Patent ordinance

Innovator still to get desired comfort

UTTAM GUPTA

ON December 26, 2004, the Government promulgated an Ordinance to provide for product patents in all areas of technology — agrochemicals, pharmaceuticals, bio-technology, food, and so on — and made other changes in the Indian Patent Act (1970) to make our laws compliant with the WTO's TRIPS Agreement. The Ordinance takes effect from January 1, 2005.

The Union Minister for Commerce and Industry, Mr Kamal Nath, has stated that the introduction of product patents will boost research and development (R&D) and fully exploit the talents of the country's scientists and engineers. He has also ruled out any increase in prices as 97 per cent of essential drugs are not covered by patent.

Likewise, in the crop protection sector, a majority of about 180 pesticides now sold in India are off-patent and, therefore, their supply and prices are unlikely to be affected. Even for the very few products that may get a patent, substitutes are available in the market. The domestic industry does not seem to agree. It has said that the flexibilities provided for under the TRIPS Agreement have not been effectively used to address public health concerns. To know where the truth lies, let us take a close look at some key provisions.

At the outset, let us look at the treatment of applications in the mail-box. There are about 9,000 applications (7,000 in pharmaceuticals and 2,000 agrochemicals). Of these, for about 2,500, applicants have made a request for examination. These will now be taken up for processing.

These include applications for a number of molecules whose copycats are already in the market. The industry's concern is, in fact, about the supply and increase in prices of these products. While this is a fraction of the total, a wrong impression is being created that all products would get affected!

How would the dynamics of these copycats work out? The generic companies will be forced to withdraw these the day the innovator company gets its product patent. The consumers will, therefore, have to depend solely on the latter for their requirements.

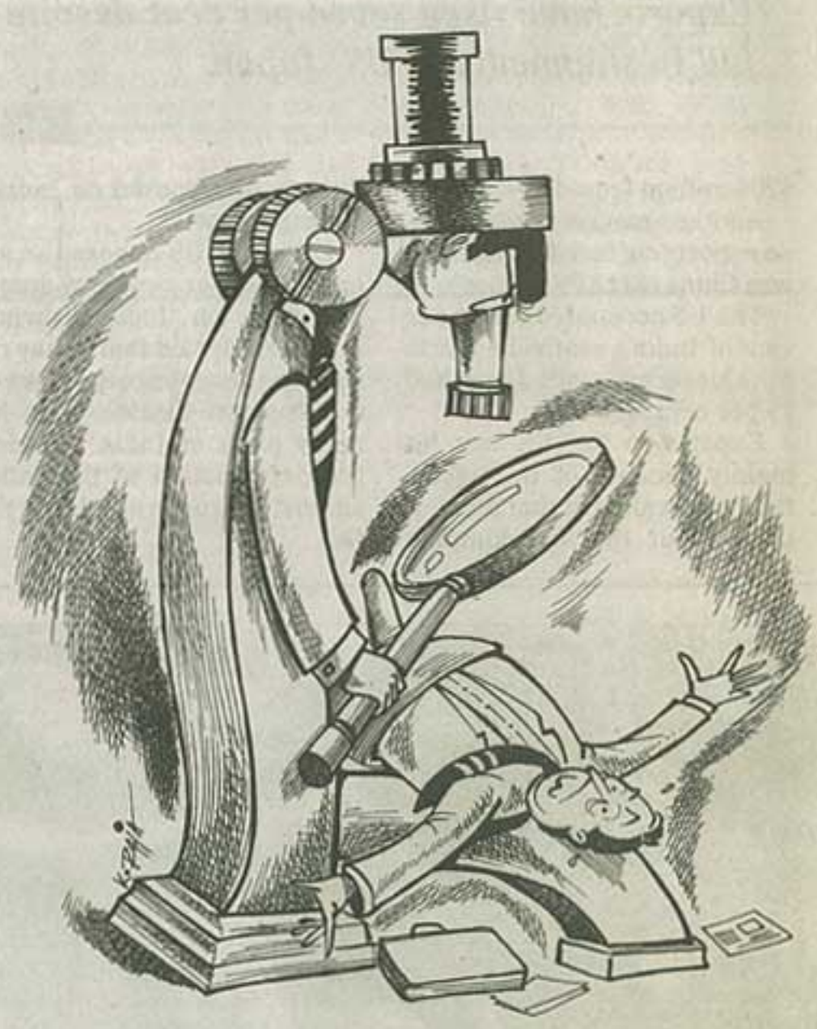
Patent protection confers exclusivity for a certain period of time to the patent-holder. This enables him to charge a suitable price for the product. This needs to be seen in the correct perspective as a reward for sharing his innovation with society for its benefit in the long-term.

In high-technology sectors such as drugs and agrochemicals, innovation involves huge expenditure on R&D. For a new drug molecule, the R&D cost is about $1 billion and for a new pesticide molecule, it is about $300 million. Therefore, such a reward becomes an absolute necessity. Without exclusivity, the innovator company would simply not be able to generate the revenue streams needed for fully amortising the sunk cost on R&D. Product patent gives it a chance to avoid this situation.

