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from the ringside

Patents Act: No magic bullet but a necessary pill

The recent ordinance promulgated by the Government amends the Patents Act to provide for product patents covering pharmaceutical, chemicals and food. This is in compliance with the TRIPS obligation undertaken in the WTO. India has an enviable record of fully adhering to its international obligations. It has done so in the midst of even a balance of payment crisis; never resiled from its debt, sought rescheduling or waiver. Adhering to the date of January 1, 2005, is part of this consistency. Nothing is lost because while on the one hand we have adhered to our commitment, on the other Parliament will fully debate the Bill in the House or its Standing Committee.

The patents ordinance has not pleased anyone. It may well be that since all parties are equally unhappy, the statute appropriately balances the rights and obligations of all stakeholders! Consumers fear that it may lead to price hikes making medicines unaffordable to the poor. Clarification that only an insignificant percentage of medicines is likely to be covered, the law is prospective and that the Drug Price Control Order would continue should help allay misgivings.

The domestic industry fears that increased competition, import surges, the deep pockets of MNCs constitute a non-level playing competition. However, the pharma industry in India has come of age, enjoyed the benefits of 'reverse engineering' for long, is seeking global opportunities and is well poised to face enhanced competition. Large pharma companies, including foreign ones, fear that the new Act does not provide adequate protection, loopholes are large, its application is only prospective, patent procedures remain cumbersome and compulsory licensing provisions are unduly open-ended and its application to new innovations unduly restrictive.

Some of these concerns deserve fuller consideration and hopefully the ensuing debate in Parliament will iron out these wrinkles. The pharmaceutical industry in India has made rapid strides sheltered partly by the absence of a product patent regime, which has permitted specialisation in reverse engineering—often a polite word for 'successful copying'. Be that as it may, it has served an important social purpose in making medicines available at costs which are significantly lower than even neighbouring Pakistan's. Indian companies are well-positioned to expand their global presence based on growing competitiveness, strong manufacturing base, availability of skilled manpower and an expanding bio-tech industry. Low investments in R&D, absence of dynamic linkages between industry and academia, absence of a culture to innovate and inadequate regulatory standards will be a handicap.

It is however worthwhile to examine the basic design of the proposed patent regime.

Why are patents necessary? Its economic rationale lies in enabling pioneer firms lead time to recoup sunk cost on R&D. This assumes that innovative firms have significant sunk costs which cannot be recovered by mere realisation of marginal costs, which are low. The problem with drugs is that they are a high-fixed-cost industry with low marginal costs. The high fixed costs are also uncertain and dependent on effort and expertise of scientists, which makes them difficult to determine. The fixed cost of any successful drug might not be so high, but this is not what the investor sees ex-ante. Besides the fixed cost of a successful drug, he must also reckon with the probability of success among many failures. So what does this mean? Competition would ordinarily drive the cost of the drug down to the marginal cost, so that the fixed cost could not be apportioned and recovered. So there may be no investment. This is why we have patents in the first place. But then the question is, do patents apportion the 'fixed costs' equitably? And do they ensure that the drug companies retain zero economic profits as they would in competition (in other words, collect fixed plus marginal costs only, nothing more)? Not necessarily.

As far as apportioning fixed costs goes, does equitably mean evenly? So that everyone pays the same price? Or does equitable mean according to means? Which implies some kind of restricted distribution that would be difficult to protect from opportunism. This is a difficult question, related to subsidy design.

But keeping prices to a minimum, while allowing fixed cost recovery, is a matter of patent design. And here the difficulty is that actual fixed costs are not observable and can be manipulated. So if you offered a kind of cost-plus regime, in which the patent for an individual drug allowed the company to recover its stated costs, no more, no less, then you would have the typical cost-plus problem. But then if you offer a flat fee, or flat protected period, then you are either over-rewarding the producer (having easy performance measures in performance-based pricing) or stifling investment. How to balance and walk the line between these two sides without knowing what the costs really are, or the lowest they could be if the patent got the incentives right? It's not as if the drug companies will ever say ''this is the minimum patent length and protection we'll accept and still innovate''. Empirical evidence on historical patent protection and investments globally remains inconclusive. It would be useful for India to have a study to figure out how well India is doing in balancing the need to attract investment with the need to keep costs low.

There are no fixed paradigms nor a model on patent design which would fit the needs of all countries. While apportioning risks and ensuring R&D is adequately rewarded but not unduly so, four issues need to be kept in view:

i) Vary the length of the patent depending on the sunk cost; instead of 0-20 years, it can be 5, 8, 15 or 20 depending on costs based on credible disclosures;

ii) Assign the breadth of the patent. A more rigorous definition of the product or a somewhat broader definition;

iii) What product classes would receive patent protection;

iv) Bear in mind the distinction between techniques, accidental discovery and

innovations.

The design of the patent law would be critical in harmonising the somewhat divergent interest of pricing drugs as cheaply as possible and at the same time encouraging investments in R&D. Hopefully, the debate in Parliament would consider some of the economic aspects of a patent regime to bring symmetry between what economists describe as the ‘Patent Theory versus Patent Law’.

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