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Biotech Industry: IPR and Other Legal issues

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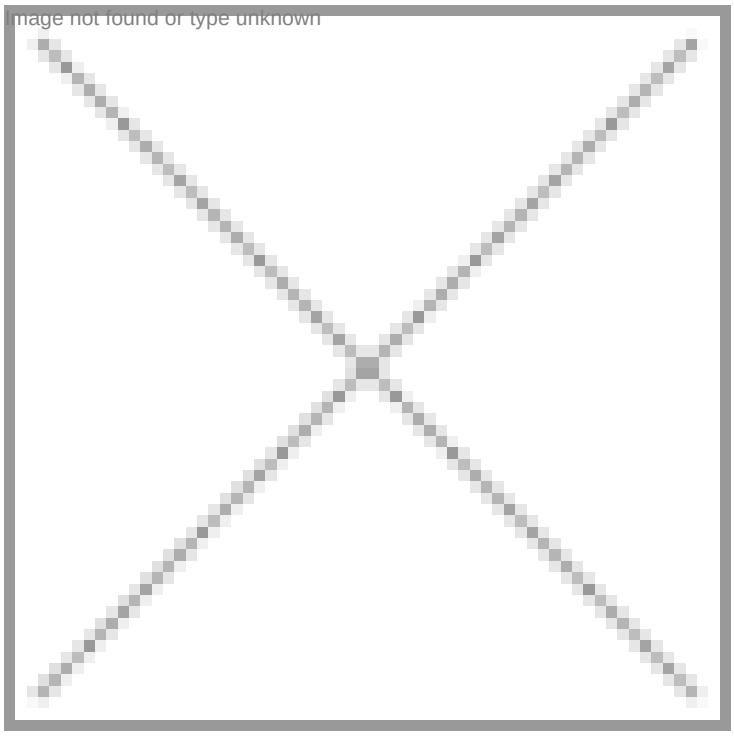

Intellectual Property in India has remained a mystery to many, the main reason being ignorance.

Since 1991 when India took the first step towards liberalization of its economy, there has been a constant progress in the area of Foreign Direct Investments (FDI) in Indian companies. With the Government of India having virtually abandoned the "licence raj", FDI is happening in almost all the sectors, barring certain sensitive areas such as nuclear power and agriculture.

The Government of India classifies various industries into a number of sectors. While 100 percent FDI is allowed in most of the industries, restrictions are imposed in certain sectors such as telecom, print and media, which are called as "sectoral caps". Biotechnology as such is not classified as a specific sector nor is there any specific definition available in the statute. Perhaps this might be one of the reasons which made a number of entities proclaim themselves as biotech industries despite having nothing to do with biotechnology. Without going into the controversies surrounding such claims, one can broadly classify the biotech industry into agri-biotech, bioinformatics, pharma biotech, industrial biotech, biotech research services and biotech supplies.

Agribiotech has made a tremendous contribution into India's green revolution.But this growth could have been better had there been no restrictions imposed by many states in India on corporate entities holding agricultural land and carrying out research activities. The Karnataka government has now amended its Land Reforms Act which would enable agro-based companies to acquire agricultural land for the purpose of its business. By and large, barring a few companies in India, the R&D work in the agricultural segment has happened in government labs and universities.

Given the present socio-economic background of rural India, it is not a surprise to see opposition to the introduction of biotech seeds, especially Bt cotton. This situation is due to lack of consistent procedural law for testing, accepting, distribution and sale of seeds among various states and above all, lack of a credible agency which would place the facts before the masses. On account of the initiative of organizations such as ABLE, the Government of India recently appointed a task force headed by Prof MS Swaminathan to streamline the regulatory process for the benefit of this industry.

Bio-IT and Bio-informatics

There has been a significant growth in the bioinformatics area which includes curatorial services, data banks, support services in healthcare such as online diagnostics, online medical consultations and also extends to claims processing and hospital data management. Being an Information Technology-driven segment, the Bio-IT industry would fall within the scope of the Information Technology Act 2000 (IT Act). This law recognizes digital data, in whatever form it may be, as an evidence acceptable in a court of law. Even though there is no specific law for data protection or privacy, The IT Act can be an effective tool for data protection and can be implemented for any willful data loss or misuse.

Industrial biotech would mean the manufacture and production of enzymes used for healthcare, drugs, breweries, chemical industries, garments, leather, and food processing etc. The general law that would govern such activity would be the Factories Act and related industrial law and depending upon the nature of work certain enactments cited under pharma biotech would apply.

