TRIPS, WTO and IPR: Impact of Indian Patent Act 2005 on Indian Pharmaceutical Industry

M D Nair†
A-11, Sagarika, 15, 3rd Seaward Road, Valmiki Nagar, Thiruvanmiyur, Chennai 600 041

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The World Trade Organization (WTO) was set up in 1995 and has been the custodian of all matters related to the implementation of the TRIPS Agreement endorsed by 153 member countries. WTO is therefore the most important body which monitors and influences working of global intellectual property rights protection in all its member countries. This opinion discusses the impact of Indian Patent Act 2005 on Indian pharmaceutical industry.

India’s obligation to implement a TRIPS compliant patent system from 1 January 2005 brought in a product patent era for the pharmaceutical products. Indian companies can no longer manufacture or market patented drugs without licence from the patent holder. This development has several implications on the industry which had seen unprecedented growth during the ‘process patent’ era. Now that 15 years have elapsed since the advent of the WTO and 5 years since the implementation of the product patent era in India, it is appropriate to assess the potential implications of these developments on the Indian pharmaceutical industry.

Indian Patent Act 1970

The Indian Patent Act (IPA) 1970 which came into force in 1972 was in many ways a watershed in the history of the patent system, since it not only disallowed the grant of product patents in the highly sensitive and socially relevant health sector, but also restricted the validity period for process patents in these sectors to seven years from the date of filing or five years from the date of sealing whichever was earlier. Since the period required for discovering and developing a new drug is not less than 10 years, the provision for process patent with the shortened period of validity had made the system itself redundant. The consequence of such a radical change in the Indian patent system led to a major shift in the nature and character of the Indian industry. Many foreign companies discouraged by the provisions of IPA 1970 and the Foreign Exchanges Regulation Act (FERA) which allowed new investments only for companies with a foreign equity holding of 40 per cent or less opted not to operate in India. If India today, is an accepted leader in the production of generic drugs of high quality to meet the needs of practically all the global markets, the credit should go to this piece of legislation. In fact, within a decade of IPA 1970, the pecking order of the Indian industry changed wholly with Indian companies occupying seven of the top ten positions, a reversal of the pre-1970 era. In addition, India has the largest number of FDA approved plants outside the US and over 30 per cent of all ANDAs submitted to US FDA are by Indian companies. To achieve this status, India developed outstanding abilities in the area of chemical process technology to the extent of being capable of producing even the most sophisticated APIs. In addition to being able to cater to the domestic market with indigenously produced patented products, India had exploited the opportunity of exporting them to countries where no valid patents existed.

GATT and the Indian Pharma Industry

With the advent of the product patent era, as required by her obligations under the WTO’s mandate, India can no longer produce and market patented products in any country where valid product patents exist. During the last four decades nearly, since the advent of IPA 1970 (operative since 1972), Indian companies launched patented drugs in India within 3 years of their first launch by innovator companies at prices one fifth to one tenth of their patented versions. In the new era, Indian companies have to rely on manufacturing and marketing generic

†Email: mdnair@vsnl.com
(off patent) drugs unless they get licenses from the patent owners. If they are to launch new drugs, they need to develop strategies, skills and adequate resources to enter the drug discovery and development area. The top 15 Indian companies have already initiated major efforts in this area fully realizing that it is indeed a very expensive, long gestation and high risk activity with little guarantee of success. Total investments of the order of around a billion dollars are being expended annually which, however, is still less than one sixth of what Pfizer spends annually on R&D.

**Growth Strategies**

Being a late starter, it is unrealistic to expect the Indian companies to bank on indigenous discovery, development and marketing of new drugs as the main growth strategy. Apart from the uncertainties inherent in this activity, India even today, does not have the full capability to develop a drug from concept to the market place. The strategy, therefore will be to discover candidate drugs, patent them and license them out (after reaching defined milestones of development) to large global pharma companies, very much like the pattern adopted by the Japanese and start up biotechnology companies. This approach has already been used by major Indian companies such as Ranbaxy, Dr Reddy’s, Nicholas Piramal, Glenmark, Suven Pharma and others.

In 2001, McKinseys did a study on the Indian pharma industry which predicted the Indian industry to reach a total production value of US$ 25 billion by 2010 and US$ 100 billion by 2020. Current estimates for 2010-2011 are around US$ 23 billion with the domestic and export markets almost equal. The growth of the export market at a rate higher than that of the domestic market is not an indication of the medical needs or market needs of the domestic market; rather it is a strategy of the large Indian companies to look for larger market shares for the generic APIs and formulations in the global market. This is indeed remarkable considering the uncertainties plaguing this segment and the global economic recession of the last three years. However, to achieve the US$ 100 billion mark it is essential that Indian market share in the global generics markets increases further, India becomes one of the major hubs for Contract Research And Manufacturing Services (CRAMS) and Indian R&D delivers at least three or four blockbuster drugs for the global markets from indigenous or collaborative R&D during the decade. This is a tall order, but doable considering that India has the largest number of FDA approved manufacturing plants, submitted more Drug Master Files (DMFs) & Abbreviated New Drug Application (ANDAs) in the US than any other country and has 900 approved suppliers of APIs and formulations for the global markets, compared to 300 from China.

