

Needed, a fair deal for patent seekers

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TO HANDLE the situation arising out of a possible outbreak of Bird Flu, a number of pharmaceutical companies are gearing up to produce Oseltamivir, the drug that can effectively tackle this menace. They will have to meet two important regulatory requirements.

First, a generic company has to conduct bio-equivalence studies to demonstrate the safety and efficacy of the generic version to the regulator for getting market approval. Second, it has to get a licence from Roche/Gilead and in case the latter is granted a patent on its application currently lying in the Mail-Box (Roche/Gilead hold worldwide patents for the drug).

The application of Roche/Gilead is only one among thousands of product patent applications lying in the patent Mail-box and it is important to assess carefully their fate under the Patent (Amendment) Act 2005.

At the outset, it is important to understand what the Indian Patent Mail-Box is all about. When the TRIPS Agreement came in to force on January 1, 1995, India availed itself of 10 years exemption for complying with it (five years corresponding to its status as a developing country and another five to adopt product patents for high technology areas such as pharmaceuticals, agro-chemicals, food, and bio-technology).

Vide the first amendment to the Indian Patents Act (1970) — effective from January 1, 1995 — the Government created the Mail-Box facility for accepting product patent applications with an obligation that the Patent Office will start processing them on enactment of the product patent law from January 1, 2005.

As the D-Day drew closer, the Government promulgated the Patent (Amendment) Ordinance, 2004 on December 26, 2004, to provide for product patent from January 1, 2005. The Patent (Amendment) Act, 2005 was enacted in early April. This was the green signal to the Patent Office to open the Mail-Box and process applications.

How does the Patent Office propose to deal with the applications? First, only those applications fulfilling the patentability criteria qualify for the grant of patent. In this context, while adopting the three-fold criteria of novelty, inventive step, and industrial application as per TRIPS Agreement, the Indian Patent Act, 2005 provides a long list of

what is not patentable under Section 3 (D) — salt, ester, ether, polymorph, pure forms, metabolites, etc.

Section 3 (D) seeks to restrict patentability primarily to new chemical entities (NCEs). "New use" of an existing substance cannot get a patent. A "new form" can get a patent if it results in a significant improvement in its existing "efficacy". However, "efficacy" is not defined in the Act/Rules. This leaves ample scope for subjective interpretation; also the ability of inventor to get a patent remains uncertain.

In view of above and the plethora of exclusions/limitations, getting a patent on "incremental inventions" by itself is going to be a Herculean task. And, even if the applicant gets one, the patent grant for a Mail-Box applicant is subject to a series of other conditions that seriously undermine his or her rights.

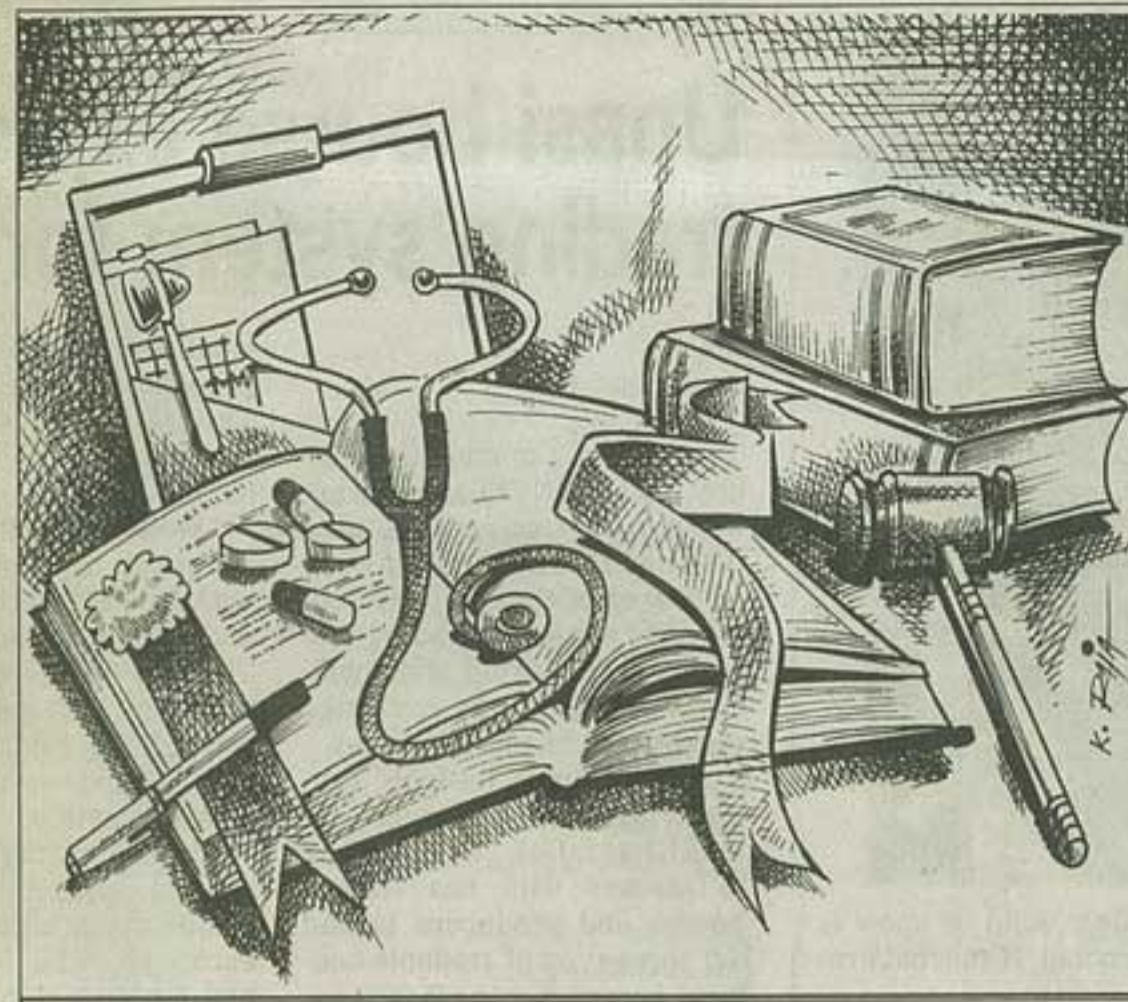
First, a Mail-Box patentee is eligible for rights from the date of patent grant whereas, for a patent on an application filed after January 1, 2005, the rights commence from the date of publication of the application. The date of patent grant being much later than the date of publication, a Mail-Box patentee is thus, put to a substantial disadvantage. He loses protection period to the extent of time taken for patent grant, that is, three-four years.

