LEGAL FALL OUT OF INTERNATIONALISATION

GATT and The Indian Pharmaceutical Industry - Meeting the Challenges

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Since June 1991, India has markedly accelerated its movement towards an open, outward oriented trade policy. This new direction stands in sharp contract to its earlier economic and trade strategies which were based on promoting domestic industry and achieving self-sufficiency in may areas of the economy through central planning, extensive Government intervention, a major role for the public sector and import substitution.

The pharmaceutical industry has experienced tremendous growth after independence. The industry today manufactures a broad range of basic products, vaccines, psychotropic preparations as well as numerous synthetic drugs including herbal preparations. Self-sufficiency in various drugs has been achieved in the country. The industry also has the capacity for producing enough surplus of bulk-drugs for worldwide import. Quality wise, the drugs conform to world standards.

After the Indian patents Act, 1970 was enacted, the production of pharmaceutical products has grown more than nine-fold from Rs 5000 million in 1974 to over Rs 45,000 million in 1991-92. In recent years there has also been a sharp increase in exports by the industry. Between 1985-86 to 1991-92, exports have grown form Rs 1,400 million to Rs 15,000 million.[1] So the domestic industry has succeded in getting access to foreign markets.

All this has been made possible largely owing to the Indian Patents Act, 1970 which envisages only the grant of process patents in the pharmaceutical field. This enabled the Indian industries to find alternate processes to manufacture a product patented in other countries. This led to a drastic decrease in the prices of drugs available so that the prices of drugs in India are one of the lowest in the world.

The grant of only process patents in the field of pharmaceuticals is in consonance with the basic philosophy of the Indian Patents Act, 1970 as enunci-

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1. Keayla, BK, "Patent Protection and the Pharmaceutical Industry" in Nair, KRG & Kumar, Ashok (Eds), Intellectual; Property Rights, (New Delhi, Allied Publishers Ltd., 1994), pp. 155-56.

ated in S.83 - "That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practical without undue delay" and "That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article". The Indian Patents Act, 1970 is based on the recommendation of the Ayyangar Committee which was appointed by the envommendation of Shri Ayyangar was that, condering the rate of the Indian Industry and market, it was in the best interests to the country to have a highly regulated patent item. This philosophy is also reflected in other provisions of the Act, namely-

a) S.47 which deals with the government's rights of importation for its own use.

b) S.86 which speaks of 'Licences of Right' if the requirements of the public have not been satisfied or if the patented invention is not available to the public at a reasonable price.

c) S.84 which provides that after the expiration of three years from the date of sealing of a patent, compulsory licence would be granted on application if the reasonable requirements of the public with respect to the patented invention have not been satisfied, or if the patented invention has not been made available to the public at a reasonable price.

d) S.89 which provides grounds for the revocation of the patents granted.

Thus the Act tries to strike a healthy balance between the interests of the pharmaceutical industry and that of the public by allowing the industries scope to grow, and yet due to the availability of non-patented drugs as alternatives, the prices are kept in check and the public benefits.

This legal regime, however, has now to be dismantled owing to India becoming a signatory to the TRIPs agreement.

a) India will have to comply with the provisions of the Paris Convention on the protection of industrial property even though it is not a member of the convention. The Paris Convention allows foreigners to obtain patent monopoly with absolutely no obligation to produce the patented article or even to ensure its supply in the patent granting country.

b) Patents will have to be made available on any invention, whether product or process, and in all fields of technology. So it would not be possible for India to continue with the existing system of process patent regime in the existing system of process patent regime in the pharmaceuticals field.

c) A uniform duration of twenty years will have to be provided for all patents.

d) The patent right will be enjoyed without discrimination as to whether a patented product is imported or locally produced. It would mean that importation of patented products would be treated as working of the patent, which is against the philosophy of our patent system as well as the Paris convention.

e) The patent holder will have exclusive rights for making, using, offering for sale, selling or importing the patented product. This will be in violation of public interest.

f) Compulsory licensing would be difficult, even if present due to constraints. Art 31 of the TRIPs Agreement lays down many conditions which have to be complied with before compulsory licensing is resorted to.

g) In case of an infringement, the burden of proof will be on the defendant unlike under the Indian Patents Act where the burden of proof is on the plaintiff.

