, it is well argued by the CIPR that developing countries should fully exploit the flexibilities within TRIPS for determining compulsory licensing, as well as for non-commercial use by the government, including production for export.

However, the compulsory licence provisions in the bill do not satisfy the above-mentioned processes. Even though, the language of Section 83 of the Patent Act reflects the spirit of Articles 7 and 8 and Doha Declaration on TRIPS and Public Health, the subsequent sections fail to reflect the spirit of Section 83. With the exception of a national emergency, extreme emergency or public non-commercial use, a compulsory licence is available only after three years from the date of grant of the patent. Further, clear and effective grounds for the issuance of a compulsory licence have not been provided in the legislation. For instance, can a compulsory licence to be issued when a patentee refuses to issue a voluntary licence on reasonable commercial terms? The details of anti-competitive practices are not spelt out clearly in either the Patents Act or Competition Act. This leaves a gaping hole in the process, which is likely to be exploited by the patent holder. The procedural

requirements to issue a compulsory licence are too cumbersome and do not provide any strict time frames for the conclusion of the process. This will result in extreme delays in the issuance of a compulsory licence. In addition, there is no ceiling on the remuneration payable to the patent holder, which will inevitably lead to demand for excessive royalty and unnecessary litigations. Furthermore the injunction remedy, not required under TRIPS, with regard to compulsory licence litigations, gives an extra power to the patentee to block the compulsory licence for a long period of time. All these requirements cumulatively make the compulsory licence system potentially an unworkable option in India.

Contrary to the reports, which have been circulated, the amendment has only made cosmetic changes to quickening the process of dealing with an application for a compulsory licence under Section 84(6). That is, where the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period, the controller can now interpret 'reasonable period' to mean a period not ordinarily exceeding six months.

However, the real issue is the failure to remove the existing requirement which stipulates that only after the expiry of three years from the grant of a patent; can a person make an application to the controller for the grant of a compulsory licence.4 Therefore, in total the request for a compulsory licence does not have to be considered for at least three years and six months from the date of the grant of the patent. Furthermore, one also has to take into the account that the bill fails to provide a timeline within which the controller must deal with a compulsory licence application after the six-month period mentioned above lapses. This could lead to a further delay before any licence can be issued. It is common knowledge that pharmaceutical MNCs often refuse to deal with requests for compulsory licences or demand exorbitant royalties while considering such requests.

With respect to exporting drugs to a country which makes a request for a generic drug, the amendment now gives the option of the requesting country to simply give notification to the exporting country or to issue a compulsory licence itself before making the request.5 As a result, exports from India to a country having no or insufficient manufacturing capacity can take place even in the

absence of a compulsory licence in the importing country. However, one question that is not entirely clear is whether the procedure for the grant of the compulsory licence for the domestic market (under Section 84(6) discussed above) will also be the same for compulsory licences for the purpose of export. Although the provision relating to export of drugs falls under the heading of 'General and Special Provisions' in the act, that normally should be treated as an urgent matter, there is no clarity in the amendment about the procedure. Further, absence of a ceiling on royalty and availability of injunction remedy will be used by the patent holder to slow down the matters, it could quite possibly argue this point, and delay the introduction of new drugs that a developing or least developing country may urgently require.

The bill further fails to provide the safeguard available within Article 44 of TRIPS, which effectively allows member states to limit remedies on the remuneration that would be available to the patent holder where third parties are authorised by the government, without the authorisation of the right holder, to use the patented good rather than issue an injunction.

Quick Examination

As per the Ordinance the time frame for making the examination report is left to the rules. The new rules provide a period of one month for the examination report to be issued following the application. This was previously an 18-month period.

This is likely to create immense pressure on the Patent Office as there will not be enough examiners to deal thoroughly with the flood of applications which is likely to occur, thus resulting in improperly examined and legally invalid patents. The Patent Office in India does not have the infrastructure for research, access to information and capacity to face the challenges that the new act will bring.

The amendment takes away the limitations imposed by the act, and makes rule making a matter of discretion for the Patent Office. As a result, the Patent Office can now tamper with the various time lines by amending the rules as and when it requires, which may not be in the interests of the public.

Conclusion

The legislature has chosen not to incorporate the flexibilities that are available within TRIPS to safeguard public interest, particularly when it concerns pharmaceutical products. It is imperative that the compulsory licensing provisions are changed in order to prevent the dominant and abusive use of patents and allow the much-needed access to medicines and drugs. Similarly, a viable pre-grant opposition process needs to be installed to allow public interest groups to protect their rights. As the bill now stands, it fails to protect the public from aggressive monopolies that patents confer, and for many, the era of cheap affordable drugs is at the beginning of its end.

Email: kumargopakm@yahoo.com

Notes

[The authors are thankful to V K Unni, NALSAR University of Law, Hyderabad for his comments and suggestions.]

1 As on July 1, 2004.
2 However, according to latest reports data shows that there are 8,926 applications pending for examination in the mailbox in India, the vast majority by US and EU multinational pharmaceutical companies – Financial Express, March 21, 2005.
3 Obtained from the USFDA Web site.
4 Unless there is a national emergency, extreme urgency, etc.
5 Section 92 A. This provision is introduced to implement the August 30 Decision of the TRIPS Council, which permits compulsory licence for exportation to countries having no or insufficient manufacturing capacity in the pharmaceutical sector. However, the procedural and packaging requirements make it an unviable option.