Chapter VIII

Conclusion

With the enactment of the Patents (Amendment) Act of 2005, the three decade exclusion of product patent in drugs has gone, Indian patent regime is said to be integrated with the TRIPS provisions. This much awaited and watched legislation in turn will also impact the future of not just Indian Drug manufacturers but also impact the health sector as a whole. Apart from various procedural changes regarding filing, opposition and revocation, the Amended Act has two important sections relating to what are not inventions and what could be patented which is the crux of the future contours of the drug industry and the health sector as a whole. One can analyse these two crucial changes and its impact and future response of various stakeholders in the health industry namely that of generic players, innovators, and that of the consumer at large.

The impact of the changes is perceived by different interest groups in different ways. One perspective of the association warns of adverse impact. The Indian Drug Manufacturers Association states that - This will close the option of reverse engineering which has

largely contributed to the excellent growth and progress achieved by the Indian drug industry since 1972. It will not be possible to produce the patented product by adopting a different process. In absence of competition, the patent holder will be able to demand excessive prices denying availability of such drug to large majority of the people. Research and benefit of more economical or efficient processes will be denied to the people.

All fields of technology to be covered by patents protection without discrimination. This means patent protection has to be provided even for new or uncovered fields of technology like bio-technology, genetic-engineering, micro-organism, and agriculture etc.

These are new fields of technology having vast scope and potential for development and improving living standards of people. India is only beginning to acquire the expertise and set up research facilities. It is said that most of the drugs in current use are chemical products and would soon be replaced by more effective drugs based on bio-tech and genetic engineering. Monopolisation by foreign companies in this field of technology at this initial stage will almost totally close the door for India and the Indian drug industry for future research, growth and development in this vital

field. The nation and consumers will be dependent on foreign companies for such products.

Importation to be accepted as working of the patent for the purposes of enjoyment of patent rights.

This means patentee will be under no obligation to produce the patented product locally. The removal of import and tariff barriers as per the WTO requirements will further facilitate the patentee to avoid local production and to rely on imports from its own home country. This will mean dependents on foreign supplies and drain on foreign exchange. The nation and the consumers stand to loose.

Twenty-year term for all existing and future patents.

This will mean longer term of monopoly. In absence of competition nation and consumers could be denied availability of the patented product for long. In case of pandemics like AIDS/HIV, large majority of the poor would be denied benefit of research and new drugs for twenty years - which in most cases may be during their life time. On the other hand, the generic industry will not be able to take up the production of these drugs for twenty years. It will discourage further research and development on the patented product.

Adverse impact of TRIPS –

These changes will have adverse implications for the drug industry and consumers in India. As recently observed in Sub-Saharan African countries, the impact of the strong product patent protection could indeed be very grave, if the national patent law fails to provide for effective and efficient compulsory licence system. Fortunately, many of the doubts and controversies about the interpretation of some of the TRIPS provisions are now cleared and set at rest by the Doha Declaration on TRIPS and Public Health (Declaration). Understanding and applying TRIPS provisions correctly, and as reaffirmed by Doha Declaration, can considerably remove the problems and remedy the situation.

The Doha Declaration on TRIPS –

This Doha Declaration aims at providing 'access to medicines for all' and recognises and reaffirms the flexibility of TRIPS provisions and the right of Members to use to the maximum these flexibilities by adopting effective compulsory licences systems to provide affordable medicines for its citizens. India had played a very decisive role in drafting and adoption of this Declaration. A balanced, effective and efficient compulsory licence system, which is permissible under TRIPS, can considerably resolve the problems.

The Patents (Second Amendment) Act 2002 - Restricted compulsory licence system

However, The Patents (Second Amendment) Act 2002, adopted by Parliament during the budget session, has unnecessarily deleted some of the beneficial provisions of Patent Act 1970, and adopted more restrictive compulsory licence provisions than required either by TRIPS or the Doha Declaration. Bill has deleted the automatic licences of right provisions of Sec 84, 87 & 88 of Patent Act 1970, and prescribes onerous conditions and procedural requirements for grant of compulsory licences. This has to be further amended to provide effective and efficient compulsory licence arrangement. What is required are national and political will and determination to adopt such effective compulsory licence system.

The future –

The experience gained, the know-how and technology developed, the cost effective production facilities established, availability of low cost technical man power and labour, the doctors' and consumers' confidence established, during last 3 decades, by the Indian drug industry gives confidence and assurance that Indian drug industry can and will be able to meet the new challenges even under the TRIPS product patent regime.

The WTO and TRIPS Agreements have brought some side benefits for the Indian drug industry. On expiry of the patent term, it is open to generic manufacturers to produce and market the drug. Because of the cost and price difference, it is possible for them to derive maximum advantage when the market is thrown open on expiry of the patent term. The introduction of the Bolar type provision by the amending Act permits generic manufacturers in India, to obtain market approval from the regulatory authorities during the patent term itself, so that immediately expiry of the patent terms they can produce and market the drug, not only in India, but also in other countries. Because of the established capacity, potential for expansion, technical capability, international quality standards, low cost production, the generic manufacturers in India stand to gain considerably. This may induce even foreign patent holders to have their patented products manufactured by Indian companies for their exports to other developing countries. The cost of research being much lower than in most advanced countries, the Indian drug industry may also find foreign companies entering into arrangements for research.

Though therefore, TRIPS patent regime has certain disadvantages, it also brings some benefits for the Indian drug industry. By

adopting a more efficient and effective compulsory licence system, the possible adverse impact of the new patent regime can be substantially over come.