Pharma biotech signifies the outcome of intense research and development in drugs and chemicals which involves testing at various levels and ending in manufacture and distribution of drugs. This industry comes under the stringent provisions of The Drugs (Control) Act 1950, The Drugs and Cosmetics Act 1940, the Patent Act 1970 and falls within the purview of various regulators. The Indian pharma industry has made considerable progress and has also made inroads into other third world countries. There are a few disputes regarding patent infringement. One needs to wait and watch the ruling of the courts and enforcement of any decrees beyond the territorial jurisdiction of a country in which the decree is passed. Foreign companies were hesitant to introduce new drugs without the product patent regime in India. The amendment to the Patent Act 1970 allowing product patent needs to be observed as it is too early to see the trend.

Thanks to the efforts of ABLE, the Union Government has formed a high-level task force headed by Dr RA Mashlekar to streamline the regulatory process under the "Rules for Manufacture, Use, Import, Export and Storage of hazardous micro organisms / Genetically Engineered Organisms or Cells 1989" notified under the Environment (Protection) Act, 1986 Research ServiceForeign biotech and pharma companies find India as an attractive destination to carry out biotechnology-related research on contract basis. This is due to the availability of domain experts and low establishment cost. This win-win enterprise is seen as a major source of forex earner for the country.

Foreign Direct Investment

Prior to the setting up of any company in India, one needs to find out whether FDI is permitted in that particular sector. As mentioned earlier, the FDI policy does not classify biotechnology as a specific industry. While FDI in agriculture per se is not allowed, there are no prohibitions in the agri-biotech industry. Foreign Direct Investment upto 100 percent is allowed in pharmaceutical and drug industries. However, no FDI is allowed in industries involved in recombinant DNA technology and specific cell / tissue formulations, In such cases, prior approval has to be obtained from the Secretary Industry Assistance (SIA), Government of India, followed by an approval by the Foreign Investment Promotion Board (FIPB). However, no specific license is required for a contract research unit which deals with recombinant DNA technology so long as there is no commercial production of drugs or pharmaceuticals emanating from such R&D work in India. Even though there is no written code to this extent, investors are advised to seek endorsement from the Department of SIA, that says no specific license is required for mere R&D work when there is no commercial production.

A company can be incorporated in India within 45 to 60 days from the date of application. However, one needs to get the name approved from the appropriate Registrar of Companies, which is granted within six working days before making such an application.

Intellectual Property

Intellectual Property (IP) in India has remained a mystery to many and the main reason for this is ignorance of both law and facts. While issues regarding Trade Mark and Copyright may not be all that relevant to the biotech industry, the Patent Act 1970 has a major impact. India is one of the first few countries to have its Patent law in place which was evolved on the basis of its socio and economic conditions - a law that would support its closed-door economy.

India having become a signatory to the TRIPS agreement (Trade Related Aspects of Intellectual Property Rights) had to adhere to the pledge made in the agreement by carrying out considerable amendments to the Patent Act 1970. These

amendments were effected into two phases - first in the year 2002 and lastly in 2005. Some of the salient provisions of the Indian Patent Act relevant for the biotech industry are -

The following are not patentable:

- Mere discovery of a scientific principle or the formulation of an abstract theory.
- Or discovery of any living thing or non-living substance occurring in nature.
- The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs atleast one new reactant;
- A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- Any process for the medicinal, surgical, curative, prophylactic (diagnostic therapeutic) or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
- Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals;

By the Amendment Act of 2002, the law has been made clear that any plant, animal in whole or any part thereof, including seeds, varieties and species which have been processed using biotechnological means cannot be patented. However, there is an exception to the extent that any micro-organism which has been created using biological process is patentable.

Prior to the Amendment Act 2005, Section 5 of the Patent Act did not allow grant of Product Patent to inventions relating to drugs, chemicals and food processing. In line with the TRIPS, such restriction was dropped and the inventions mentioned, can qualify for the grant of product patents too.

Another significant amendment is that mere discovery of a new use for a known drug cannot be patented. With effect from January 1, 2005, fresh grant of exclusive marketing rights remains abolished.

Answering to global needs, India has introduced a new provision for compulsory licensing of pharmaceutical products. When at the request of any country facing a shortage of a patented drug, and that country having ordered compulsory licensing, but not in a position to manufacture such a drug, India can order compulsory licensing of such a patented drug exclusively for the purpose of export to that country alone.

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