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DEVELOPERS VS GENERIC MANUFACTURERS

Innovators need a booster dose

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There is a looming apprehension that under the product patent regime in force since January 1, 2005, the prices of all pharmaceuticals, agricultural chemicals and bio-technology products will shoot up, affecting millions of farmers and patients.

The view that the patent holder — armed with exclusivity over making, selling and using the innovation — will exploit the users, ignores the huge efforts of the former that led to the innovations that benefit the latter.

It costs over $1billion to innovate, develop and bring a new drug to the market. The cost of bringing a new pesticide molecule to the farmer is about $300 million.

HIGH COST OF INNOVATION

While these figures relate to the research and development costs in developed countries, those in India may be less due to availability of inexpensive scientific talent and other infrastructure, but would nevertheless, run into crores of rupees.

After innovation follows the long journey of product development and regulatory approvals, usually 10-15 years. Should not the innovator company get a reasonable opportunity to recover the huge R&D investment and generate some surplus for further research? The grant of a patent offers the company such an opportunity by providing an exclusivity period.

NOTIONAL EXCLUSIVITY PERIOD

Yet, the patent term of 20 years (or exclusivity period) is notional. For a new chemical entity (NCE), the protection period actually available is much less. It could be as low as five years if the product gets market access after 15 years from the date of innovation. Despite being armed with exclusivity, the innovator faces the daunting task of having to amortise the huge R&D and registration costs over a short time-frame (five years, in the above example), besides meeting the product stewardship cost.

This is possible only if the product is suitably priced. But this price gets branded as exploitative when compared with that of a "generic", or bio-equivalent product. A generic manufacturer spends virtually nothing on R&D and is, therefore, able to supply the product at a fraction of the cost of innovator. It is also important to remember that without the effort of the innovator, who demonstrates to the regulator that the product is safe and effective, generics cannot bring bio-equivalent products to the market.

Innovations are key in the pharma and agro-chemicals sectors, and innovators must have the chance to recoup R&D and product stewardship costs.

Unfortunately, these fundamental differences are ignored and a generic manufacturer is portrayed as the real benefactor of the consumer while the innovator is reviled as an exploiter.

This perception has even led policy-makers to taking steps that stifle innovators, seriously jeopardising R&D. For, the Patent (Amendment) Act 2005 allows generic manufacturers who were in the market before January 1, 2005 to continue making products for which someone else held the patent, on payment of reasonable royalty. The Act/Rules do not prescribe any formula for computing the royalty. With product patent coming into force from January 1, 2005, logically, generic manufacturers should withdraw their products, leading to a correction in prices that would enable the patent-holder to recover R&D costs. But the Act does not permit this, defeating the very objective of patent grant.

The Act provides for filing of pre-grant opposition representation by anyone, any time before the grant of a patent. This can trigger a spate of such representations, delaying grant of patent. This enables generic makers to make and sell bio-equivalent products without facing an infringement.

ADVANTAGE GENERICS!

The Patent (Amendment) Ordinance 2004 allowed parallel import of a product patented in India subject to authorisation by the patent-holder. The amended Act dispenses with this requirement. As a result, generic manufacturers can make the product in a country where it is not protected by patent and export it to India.

The Act allows for issue of Compulsory Licence where the innovator is unable to ensure supply of the product at an "affordable" price. What is perceived to be affordable to the user may not be a viable price for the innovator company. If the Government is really keen to reward an innovator by granting a patent for his invention that benefits society, then it must ensure that the innovator fully enjoys the intended exclusivity for a reasonable, fixed period. An apprehension that the innovator will fleece users is totally misplaced. The patent protected product has to compete with established alternative solutions. A user will not go for it unless it offers value for money. Even where there are no established alternatives (such cases are rare though), the innovator cannot afford to break the purchasing power barrier. For any business to be economically viable, there has to be a critical mass and that cannot be attained if the price is prohibitive.

PRICES FALL AFTER EXCLUSIVITY

Even so, the initial high price rules only during the period of effective patent protection. Thereafter, the price falls dramatically (in some cases by as much as 95 per cent) and the product is available for public use at a throwaway price.

There may be patients who cannot afford high cost of a new drug. However, this is a much larger issue of social welfare, and needs to be addressed through other means in a totally different forum. Globally, the returns on investment in R&D have declined sharply even as the cost of discovery and development continues to escalate. On top of this, if in the zeal to make new discoveries available to users at the generic price from day one, the milieu for protection of intellectual property is made adverse, the benefits of science and technology will be denied to the public forever.

Innovations hold the key to not only solving health problems of humans and plants but also to achieving rapid economic development and making Indian agriculture and industry competitive in the global arena.

In this backdrop, there is an urgent need to take a re-look at the Indian Patent Act, 2005 to remove the anomalies in its various provisions and ensure effective implementation. This will inspire Indian companies to adopt R&D as a model for growth and encourage MNCs to set up R&D bases in India.

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