Impact on the Generic Players

The New Act will certainly affect the Generic players-read as majority of the Indian drug companies-who hitherto could grow at a fast pace in the absence of the product patent regime. A recent study commissioned United Nations University-INTECH reports: "Product patent protection in India is emerging to be a very decisive factor in determining access to medicines, both in India and other third countries in Africa. The survey shows that Indian firms will face severe challenges to adapt to the emerging patent regime while (a) operating in an industrial and regulatory climate that still is not fully geared towards its needs in the light of tough international competition, and; (b) coping with the losses induced by the restrictions placed on them by the new patent regime. This is in keeping with earlier studies on the topic such as Chaudhuri, Goldberg and Jia (2004), which show that the losses to the Indian industry in certain segments following India's full scale TRIPS compliance are very high. Therefore, emerging strategies of Indian firms will continue to be dictated mostly by survival needs and not

by issues related to access to medicines of the general public, whether in India or other least developed countries. Indian firms will adopt a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize on opportunities created by the new patent regime.

This is very different from what was observed in several Latin American countries, where local firms mainly adopted a cooperative strategy upon entry of foreign MNCs, thereby leading to their acquisitions by the latter, resulting in steeper increase in prices of drugs. The behavior of the Indian industry is more in keeping with what one would expect to see in an environment where a well-to-do local industry with clearly established areas of expertise is faced with strong international competition. Newer technologies and evolving market structures (in this case, as induced by the product patent regime and strong competition from global firms) almost always create new market segments and niches with many opportunities for specializations that the Indian industry will be quick to capitalize upon, although this will also be accompanied by a high degree of consolidation in the industry in the coming years.

The study also found that Indian firms are focusing very little on health priorities of the developing world. This can be attributed to two main reasons. Export demand shapes innovation strategies of firms in the Indian industry to a very large extent, and Indian firms are hard-pressed to survive amidst little government support and tremendous external pressures of global competition. Given that almost all Indian firms fully fund their own research activities through their profits; their concern is primarily on how they can increase their profits and invest into R&D efforts. Therefore, this finding, although disappointing is not counter-intuitive." See-United Nations University-INTECH on the 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry' by Padmashree Gehl Sampath

The market for the future will not grow at the pace with the introduction of the product patent regime. This does not need any data or research. Only a handful of the Indian companies have embarked on serious R & D effort and that too not with any great success. The successful generic players have also been helped by a substantial export market which may also get affected with the TRIPS compliance in those countries.

The Patenting business is again new to many generic players and at the best has been patenting smaller changes and modifications as any major patent

is directly proportional to that of the R & D efforts which in turn is linked to deep pockets and scale of operation. In such circumstances what will be the future of these players. Barring few major players many will shift their strategies to be collaborators, marketing arms and licensed manufacturers to the innovators. Again the brighter side is that of the huge talent pool available in this country and the enormous potential for CRO business. On the core R & D side again India does offer the requisite research skills and cost advantage. This needs to be augmented by the support of the Government in reducing regulatory bottlenecks and red tape.

The talent pool, cost competitiveness of delivery will help them in that record. But in essence the strategy will be based on the opportunities provided by the innovators rather than on their own due to the changed patent regime.

IMPACT ON INNOVATORS

The innovators stand to gain with control over the market and business strategies with the product patent regime. The major critique of the innovators is that of the section 3 d which has omitted the intermediaries like salts, esters, etc., . They argue this is against TRIPS mandate of product patent regime across the board and will even impact patents of other smaller players who could come with these innovations which are feasible in their scale of operations. The logic of 'evergreening' of patents is rejected by them quoting the practice of issuance of patents in the developed world. Nevertheless many smaller players –mostly generic – companies are happy about this provision as it would avoid many infringement litigations. Another area of concern for the innovators is the provision of the act is that of the section 10 which states:

" Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.".

This in effect makes the entire mail box system ineffective as they are forced to negotiate with the existing players. However this will be a temporary phenomenon relating to drugs which could be patented by the innovators between the period of 1995-2005. On the whole, the innovators lobby should be a satisfied one with the long term benefits of the Act

IMPACT ON THE CONSUMER

Various research studies by Columbia University, United Nations University and others have indicated the negative impact on the consumer in terms of the pricing of the drugs under product patent regime. When analysed from Indian perspective, the issue is aggravated from the fact that the majority do

not have reasonable health care access where they have to fend the costing from their own sources and not by any schemes; the impact will be very adverse. It is often argued that the drug cost is not a major component in the entire health care system. Given the fact that the per capita expenditure on health in India is abysmally low the logic that drug prices will not impact is not an acceptable argument. This warrants a serious response from the Government in off setting the negative impact of the price raise as a

consequence of the product patent. The deregulation in the IP sector needs to be balanced by other regulations. One of the methods should be to have effective price control mechanism on patented products. This again should not become a bottleneck to introduce drugs faster. The other methods are to increase the health spend and also subsidy coupons for below poverty line families in the lines of food subsidy. It also needs to simplify regulatory procedures for generic players to conduct their existing business.

THE ROAD AHEAD

The logic of IPR as individual private right needs to be balanced with health as a public good. This requires a dynamic response from the government in framing the public policy choices which has to balance the innovator and the consumer. It is also essential for the innovator interest groups to understand the dynamics of different environment and composition of economic and social space in applying the yardsticks of IP jurisprudence. The road ahead for Indian pharma industry and Indian health care system will depend upon the public policy choices and policies framed on the ground realities and innovative protection measures embarked by the government with the private players. Most importantly there is

an urgent need to embark on capacity building exercise of the human resources needed in the field of Patents. We need to train and update the skills of scientists, lawyers, judiciary and patent offices to cope with the new regime and interface with patent regimes of the other parts of the world.