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FOREIGN INVESTMENTS IN INDIA

The Reserve Bank of India ("RBI") has recently announced recent liberalisation measures relating to foreign investments in India. by its A.P. (DIR Series) Circular No.38 dated December 3, 2003

Foreign investments in India can be made either with the specific prior approval of the Secretariat for Industrial Assistance/Foreign Investment Promotion Board ("SIA/FIPB"), or under the Automatic Route of the RBI.

A person resident outside India, or an incorporated entity outside India, has general permission to purchase shares, convertible debentures or preference shares of an Indian company, subject to relevant SIA/FIPB/RBI approvals. Indian companies also have general permission to issue partly convertible debentures or partly convertible preference shares, to non-residents.

General permission is also available for Indian companies to issue bonus or rights shares. The rights shares or debentures purchased by the person resident outside India, shall be subject to the same conditions, including restrictions in regard to repatriability, as are applicable to the original shares against which rights shares or debentures are issued. Further, the existing non-resident share holders may apply for issue of additional shares, and the issuer company may allot the same, subject to the condition that the overall issue of shares to non-residents in the total paid-up capital does not exceed the sectoral caps prescribed by SIA/FIPB/RBI. In other words, non-residents may subscribe for additional shares over and above shares offered on rights basis by the Indian company, and renounce the shares offered either in full or part thereof, in favour of a person named by them. Residents may subscribe for additional shares over and above the shares offered on rights basis by the company, and also renounce the shares offered either in full or part thereof, in favour of a person named by them.

Where a scheme of merger or amalgamation of two or more Indian companies has been approved by a court in India, the transferee company may issue shares to the shareholders of the transferor company resident outside India, subject to ensuring that the percentage of shareholding of persons resident outside India, in the transferee or new company, does not exceed the percentage specified in the approval granted by the SIA/FIPB/RBI. In case the percentage is likely to exceed

the percentage specified, the transferor company, or the transferee, or new company may, after obtaining approval from the SIA/FIPB, also apply to the RBI for its approval. The company may also issue shares under the Employees Stock Option Scheme to its employees, or employees of its joint venture or wholly-owned subsidiary abroad, who are resident outside India.

An Indian company may issue its Rupee denominated shares to a person resident outside India being a depository, for the purpose of issuing Global Depository Receipts ("GDRs") or American Depository Receipts ("ADRs"). A registered broker may purchase shares of an Indian company on behalf of a person resident outside India, for the purpose of converting the shares into ADRs or GDRs. An Indian company may sponsor issue of ADRs or GDRs with an overseas depository, against shares held by its shareholders, at a price to be determined by the lead manager.

Pending repatriation or utilisation of the foreign exchange resources raised, the Indian company may invest the foreign currency funds in deposits with, or in Certificate of Deposits, or other instruments of banks which have been rated not less than A+1 by Standard and Poor, or P1 by Moody's, for short-term obligations, or in deposits with a branch outside India of an Authorised Foreign Exchange Dealer ("AD") in India, and in treasury bills and other monetary instruments, with a maturity of one year or less.

In order to encourage Indian companies to list ADRs or GDRs on overseas exchanges, through the schemes of sponsored ADRs or GDRs, resident shareholders of Indian companies have been permitted to offer their shares for conversion to ADRs or GDRs, and to receive the sale proceeds in foreign currency with SIA/FIPB approval. The ADR or GDR proceeds may be utilised in the first stage acquisition of shares in the disinvestment process, and also in the mandatory second stage offer to the public.

Indian companies receiving subscription from non-residents for issue of shares have also got general permission for refund of funds received towards allotment of shares, remittance of surplus funds received for purchase of shares offered on rights basis, remittance on account of surplus funds received for purchase of shares or on account of cancellation of trade, under two-way fungibility of ADRs or GDRs.

General permission has been granted to non-residents for transfer of shares and convertible debentures of an Indian company, by way of sale or gift of the shares or convertible debentures, to any person resident outside India, provided the transferee has obtained prior permission of SIA/FIPB to acquire the shares, if he has a previous venture or tie-up in India through investment in shares or convertible debentures, or a technical collaboration or trade mark agreement or investment in the same field or allied field, in which the Indian company whose shares are being transferred, is engaged.

