BioSpectrum
the business of Bio & Health Sciences

FDI in biotechnology

10 June 2004 | News

Image not found or type unknown

FDI in biotechnology

Image not found or type unknown

Investment in the Indian biotech industry is currently estimated at about $2 billion and is expected to reach about $10 billion by the end of this decade, largely due to growing multinational collaborations and indigenous R&D efforts.

Realizing the importance of biotechnology, the Government of India through its Department of Biotechnology (DBT), has recently came out with a 10-year plan. The plan identified major areas for research, development and commercialization, which include genomics, bioinformatics, agriculture, plant and animal biotechnology, etc. In the healthcare segment, four areas have been earmarked for investmentâ€"medicines, vaccines, diagnostics and gene therapy.

Several Indian states including Karnataka, Tamil Nadu, Andhra Pradesh and Maharashtra have framed policies for attracting investment in this sector and offer fiscal benefits and other incentives such as land grants for training institutes, labor concessions and assistance with funding.

Bioinformatics

Computing has joined forces with biology to create bioinformatics, which is concerned with the acquisition, storage and analysis of biological data. Once an obscure part of computer science, bioinformatics has become a linchpin of

biotechnology's progress. This opportunity has not been lost on IT companies.

Governance of biotechnology

The following legislation are relevant:

- Environment (Protection) Act, 1986 (hereinafter referred to as EPA)
- Rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells, 1989 (hereinafter referred to as Rules)
- Department of Biotechnology Guidelines, 1998

Related laws

- Protection of Plant Varieties and Farmers Rights Act, 2001 and Rules 2003
- Indian Patents Act, 1970, Amendment Act, (1999) and (2002)
- Seeds Act, 1966 and Seeds Rules, 1968
- The Plants, Fruits and Seeds (Regulation of Import in India) Order 1989
- Public Liability Insurance Act, 1991
- EXIM Policy,
- Proposed new Acts/Amendments to be brought out by the Government
- Seeds Bill, 2003
- Patents (Amendment) Act, 2003

The DBT and the Genetic Engineering Approval Committee (GEAC) constituted under the Ministry of Environment and Forests are the lead regulatory bodies for biotechnology in India.

Agricultural biotechnology

In the field of agricultural biotechnology, huge business opportunities lie for foreign bioscience firms seeking research and business alliances with Indian firms.

Under the Government of India's foreign investment policy, a person residing outside India, including a corporation, can invest by way of subscription to shares of an Indian company, provided the Indian company is not engaged in any activity listed in Annexure - A to the Foreign Exchange Management Regulations, 2000. This would include agriculture and plantation activities. For other sectors, including biotechnology, the automatic approval route of the Reserve Bank of India (RBI) would be available, subject to equity caps provided in Annexure - B of the said Regulations.

A proposal to carry out any project involving GM/transgenic crops including planting, testing and handling of GM/transgenic crops in laboratory and greenhouse/net-house experiments and trials, small-scale and large-scale open field trials and the import of GM crops, will require clearances and approvals from the following authorities:

- Institutional Biosafety Committee (IBSC) - Implements and enforces biosafety guidelines on specific projects in research centres, universities and other national laboratories.
- Review Committee on Genetic Manipulation (RCGM) - Authorizes containment conditions for experiments, small-scale field trials and monitors those trials to ensure that safety standards are met. The RCGM also approves import requests for products needed for experimental work/training and research, such as agents, vectors, germplasms, etc.
- Genetic Engineering Approval Committee (GEAC) - It regulates large-scale trials and environmental release of all GM organisms, as well as, all imports and exports of GMOs. GEAC also issues licenses under the said Rules after reviewing all the necessary studies of trials, environmental safety aspects and other supporting documents.

Import of GM/transgenic crops

The import of GM/transgenic crops is allowed for limited research purposes. These imports require an import license in terms of the EXIM Policy of the Government and other applicable legislations regulating the import of GM/transgenic crops including the Order. An import license can be obtained from the Department of Agriculture and Cooperation, Ministry of Agriculture (DAC).

Pharmaceutical biotech

DBT has developed guidelines for clinical trials of recombinant products. Promising leads now exist to develop vaccines for rabies, tuberculosis, cholera and other diseases. Recombinant hepatitis B vaccine and LEPROVAC are already in the market.

Any person residing outside India including foreign companies, non-resident Indians and overseas corporate bodies can invest upto 100 percent under the automatic route of RBI by way of subscription to the shares of an Indian company engaged in the manufacture of drugs and pharmaceuticals. But this is subject to the condition that the activity does not attract compulsory licensing or involve the use of recombinant DNA technology and specific cell/tissue targeted formulations. Investment in Indian companies engaged in manufacture of licensable drugs, pharmaceuticals and bulk drugs produced by recombinant DNA technology might also require regulatory approval.

Taxation

Since 2001, the Indian government has been providing for a huge increase in research and development expenditure in its annual union budget and provides biotechnology companies with an R&D tax deduction of 150 percent. However, this does not include expenses incurred for the cost of any land or building. In a bid to attract investors, some Indian states have offered concessional or nominal sales tax rates for "high-end" new biotechnology products (as notified by the state government) manufactured by units located within biotechnology parks established within those states.

Intellectual Property Rights

India is a signatory to the Trade Related Intellectual Property Rights (TRIPS) Agreement, which has been incorporated in part, in different Indian legislations including the Patents (Amendment) Act 1999, 2002, the Protection of Plant Varieties and Farmers Rights Act 2001 (PPV Act) and the Trade Marks Act 1999. The PPV Act provides for protection of registered varieties of plants, for a period ranging from 15 to 18 years (depending on the kind of plant variety), and includes the exclusive right to produce, sell, market, distribute, import or export the variety or its propagating material and license it to other persons to do the same.

Conclusion

There are numerous opportunities in the biotechnology sector in India. However in order to harness these care must be taken to address the above issues in an enabling business environment with a pragmatic, entrepreneurial mindset.

Kirit Javali

Partner

Law Offices of Jafa & Javali

advocates@jafajavali.com