To comply with these conditions the entire legal system needs to be overhauled. For this, a ten year transition period is provided by the TRIPs Agreement itself. But ten years is not a very long time in the life of an industry. Moreover, even within the transition period, India has to fulfil certain obligations that must take effect immediately. Firstly, India has to provide means for filing of applications in the areas of pharmaceutical and agricultural chemicals.[2] and on fulfilling certain conditions, grant exclusive marketing rights for a period of five years or until the patent is granted or rejected, which ever is shorter.[3] In this regard the Patents (Amendment) Ordinance 1994 introduced the requisite changes. But since the Patents Bill could not be passed in the first Parliamentary session of 1995, the Ordinance also automatically lapsed. The Patents Bill will again be considered by the Parliament in the monsoon session.

Any law in consonance with the TRIPs Agreement would erode the basic philosophy behind the Indian Patents Act. But realism demands that one recognises the inescapable fact that India cannot backfoot on the international obligation it has shouldered by virtue of this agreement.

One answer to meet the challenge seems to be to increase the investment in R & D so that there are better chances of producing totally new drugs for which product patents might be obtained. Given the situation, this is impracticable. Though the pharmaceutical industry has achieved substantial growth, the investment in R & D in terms of the percentage of production has shown a steady decline unlike foreign countries like Japan where 70% of the investment in R & D is by the industry, 20% by the Government and 10% by the Universities.

Indian Drug Industry (Rs crores)

	1965-66	1991-92
Production	168	4990
R & D Expenditure	3.0	70

2. Art. 70(8) of the TRIPs Agreement
3. Art. 70(9) of the TRIPs Agreement

% of R & D expenditure in terms of production	1.8%	1.4%

Further in India, the pharmaceutical industry comprises of mainly small proprietary concerns and only a few companies. The proprietary concerns do not have the resources or the inclination to increase the investment in R & D because apart from the fact hat such investment is a long term investment, returns are not guaranteed. So it is only the companies that can increase their R & D investment. This does not augur well for the industry.

To day the Government is the biggest investor in R&D in the drugs sector. For the pharmaceutical industry to generate more investment in R & D, a major restructuring of the industry is required and this is where the Government can step in. But even for the government to generate intellectual property in terms of product patents, the present investment in R & D has to increase tremendously. But this is a short term answer. After this, the pharmaceutical industry will have to start increasing its participation in R & D. Here, market forces may operate to bring about such a restructuring.

Another answer would for the government to distribute the rights over the intellectual property it has generated only to such pharmaceutical companies which have a certain prescribed minimum capital base so that these companies which actually have the capacity to invest in R & D can grow further and be able to control the pharmaceutical industry.[4]

Along with such a restructuring, certain strategies have to be adopted so that, in the long run the industry gets into a position to generate enough intellectual property to maintain itself and a certain minimum growth rate. Some strategies which must be adopted are suggested here.

1. Existing products must be evaluated, and if necessary, reformulated to meet international regulatory and quality rquirements.
2. As regards new products, the same standards should be applied for production for domestic consumption and for exports.
3. R & D should try and ensure competitive prices and the quality of the product at the development stage itself.
4. R & D must observe good laboratory practices to ensure necessary recognition and certification of facilities by collaborators from developed counties.
5. R & D should take care of value addition by product, process improvement, process simplification, component reduction, reduction in set up time and standardisation.

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4. This may be open to serious contitutional challenges- Intellectual property generated by the Government is government largess, the distribution of which would therefore have to comply with the norms of Art 14.Giving intellectual property rights only to the bigger companies may not stand the test of Art.14.

6. The technological capability must be strengthened to enable development and production of advanced and drug delivery systems.

7. Most importantly, there must be a realisation within the industry of the crying need for collaboration and cooperation between pharmaceuticals units. It is imperative that the pharmaceutical companies enter into strategic alliances with themselves for pooling of resources and key information which would create a better and more extensive data base which in turn would go a long way in increasing the efficacy of R & D.

It could be urged that it is more convenient to simply enter into collaboration agreements with foreign companies and 'borrow' the required technology and know-how for manufacturing new drugs. But this would only perpetuate technological dependence on the West. Independent economic development must be rigorously pursued and must not be sacrificed through passive submission to the designs of the developed countries. The Government can also actively encourage investment in R & D by declaring tax holidays and providing other incentives for pharmaceutical industries that plough back more than a certain percentage of their profits into R & D.

Therefore, the best option is for the pharmaceutical industry to gear up as best as it can and try to meet the challenges head on. This will also lead to a culture of international competitiveness and the Indian pharmaceutical industry can continue to enjoy the same respect as it has been used to.