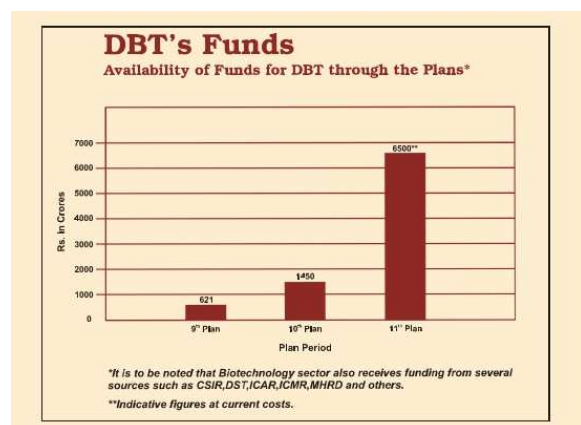


## CONSULATE GENERAL OF INDIA SAN FRANCISCO

### BIOTECHNOLOGY – NEW INDIAN FRONTIER

#### A. OVERVIEW

India's biotechnology revenues touched \$2.5 billion in 2007-08, up from \$2 billion in 2006-07, \$1.5 billion in 2005-06 and \$1 billion in 2004-05. The growth of india's biotechnology sector has been overshadowed only by the dazzling achievements of its information technology (IT) counterpart. This shows an average growth rate of 18% per year. The Indian biotech sector has set a target of \$5 billion in revenues by fiscal 2010-11 and could even reach \$25 billion by 2020. In terms of volume the Indian biotech business is ranked 4<sup>th</sup> in the world and 13<sup>th</sup> in terms of value.<sup>1</sup>



(Source: Dept of Biotechnology Annual Report)

Biotechnology has transformed many parts of the chemical industry, agriculture and medicine. Innovations, techniques and tools that have emerged in this field and have revolutionized our lives include genetic engineering, cell fusion technology, bioprocess technologies and structure-based molecular designs including drug development, drug targeting and drug delivery systems. **India with its acknowledged IT strength can play a vital role of 'converting' the huge array of chemical data available into drugs discovery. Indian companies appear well positioned to take advantage of their low cost manufacturing**

**capabilities to corner this market and compete on a global scale.**

Shantha Biotechnics of Hyderabad helped reduce the price of hepatitis B vaccine when they introduced the generic version Shanvac-B. Shantha today supplies nearly 40% of the UN Children's Fund's (UNICEF) global Hep-B vaccine supplies, distributed worldwide. Shantha also produced its recombinant interferon alpha (IFN- $\alpha$ ) drug cutting the previous market price of comparable imported drug by 75%.



Another success story is the Serum Institute of India (Pune) which has become the country's largest domestic vaccine supplier and exporter, its products reaching 138 countries. Through UNICEF and Pan American Health Organization, it helps immunize half the world's children against several diseases.

Biocon is another shining example of how India has transformed over the last 15 years. During its initial years it manufactured industrial enzymes – today it is an integrated billion dollar bio-pharmaceutical company developing the world's most affordable therapies for some of the most debilitating diseases. It has successfully commercialized the large scale manufacture of human insulin. It has developed extensive in-house R&D programs and does research for other firms besides making its own name products.

Bharat Biotech International is the first developing country firm to manufacture a foreign

<sup>1</sup> [http://www.atimes.com/atimes/South\\_Asia/IF19Df01.html](http://www.atimes.com/atimes/South_Asia/IF19Df01.html).

proprietary vaccine product. **It is contracted by the US Wyeth Company to produce its Haemophilis B (Hib) vaccine.** Wyeth also uses Indian firms to do “contract manufacturing” and “contract services”. For Wyeth and Indian firms the biggest areas are API manufacturing which is already large, and drug discovery, which is expected to increase in the future and for these one of the big factor is cost.

Multi-national corporations increasingly conduct clinical trials in India and rely on Indian contract research organizations to manage these trials. Huge global firms like Pfizer, Merck AstraZeneca, Novartis, Wyeth and Bayer are among the many who have “outsourced” their trials to Indian companies. **India’s vast pool of skilled manpower and low costs is drawing biotech giants to partner with Indian companies.**

Global giants like Biogen Idec have set up an Indian subsidiary in India. Other majors like Genentech, Genzyme, Pall Life Sciences, Agilent Technologies and HistoGenetics have set up base in India or are in the process of doing so.