A person resident outside India may also transfer any security to a person resident in India by way of a gift. A person resident in India who proposes to transfer any share or convertible debenture of an Indian company by way of sale or gift to a person resident outside India, will have to obtain prior approval of SIA/FIPB, followed by permission from the RBI. The above two-stage approval is applicable even when the transfer is made on a non-repatriation basis. A person resident outside India holding shares or convertible debentures of an Indian company, may transfer by way of sale to a person resident in India, after obtaining prior permission from RBI.

Prices of shares issued to persons resident outside India shall not be less than the price worked out in accordance with the Securities and Exchange Board of India ("SEBI") guidelines, where the issuing company is listed on any recognised stock exchange in India, and fair valuation of shares is done by a Chartered Accountant as per the guidelines issued by the erstwhile Controller of Capital Issues, in all other cases.

An Indian company issuing shares or convertible debentures shall submit to the RBI the details of advance remittance. The RBI may permit an Indian company issuing shares to persons resident outside India to retain the subscription amount in a foreign currency account, subject to such terms and conditions as it may stipulate.

Foreign Institutional Investors ("FIIs") registered with SEBI are eligible to purchase shares and convertible debentures under the Portfolio Investment Scheme. The concerned entities may apply to the RBI for permission through a designated bank, which is granted along with permission for opening foreign currency account or a Rupee account with a designated branch of an AD.

In the case of FIIs, the total holding of each FII or SEBI approved sub account shall not exceed 10% of the total paid-up equity capital, or 10% of the paid-up value of each series of convertible debentures issued by an Indian

company. The total holdings of all FIIs or sub-accounts of FIIs put together, shall not exceed 24% of the paid-up equity capital or paid-up value of each series of convertible debentures. This limit of 24% can be increased to the sectoral cap or statutory limit as applicable to the Indian company concerned, by passing of a resolution by its board of directors, followed by passing of a special resolution to that effect by its general body.

FIIs are also permitted to trade in all exchange traded derivative contracts, subject to certain limits. ADs can also offer forward cover to FIIs, to the extent of total inward remittance, net of liquidated investments.

Registered FIIs have been permitted to purchase shares or convertible debentures of an Indian company through offer or private placement. The FII shall restrict allocation of its total investment between equities and debt, including dated Government of India securities and treasury bills in the Indian capital market, in the ratio of 70:30. FII's can form a 100% debt fund, and get registered with the SEBI for investment in debt investments.

FII's can buy with repatriation benefits dated securities or treasury bills, non-convertible debentures or bonds issued by Indian companies, and units of domestic mutual funds, either directly from the issuer of such securities, or through a registered stock broker on a recognised stock exchange in India.

A SEBI registered Foreign Venture Capital Investor ("FVCI"), with general permission from RBI, can invest in Indian Venture Capital Undertaking ("IVCU") or in a Venture Capital Fund ("VCF") or in a scheme floated by such VCFs. They can purchase equity or equity linked instruments or debt instruments, debentures of an IVCU or of a VCF through initial public offer or private placement or in units of schemes or funds set up by a VCF.

The RBI, on application, may permit a FVCI to open a foreign currency account or Rupee account with a designated branch of an AD. The purchase or sale of shares, debentures or units can be at a price that is mutually acceptable to the buyer and the seller or issuer. ADs are also authorised to offer forward cover to FVCIs, to the extent of total inward remittance, net of liquidated investments.

BIOTECHNOLOGY : A FOREIGN INVESTOR'S PERSPECTIVE

Introduction

From healthcare to agriculture to pharmaceuticals to manufacturing processes, and drug discovery, biotechnology is creating platforms for new products and

markets on many fronts. Investment in the Indian biotechnology industry is currently estimated at about US\$ 2 billion and is expected to reach approximately US\$ 10 billion by the end of this decade, largely due to growing multinational collaborations and indigenous research and development efforts.

Realising the importance of this sector, the Government of India through its Department of Biotechnology, Ministry of Science and Technology recently came out with a 10 year plan. The plan also identified major areas for research, development and commercialization including genomics, bioinformatics, agriculture, plant and animal biotechnology, environment and biodiversity, and medical biotechnology. In the area of healthcare, four areas have been earmarked for investment : medicines, vaccines, diagnostics and gene therapy.