Second, the date of putting the application in the Mail-Box is taken as the filing date. It is illogical to get the clock ticking (commencement of patent term or filing date) from any date earlier than that on which the product patent law came in to force, that is, January 1, 2005. The effect of doing so is unjustifiable erosion of the patent term. For instance, for an application put in the Mail-Box in 1995, the applicant loses 10 years.

The cumulative effect of both the limitations can be deadly. Thus, even as the Act provides for a patent term of 20 years (uniform for all innovations), in reality, effective protection enjoyed by a Mail-Box patentee is much less. In the above example, he will have a protection period of only six-seven years!

Third, a person already manufacturing and selling the generic version of the patented product of Mail-Box applicant prior to January 1, 2005, and continues to do so as on this date, will co-exist with the patent holder on payment of "reasonable" royalty without having to face infringement suit ("reasonable" has not been defined in the Act/Rules).

The resulting scenario can be likened to some one forcibly occupy-



ing a house without the authorisation from the owner and his occupation subsequently legitimised by the government. This provision knocks at the very foundation of the patent grant. It is tantamount to granting a patent with one hand and taking it away by the other.

Fourth, vide an Order of the Controller General (issued in January 2005), an application filed before January 1, 2005 that did not carry the "WTO" mark was not entitled to the benefit of the product patent regime. Accordingly, the Patent Office did not process such applications for patent grant. However, following judicial intervention, the above Order has been withdrawn.

But for the withdrawal of the above Order, thousands of applications — all those that did not carry the WTO mark — would have been rejected even before being examined for grant of patent. A typical case of some one losing the race without being allowed to participate!

To summarise, the effect of first and second limitation is to drastically reduce the protection period available to a Mail-Box patentee whereas, the impact of the third is devastating as it virtually takes away all the rights and privileges conferred by the patent grant on the innovator. However, all this should be music to the ears of the generic manufacturers.

All those already producing and selling the generic version before January 1, 2005 and continuing to do so as on date, are most comfortably

placed as the patent holder cannot file an infringement suit even for the period after grant of patent. The provision for payment of "reasonable" royalty is little consolation to the latter, as without the enabling provision of taking the former to the court, he cannot hope to get the compensation needed to fully recuperate the investment on innovation. Where the generic manufacturer has started manufacturing and selling the generic version of the patent protected product of Mail-Box applicant after January 1, 2005 (the instant case of Oseltamivir falls in this category), they may not enjoy immunity from an infringement suit. However, they can safely bank on the second limitation.

Thus, if a patent is granted after three-four years of opening of the Mail-Box, that is, by 2008-09, the generic companies could manufacture and sell the patent protected product of Mail-Box applicant during 2005 to 2008/2009 without having to face any infringement suit. This is because the patent holder starts enjoying the rights and privileges only from the date of patent grant, that is, 2008/2009 onwards.

Such producer/seller of the generics (post January 1, 2005 vintage) could possibly face a risk in case the patent office grants patent to the Mail-Box applicant at an extraordinary speed say within 6-12 months of opening the Box. But in view of the inadequacy of the available infrastructure (despite three fold increase in number of examin-

ers), such a possibility is remote.

The provisions of the Patent (Amendment) Act 2005 relating to Mail-Box applications may have been framed to protect the companies who launched the generic versions before January 1, 2005 (and perhaps, even those who may be contemplating to do so even there after). Of course, there is the related issue of price to the consumer.

However, the Government seriously needs to introspect on the huge cost it entails in terms of the set back to the innovators. The innovators as a class transcend all boundaries (applications in Mail-Box belong to both domestic and foreign companies) and deserve the much needed incentive for their R&D efforts especially the efforts that entail huge investment and commitment over a long time horizon. Giving a fair deal to the innovator may result in the consumers having to pay a little extra for the patent protected product. But, this is worth it as in that case the former will be able to wholeheartedly concentrate on R&D to come up with new solutions to a variety of the problems faced by the masses, which will benefit successive generations. Needless to say, that on expiry of patent term, the consumers will pay much less.

In this broad spirit, the Government may consider re-looking the relevant provisions. It should consider:

- Withdrawing the proviso that denies rights to the Mail-Box patentee even for the period after grant of the patent.

- For applications put in the Mail-Box during 1995-2000, the filing date should be taken as January 1, 2005.

- Patent granted on Mail-Box application should enjoy rights from the date of publication.

Finally, there is an urgent need to review the provisions relating to patentability. The Patent Act should allow for the possibility of patenting all innovations that fulfil the three fold criteria irrespective of whether these are NCE or fall in the domain of incremental innovations.

This is necessary to not only make our law fully compatible with TRIPS Agreement (it provides for patenting of all innovations without discrimination between NCE and incremental inventions) but also to ensure full exploitation of India's inherent comparative advantage originating from a huge pool of scientists and their creative talent available at low cost.

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