### **B. Bilateral Developments**

Several of India’s largest companies have acquired US companies to gain a foothold in the US markets and gain technical and scientific expertise. Ranbaxy acquired ohm Labs(US), Dr Reddy’s acquired Trigenics(US), Sun Pharma acquired Able Labs and Careco(both US), Orchid acquired Bexel Pharma(US) and Biocon acquired Nobex(US).

An Indo-US workshop on Low Cost and Therapeutic Medical Technologies was organized by the Centre for DNA Fingerprinting and Diagnostics (CDFD) on behalf of the Institute of Biomedical Imaging and Bioengineering (NIBIB), USA during Nov 2008 at Hyderabad. The areas studied included cancer screening, cardiovascular diseases, digestive diseases diabetes and liver diseases, etc. Such workshops improve the collaboration between the two countries and can open the door for further increase in trade.

The USA-India Chamber of Commerce has been actively promoting and facilitating partnership and investment between US and

India, inter alia, through holding annual biotechnology summits which facilitate discussions on vital issues relating to the development, discovery, intellectual property, regulatory issues, investment opportunities and cross-border mergers and acquisitions. These summits evoke very high levels of interest and participation from across the US/India and other countries as well. Several academicians/experts of prestigious schools like Harvard Medical School, Tufts Medical School, Massachusetts Institute of Technology and Boston University participate.



India is among the 8 countries in the International Cancer Genome Consortium (ICGC) which has set out to generate comprehensive, high-resolution analysis of genomic changes for 8 forms of cancer based on the International Cancer Genome Atlas programme implemented by the national Cancer Institute of National Institute of Health (NIH), USA. Each organization will be coordinating studies of at least one specific type or sub-type of cancer. ICGC projects will use common standards of data collection and analysis. The project will generate datasets that are 25,000 times larger than the Human Genome Project which will be freely available to the global research community.

### **C. Other Recent Developments**

Patent reform is one area presently under review in the US and is currently making its way through the US Congress once again with the introduction of the Patent Reform ACT of 2009. This ACT may pit biotech against the high-tech sector. Both of them are in the business of innovation but they build their projects in different ways. They are at odds over Intellectual Property rules. To sum up their differences, high-tech companies see themselves as

potential infringers, while bio-tech companies' worries are those of patent holders. Allies of biotech include even unions that are worried that loosening patent laws would cost jobs by opening the doors to cheaper imports. The "Damages" provisions under the new bill are not acceptable to bio-tech industries. They argue that recent court cases have already weakened and reshaped patents and would invite infringement and generate more litigation<sup>2</sup>.

Maryland's governor said in Nov. 2008 at the 4<sup>th</sup> Annual Maryland-India Business Roundtable (MIBRT) that his state was keen to expand trade ties with India especially in the cutting edge fields like biotech. Maryland, a life sciences hub is home to various agencies like University System of Maryland, John Hopkins University, Howard Hughes Medical Institute, Celera Genomics, Human Genome Sciences(HGS), J Craig Venter Institute(JCVI), Food and Drug Administration (FDA) and National Institute of Health (NIH). He noted that a number of Maryland counties have organized delegations of business executives to India. To attract Indian companies to Maryland, the state plans to focus on industry sectors in which both Maryland and India are strong among which is Biotech. The MIBRT aims to foster cooperation and promote trade and investment between businesses operating in India and Maryland<sup>3</sup>.

**D. Visit of Secretary, Department of Biotechnology, Government of India**



Dr M K Bhan, Secretary, Department of Biotechnology of Government of India, accompanied by Dr S Natesh, Senior Adviser DBT and other scientists/researchers from National Institute of Immunology, New Delhi and National Centre for Biological Sciences, TIFR

<sup>2</sup> [http://www.genengnews.com/news/bnitem\\_print.aspx?name=50688785](http://www.genengnews.com/news/bnitem_print.aspx?name=50688785)

<sup>3</sup> Thaindian News-23-11-2008

Bangalore visited US from June 10-15, 2009. They visited San Francisco, Boston and Seattle where they met with senior experts, post-doctoral students and researchers from premier institutions working in the area of biotechnology. The objective of the visit was to promote Indian biotechnology in USA, increase awareness about re-entry packages in India as well as about the biotechnology clusters in Mohali, New Delhi and Bangalore.