It is illogical to compare the price charged by innovator with the price of a generic producer. The latter spends "negligible" sums on R&D and is, therefore, able to sell the copycat at a throw-away price. If all these years, consumers had access to new "innovations" at low prices, it was because the Government had the benefit of the 10-year exemption from the requirement to introduce product patent. Now that this transitional phase has come to an end, we need to face the implications head on.

It must be remembered that these implications are confined to a very narrow range of patented products (corresponding to Mail-Box applications) even as the majority of products remains unaffected and overall consumer welfare is not compromised.

Ironically, even now, a conducive environment has not been created to effectively address the concerns of the innovator company. Far from that, the Ordinance contains provisions that will only tilt the scales heavily in favour of the generic companies.



For an application in the Mail-Box, the rights of the patent-holder will be reckoned only from the date of grant (for applications filed after January 1, 2005, the corresponding benchmark will be date of its publication).

From a close reading of the procedures and time-lines drawn up, it would appear that the first patent would be granted by 2009. Until then, the innovator will continue to be denied protection. Concurrently, generic companies will continue to sell copycats and enjoy the associated benefits.

Will the patentee be able to enjoy the benefit of patent protection for 20 years that has been provided for under the Act following the second amendment? On this front also, he is in for disappointment as effective protection will be substantially lower than 20 years. Let us consider an application that was put into the Mail-Box in 1995. The protection will expire in 2015 as the patent term of 20 years is reckoned from the date of application. However, since the rights will commence only from 2009, effective protection is only for six years.

The Patent Act (1970) provided for "process patents", which gave no protection at all as anyone can reverse-engineer. Even the notional protection or patent term was small — seven years from application date or five years from date of grant, whichever is earlier.

The Ordinance has not done much to improve the situation for the Mail-Box applications. In fact, these will be at a substantial disadvantage *vis-à-vis* applications filed after January 1, 2005, which get a reasonable protection period (subject to expeditious grant of patent).

For applications in the Mail-Box, the situation can be remedied by allowing the rights of applicants (especially the 1995-2000 cases) to commence from January 1, 2005. Had the Patent Office taken up processing of these cases in 2000 (on the basis that product patent would come into force on January 1, 2005, keeping to the WTO commitment), by this date, the applicants concerned would, anyway, have been granted patent.

Alternatively, the date of application of such cases may be taken as January 1, 2005. This makes eminent sense as prior to this date, the product patent law just did not exist. This would preserve the protection period of innovator without giving the generic company a sudden jolt (it can continue to sell until the grant of patent).

The procedures need to be so galvanised to keep the time for grant of patent to the bare minimum. In this backdrop, retention of the provision for pre-grant opposition of patent applications could be a major stumbling block. The law should provide for post-grant opposition only. The procedures for this should be such as to enable a time-bound decision.

The Ordinance permits preparatory action by non-patentees during the life of a patent to facilitate production and marketing of the patented product immediately after the expiry of the patent. When the Government is so keen to ensure that the generic companies do not have to wait for a single day, why should it not view the innovator from the same mindset and arrange for the grant of patent expeditiously?

Once a patent has been granted, the patent holder should be allowed to live in peace. In other words, during the period of exclusivity, the Government should not allow unwarranted encumbrances in his territory. The interventions, if any, should come only in extraordinary circumstances like a national emergency.

But there are reasons to believe that even under normal circumstances, he will not be at peace. The provision that compulsory license can be issued to a local company if the patented invention is not available for the public at "reasonably affordable price" could be prone to misuse at the slightest opportunity. This will defeat the very objective of patent protection!

Hitherto, "new use of an old molecule or any new property of a known substance was not eligible for patent". The Ordinance pre-fixes this formulation by the word "mere". This creates uncertainty in regard to whether new use/new property is patentable or not.

There are a host of opportunities available in the area of incremental innovations. This is particularly suited to a country like India which has a vast pool of scientists and at the same time, we do not have the resources needed for discovery and development of new molecules.

The perception, in certain quarters, that patenting of new use of an old molecule is an attempt to evergreen a patent (a euphemism for extending the patent term) is a myth. On expiry of patent term, generic companies can freely take up production and marketing of the old/off-patent molecule.

In view of the potential benefits, the Government should clearly provide for granting patent protection to incremental innovations provided these meet the three-fold criterion, that is, "non-obviousness", "an inventive step" and "capable of industrial application" as provided under the TRIPS Agreement. The present formulation, "mere new use of an old molecule or any new property of a known substance is not eligible for patent" could be dangerous for all stake-holders as it will be susceptible to varying interpretations and lead to endless litigation.

A careful consideration of the above points would be helpful in bringing about the necessary refinements in the relevant provisions of the Third Patent (Amendment) Bill to give the required comfort to the innovator without compromising the national interest.

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