**Mergers and Acquisitions**

With the Indian industry entering the global arena for supply of generic drugs and India adopting global standards acceptable to international regulatory agencies, including cGMP (Good Manufacturing Practices), GCP/ICH (Good Clinical Practice/ International Conference on Harmonization) guidelines, the harmonized IP protection systems under TRIPS etc., it was anticipated that there will be consolidation in the Indian industry, which had become highly fragmented partly as a consequence of the IPA 1970. The new patent regime has compelled the Indian industry to restructure its operations to enable it to compete with global players. During the last few years, there has been a spate of mergers and acquisitions in addition to large number of collaborations in R&D, contract custom manufacturing and clinical research. A matter of great concern has been the acquisitions by large global pharma companies of some of the leading Indian companies in the recent past. Cases of Matrix and Mylan, Ranbaxy and Daiichi, Shanta Biotechniques and Marion, NPIL and Abbotts, Orchid and Hospira etc., are illustrative of this phenomenon. To what extent these were triggered by considerations of access to large markets that India offers or to what extent they are based on considerations of cost reduction through decentralization of activities is not clear. In any case, if the product patent era had not dawned in India, none of the R&D based large pharma companies of the West and Japan would have invested in India. The concern that dominance of the MNCs will once again surface as a result of these takeovers, while genuine, may not adversely affect the Indian industry since with larger resources, it is possible for these new entities to invest into drug discovery R&D which in any case is the lifeline for survival and growth.

**Patenting Activity**

As far as the pharma sector was concerned, the 1970 Patents Act had considerably watered down the role of patenting as a strategy for ensuring exclusive
market presence and growth. Filing of process patents during the three decades dwindled and practically no pharmaceutical patent applications were filed in India by the MNCs during this period. The situation changed dramatically post-1995 with the total number of filings in 2008 for all sectors reaching 32,000 of which one fifth was from the health sector. The Indian Patent Office was ill prepared to handle such a spurt in activity, even though all efforts are made to modernize and expand the facilities. Just to compare, while the US Patent Office which handles over ten times the number handled by its Indian counterpart has over 6,000 patent examiners, the Indian patent office has only 200 examiners. Thus, in spite of the fact that IPA 2005 carries out examination only on request by the applicant, there are over 70,000 applications pending at the Indian Patent office. With the provision for pre-grant opposition, there is additional burden on the patent office to dispose off opposition cases, which can be a cumbersome process. With increasing awareness of the role of patenting on the promotion of R&D for indigenously developing new drugs, patenting activity will increase several folds and will put additional strain on the Indian Patent Office.

Disputes and Litigation
IPA 2005 and the rules related to it, has several sections which will lead to disputes and litigation in the coming years. The protracted litigation on the validity of the Novartis anti cancer drug, Gleevec which has gone to the Supreme Court is a case in point. Apart from issues on novelty, issues on patentability as defined under Section 3(d) related to ‘trivial inventions’, patentability of microorganisms, compulsory licences under Doha Declaration, non-working of patented inventions, access to drugs etc. are all going to be issues for future litigation. There may also be disputes based on whether India’s patent system and practices are TRIPS compliant, an issue which can be sorted out only at the Dispute Settlement Board of WTO.

Traditional Knowledge and Systems of Medicine
A matter which has been taxing the minds of many policy planners involved in the equitable protection of traditional systems of medicine, has been developing a legal framework for such protection. It largely affects the developing countries which are a rich and varied source of knowledge systems and practices. WIPO,WHO, the TRIPS Council and a host of experts primarily from developing countries have been involved in several projects to develop a globally acceptable system of protection which can eventually invoke provisions under legislations on the Convention on Biodiversity, geographical indications, plant varieties protection and even trademarks and copyrights. Hopefully something tangible will evolve in the coming years.

Conclusion
IPA 2005, along with several related legislations, has far reaching impact on the Indian pharmaceuticals industry, the full import of which will be realized only in the coming years. Whether it will help maintain the momentum of growth of the Indian industry achieved during the last four decades, promote indigenous R&D, enlarge its presence in the global markets and place India as a leader and cost effective supplier of quality drugs across the world and how the new patent era will act as a facilitator and catalyst to achieve these objectives will be known in the coming decade. In the meanwhile, since the new patent regime is a reality, it will be prudent on the part of all stakeholders to clearly define and implement strategies which will convert challenges into opportunities.