Patents (Amendment) Act 2005

Setback for innovators and R&D

India wants its economy to grow at a rapid pace; it needs a Second Green Revolution; its industries have to become competitive in the world market, and energy conservation is a desperate need. Innovation is the key to achieving success on all these fronts. For this to happen, however, the Government must take urgent steps to re-draft the Patents (Amendment) Act 2005 to ensure that the interests of innovators and the generic industry are protected. Only then will R&D efforts gain the desired momentum, points out **Uttam Gupta**.

THERE is lot of unease among innovators over key provisions of the Patents (Amendment) Act 2005. These require close examination, especially against the backdrop of their having had to wait for a decade for the product patent regime to come into force after the TRIPS (Trade-Related Intellectual Property Rights) agreement came into force on January 1, 1995.

At the outset, let us look at the fate of those innovators who had put their applications for product patents in the Mail-Box (mostly for agrochemicals and pharmaceuticals) created under the first amendment to the Indian Patent Act in 1999, effective from January 1, 1995. With product patent law in place under the amended Act of 2005, the Patent Office has opened the Mail-Box and taken up scrutiny of applications filed before January 1, 2005. However, it has decided not to process those applications on which the word "WTO" is not marked.

The Patent Office has taken the view that at the time of their filing, the product patent law was not in place (Section 5(1) of the Act prohibited grant of product patent on agrochemicals, pharmaceuticals, biotechnology, etc.). The argument is fallacious.

The prohibition was applicable only for the period when the product patent law was not in force. Now, when, the law is in place, following the third amendment to the Patents Act (2005), there is no basis for disallowing certain applications on an artificial pretext.

The Patent Office's refusal to grant Mail-Box status to applications not marked "WTO" will severely penalise the applicants simply because the receiving officer in the Patent Office did not write "WTO" on their applications.

Even for Mail-Box applications, the amended Act allows patent rights to commence from the date of patent grant only. This results in a substantial reduction in the protection period. Thus, for an application filed in 1995, assuming three years for patent grant, this would only be seven years.

Of the 20-year term of a patent, the applicant loses 10 years because the date of putting the application in the Mail-Box is taken as the filing date. A filing date prior to the date on which the product patent law came into force has no meaning. And, yet, by doing so, all the Mail-Box applicants have been penalised.

It is understood that only 10 per cent of the total applications filed has been processed for grant of patent. At this pace, grant of patents for the majority of applications will be inordinately delayed. The more the delay, the less the protection period.

The amended Act allows generic manufacturers who were producing and marketing products of a Mail-Box patentee before January 1, 2005 to continue doing so on payment of a "reasonable" royalty (term "reasonable" is not defined). This means that even after patent grant, the rights of the patentee are seriously compromised.

The amended Act (2005) allows pre-grant opposition of a patent application. The person opposing the application need not even be a stakeholder. Further, he is a party to the opposition proceedings. This means that he can go ahead and prevent the grant of even a genuinely valid patent.

The Act provides for increasing the time limit for filing a pre-grant opposition request to six months from date of publication. Besides, grounds for such opposition have been increased from two to 11. These changes will inordinately delay the grant of patent and may lead to frivolous opposition.

Ironically, the applicant cannot appeal against the decision of the Controller of Patents if the latter allows the pre-grant opposition application. Thus, the former would have forfeited his right to get a patent even before the application is subjected to detailed examination!!

Following the Second Amendment to the Patents Act (1970), parallel imports of products patented in India were allowed, subject to the condition that the foreign exporter was authorised by the patentee to sell and distribute. Under the amended Act (2005), the foreign exporter need only be 'duly authorised under the law'. This change is tantamount to allowing sale of generic products without the consent of the patent-holder and defeats the very purpose of granting a patent. It will result in a flood of imports from countries where the product does not enjoy patent protection.

The Patents (Amendment) Act, 2002 had introduced the Bolar provision to allow for using and selling the patented product during the term of the patent, for obtaining regulatory approvals. The amended Act 2005 has revised this to include the act of importing as well. The provision has been selectively transposed from the US law.