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

Bioinformatics

In life-sciences establishments around the world, the laboratory rat is giving way to the computer mouse – computing joins forces with biology to create a bioinformatics market. Welcome to the world of bioinformatics - a branch of computing 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.

The changes wrought by computers in biology resemble those in the aircraft industry and car industry a decade ago. The opportunity has not been lost on IT companies.

The Governance of Biotechnology

At present the following pieces of legislation are relevant:

- Environment (Protection) Act, 1986 (hereinafter referred to as the "EPA")
- Rules for the Manufacture, Use Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells, 1989 (hereinafter referred to as the "Rules")
- Department of Biotechnology Guidelines, 1998.

Related Laws

- The Protection of Plant Varieties and Farmers Rights Act, 2001 and The Protection of Plant Varieties and Farmers Rights Rules, 2003
- Indian Patents Act, 1970, Amendment Act, (1999), (2002) and the Patents Rules, 2003
- 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 Govt.

- Seeds Bill, 2003
- Patents (Amendment) Act, 2003

The Department of Biotechnology ("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

The genetically engineered seed market in India has an estimated value of US\$ 250 million while the total seed market has been estimated US\$ 500 million with expected sales of US\$ 2.5 million by the end of 2002.

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 resident 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 (Transfer or Issue of Security by a Person Resident Outside India) Regulations, 2000. For other sectors, the automatic approval route of the Reserve Bank of India ("RBI") would be available, subject to equity caps provided in the amended Annexure – B of the said Regulations.

Any 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 the following clearances and approvals from the:

- Institutional Biosafety Committee ("IBSC")
- Review Committee on Genetic Manipulation ("RCGM") and the
- Genetic Engineering Approval Committee ("GEAC")

IBSC which implement and enforce biosafety guidelines on specific projects within research centres, universities and other national laboratories; and the RCGM, which authorizes containment conditions for experiments, small-scale field trials, and monitors those trials to ensure safety standards are met. The RCGM also approves import requests for products needed for experimental work/training and research, such as agents and vectors, germ plasmas, etc.

Specifically, the GEAC regulates large-scale trials and environmental release of all GM organisms, as well as all imports and exports of GMOs. GEAC also issues licences 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. Such import requires an import license in terms of the EXIM Policy of the Government of India and other applicable legislation 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").

Commercialisation of GM/Transgenic Crops in India

Though research on GM/transgenic crops has been in progress for sometime now. In March 2002, India's Genetic Engineering Approval Committee approved the commercial release of 3 Bt cotton hybrids that are genetically engineered to be insect resistant to Mahyco for commercial production for Bt cotton in India.

Plant Tissue Culture

Planting materials raised through tissue culture are being used for banana, pomegranates, papaya among horticultural plants and eucalyptus, sandalwood, bamboo and teak among the forest plants. The Government has extended several incentives like automatic industrial approvals and refinancing facilities through certain banks.

Pharmaceutical Biotechnology

The DBT has also developed guidelines for clinical trials for 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.

A person resident outside India including foreign companies, can invest upto 100% 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 provided the activity does not attract compulsory licensing or involve the use of recombinant DNA technology and specific cell/tissues targeted formulations. Investment in Indian companies engaged in the manufacture of licensable drugs and pharmaceuticals and bulk drugs produced by recombinant DNA technology may also require prior regulatory approval from the Government of India.

Taxation

The Government of India in its annual Union Budget since the year 2001, has been providing for a huge increase for research and development expenditure and provides biotechnology companies with a research and development tax deduction of 150%. However, such expenditure will not include expenditure in the nature of cost of any land or building. In a bid to attract investors, some Indian states in the biotechnology sector 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 parts in different Indian legislations including the Patents (Amendment) Act 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 for 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 to license other persons to do the same.

Under Indian laws, methods and processes of substances intended for use or capable of use as food, medicine or drug are provided patent protection. However, the protection as the product itself is not capable of patent protection. Though certain industrial micro-biology processes have been granted patent protection, patent protection for pharmaceutical biotechnology remains uncertain.

Conclusion

There are numerous opportunities in the biotechnology sector in India. India has the vital ingredients for success in biotec and pharmaceutical R& D, its scientific manpower. However in order to harness this talent care must be taken to address the above issues in an enabling business environment with a pragmatic, entrepreneurial mindset.