Appendix - IV

Status of Patents and Intellectual Property Rights

India's new product patent regime has emerged as a consequence of its being a signatory to the TRIPS agreement. India's parliament approved the *Patents (Amendment) Act* 2005, bringing in a system of product patents backdated to January 1, 2005. The new regime protects only products arriving on the market after January 1, 1995, abolishing the previous process patent system established by the 1970 *Patent Act*.

(i) The Patent Act and Introduction of product patents

Globalization and the WTO put India under an obligation to amend the Patents Act in compliance with the provisions of TRIPS.[22] According to TRIPS, the developing countries (including India) had time until January 1, 2005, to enact domestic legislation to conform with the agreement, whereas the LDCs were given time until 2016. And since the Indian patent regime did not provide product patents for pharmaceuticals and agro-based products, it became obligatory to provide for a 'mail box' facility for filing patent claims to protect these products with effect from 1st January, 1995. Similarly, those 'mail box' patent applications that satisfied certain conditions were entitled to receive exclusive marketing rights for five years. The date of application of TRIPS provisions, other than product patents, was January 1, 2000.[23] The amendment came into force in 1999 retrospective from 1995. In 2002 India had to amend the Patents Act again to meet with the second set of obligations, which had to be effected from January 1, 2000. This amendment provided, among other things, for a 20-year term for the patent and for the reversal of the burden of proof. The latest amendment of the Patents Act came into force on January 1, 2005, incorporating the provisions for granting product patent in all fields of technology including chemicals, food, drugs & agrochemicals.

In order to protect the interest of Indian industry, including the pharmaceutical industry, full transition period of ten years available under the TRIPS Agreement was utilized. In the amendment, a provision was made that in respect of applications for drugs and medicines filed before 1.1.2005, the rights of patentee shall accrue only from the date of grant of the patent and not with retrospective effect. The Act also contains wide and adequate provision for compulsory licensing by government as well as for export to other countries in certain circumstances.

[22] Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1991, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 ILM 81 (1994) [hereinafter TRIPS].

[23] Sudip Chaudhuri, *TRIPS Agreement and Amendment of Patents Act in India*, ECONOMIC & POLITICAL WEEKLY (August 10, 2002).

Further, given the importance of the issues, the Government undertook broad-based and extensive consultations involving different interest groups on aspect of the law. These included scientists, academicians, economists, representatives of various industry sectors (such as pharmaceutical, biotech and software), chambers of commerce, private and public sector units, journalists, non-government organisations, representatives of State Government, lawyers and attorneys. During the wide ranging consultations, it emerged that not only were the amendments necessary to meet India's international legal obligations, but also that the Indian industry as a whole had transformed itself over the past few years and would stand to gain from a strengthened and balanced patent regime.

The major pharmaceutical companies have argued that compliance of the provisions of TRIPS would stimulate transfer of technology, encourage foreign direct investment, strengthen R&D investment and also ensure early introduction of new products in developing countries. These arguments are invariably backed by data on increased FDI in some countries where stringent IPRs were introduced. On the contrary, these were countered by arguments that these measures would push the prices for pharmaceuticals beyond the limits that could be afforded by the average Indian.[24] However the Indian pharmaceutical companies have stated that it is necessary at this stage for Indian companies to create their own intellectual property.

It is clear that an internal networking and co-ordination amongst different constituents of innovation chain has not only become necessary but imperative in order to bring down the time and costs of new drug discovery and its introduction in the market place. This affords a great opportunity to Indian R&D. The industry has since sought to reorient itself as a global player by increasing its emphasis on R&D which is reflected by the increased proportion of R&D expenditure to both investment and turnover.

(ii) Data Protection

Many companies have claimed that Data Protection is a necessity for the further growth of the industry given that the industry now spends a considerable amount of time and money in R & D and in conducting trials.

Clinical trials for pharmaceutical products in India are governed by the GCP (Good Clinical Practices) guidelines provided in Schedule Y of the Drugs and Cosmetics Rules, which provides for a number of mandatory requirements regarding their conduct, such as safety regulations. However, there are currently no provisions in Indian law regarding whether or not the data collected from such clinical trials

[24] Jean O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?", Working Paper No. 6366, National Bureau of Economic Research (1998), *available at* http://www.oiprc.ox.ac.uk/EJWP0799.pdf.

can be used by the Drug Controller General of India (the Indian regulatory authority) in its approval procedures for other drugs. Specifically, the debate in India centres on whether there should be data exclusivity, data protection or no provision at all. Both "data exclusivity" and "data protection" laws in the context centre on the information provided to the regulatory authorities by the entity conducting the clinical trials. Under a "data protection" law, the regulatory authority would be able to use this information in its decisions to grant approval to generic drugs that claim bioequivalence with the drug for which the clinical trial was undertaken, although it would not be permitted to disclose such information to others. On the other hand, under a "data exclusivity" law, the regulatory authority would not be permitted to use this information at all, thereby requiring the manufacturer of the generic drug to conduct its own clinical trials.

Take the following example to see how data exclusivity can increase the costs of pharmaceutical products and act as export inhibitors for generic manufacturers:

Company A gets approval for drug X from the FDA after conducting clinical trials in the USA. Company B applies for approval to the FDA claiming bioequivalence of generic drug Y with drug X. A data protection law means that the FDA can use the data from the clinical trials of X to approve Y, whereas data exclusivity means that the FDA cannot use such data for approving another drug and company B will have to conduct trials for Y, thereby increasing the cost of Y.

However, data protection can be a method for ensuring that data generated by a company in the course of its research or clinical trials, is not subjected to unfair commercial use, thereby staying in sync with the product patent regime. There has been some debate over whether or not Article 39.3 of TRIPS requires countries to enact data exclusivity laws – while some, such as the USA, New Zealand and the EU, insist that it does, others disagree because the article requires states to "ensure that the data are protected against unfair commercial use" and it is thought that the use of test data by a government regulatory body in making decisions regarding approval cannot be said to be commercial, even if approval would mean the commercialisation of the product. While it has been alleged that the Committee for the Protection of Undisclosed Information under Article 39.3 of the TRIPS Agreement has recommended a five year period of data exclusivity, the report for the same is yet to be released.