In the US, under the Bolar provision (applicable only to pharmaceuticals), even as enabling measures are provided to ensure the entry of generics just at the time of expiration of the patent term, it also gives relief to the patent-holder by allowing a suitable increase in the patent term to compensate for the time lost in getting regulatory approval. That strikes a balance between the interest of the generics and those of the patentees.

However, under the amended Act (2005), due to the selective transposition of Bolar, even as the generics can gain entry immediately on expiration of the patent term, the patent-holders of, say, crop protection products (CPP) are at a considerable disadvantage because of the inevitable delay in getting regulatory approvals.

For getting market approval of CPP, the applicant is required to generate data from studies spread over several years to demonstrate the safety and efficacy of the product mandated by the Registration Committee under the Insecticides Act (1968). For pharmaceuticals, such studies are generally not required in India, if the product is approved by the US FDA (Food and Drug Administration). The Patent (Amendment) Ordinance, 2004 allowed for the possibility of patenting incremental innovations — new use or new property of a known substance, etc. Under the amended Act (2005), this flexibility has been substantially curtailed.

As per Section 3(d), new form of an existing substance may be patentable if it results in enhancement of known efficacy of that substance. However, the term "efficacy" used is vague and may result in considerable bias/subjectivity in assessment by the Patent Office. It seems the Government has sought to restrict the patentability of an innovation only to a New Chemical Entity (NCE). The discovery of an NCE is a hugely expensive affair (about $1 billion for drugs and $300 million for CPP). This is beyond the reach of even big companies, not to mention small entities and research institutions/universities.

India's real potential lies in incremental innovations. By discouraging these, the amended Act will actually cause a serious setback to the R&D efforts of thousands of Indian scientists. It will accelerate brain-drain as scientists look for territories outside India to get the reward for their innovations.

The amended Act provides for the issue of compulsory licences (CL) under various circumstances which include a situation where the government perceives that the patent-holder is unable to ensure the supply of a product at an "affordable" price. 'Affordable price' is a relative term, which could be interpreted variously whereby even a reasonable price could be termed as unaffordable.

From the above, one cannot escape the conclusion that, at every stage, there is an underlying attempt to infringe on the rights of the innovators. This is manifest in:

- restricting the patentability of innovations to NCE;
- restricting Indian nationals from getting patents outside India;
- diluting substantially the patent rights of Mail-Box applications;
- denying patents to non-WTO applications filed before January 1, 2005;
- affording multiple opportunities for opposing patents — pre-grant, post-grant and revocation;
- allowing parallel imports of patented product without authorisation of the patent-holder;
- enabling entry of generics just at the time of patent expiry; yet ignoring the inevitable delay of the innovator in launching the product;
- setting extremely liberal provisions for compulsory licencees to produce and sell patented products any time during the protection period.

The above changes may have been prompted by the fear that prices will rise. This is baseless as about 98 per cent of drugs and almost all CPPs currently in use are off-patent. Even for patented products, there are substitutes available and competition will rein in the price. There exists no valid reason for tightening the noose on the innovator!

India wants its economy to grow at a rapid pace of 8 per cent per annum; it needs a Second Green Revolution; its industries have to become competitive in the world market; energy conservation is a desperately need; its researchers have to look for solutions to problems unique to India's tropical conditions; and, above all, any development has to be environment-friendly.

Innovation is the key to achieving success on all these fronts. We have a huge pool of scientific manpower that can make this happen. In this backdrop, there is an urgent need to take a re-look at the Patents (Amendment) Act 2005 to ensure that R&D efforts in India get the desired momentum and protection. The Government may consider revisiting the Patent (Amendment) Ordinance 2004, which made an attempt to balance the interests of the innovator and the generic industry, unlike the amended Act 2005, which seems to be concerned solely with protecting the latter.

(The author is Resident Director, CropLife India, New Delhi. The views are personal.)