**E. Some Frequently Asked Questions**

Recognizing the potential of the biotechnology industry and keen to boost the industry's performance the Government of India has, inter alia, taken initiatives to make India a biotech hub just like its booming IT sector. Some questions raised by foreign companies interested in setting up business in India are answered below.

**1. Can an American company or their JV in India import PCR and sequencing machines into India and what would be the customs rate or import duty, etc.?**

Import of equipment by an actual industrial user is freely permitted. Equipment like PCR, Sequencing Machines etc. can be imported for R&D and Manufacturing purposes. Specified pharmaceutical and biotechnology equipment for R&D have been exempted from customs duty subject to their being registered with Department of Scientific and Industrial Research (DSIR) under Ministry of Science & Technology. Export Promotion Capital Goods (EPCG) Scheme allows import of capital goods for pre-production, production and post-production at 5% customs duty subject to an export obligation equivalent to 8 times of duty saved on capital goods imported under the Scheme to be fulfilled over a period of 8 years reckoned from the date of issuance of license. Recently, the GOI issued new import regulations on used equipment that permit free importation of used equipment that is less than 5 years old.

**2. Is there a limitation in sending saliva/hair samples in sealed containers/envelopes for DNA testing in India?**

As per ITC (HS) classifications of Export and Import items (1.9.2004-31.3.2009), notified by Ministry of Commerce & Industry, saliva and hair

samples can be imported to India without restriction. Relevant details are available at website <http://www.nic.in/eximpol>.

**3. Does Government of India have any policies or plans to promote, finance or provide line of credit for a foreign company setting up DNA testing unit with test machines in India?**

Under FDI Policy, foreign investment is encouraged in all permitted sectors. FDI in DNA testing unit is under automatic route up to 100%. DNA testing services including DNA Paternity testing, DNA forensic testing and DNA relationship testing etc. will come under the category "rendering services" and this activity is under automatic route up to 100% FDI. Under automatic route, no prior approval is required for bringing FDI and only intimation to Regional RBI Office is required to be given within 30 days of receiving remittances and again within 30 days of issue of shares to non-residents. For details, you may refer to DIPP publication "Manual on Investing in India" available at DIPP website, [dipp.gov.in](http://dipp.gov.in).

As regards incentives to promote, it may be noted that Govt. of India has set up special Economic Zones and Bio-technology Parks and units therein and these Zones/Parks are entitled for tax holidays, duty free import of raw material, Intermediate as well as capital goods to attract foreign and domestic investments and boost exports. Detailed guidelines are available at: <http://www.cbec.gov.in/customs/cs-sez-botm.htm>

Regarding financing or providing loan for such projects, the Ministry of Science & Technology have various programmes like SBIRI, BIPP in DGT and DPRP, TDB in DST, the details of which are available on the websites of these Departments viz. [www.dbtindia.gov.in](http://www.dbtindia.gov.in) and [www.dst.gov.in](http://www.dst.gov.in). Apart from this there are venture capital funds like Andhra Pradesh Industrial Development Biotech Venture Fund and Gujarat Venture Funds Ltd. Some banks like YES BANK, HDFC and HSBC etc. also have earmarked funds for biotech and Life Science Sector.

**4. Tax breaks, reduced Import and Customs duties etc. are available in India for this Industry?**

Reply against Question No. 1 above may be referred. More information on import procedures and customs duty exemptions are available on DGFT website <http://dgft.delhi.nic.in> and Central Board of Excise & Customs website <http://www.cbec.gov.in>.

**5. Any law passed for monitoring, controlling DNA business/industry in India?**

Monitoring and controlling DNA business/industry in the country are governed by "Ethical guidelines for biomedical Research on Human participants-2006" of ICMR. The detailed guidelines are available at ICMR website <http://icmr.nic.in>.

**F. Upcoming Events**

**A. Bangalore Bio India will be organizing the 11<sup>th</sup> Bangalore Biotech International Conference & Trade Show to be held at Bangalore from June 02-04, 2010.**

Firms from Leading biotech nations of the world will be present including from USA, UK, France, Japan and China. The 10<sup>th</sup> annual show was recently held from June 18-20, 2009. At the event, Minister of State for Science and Technology Mr. Prithviraj Chavan stated that India is setting up a national biotechnology regulatory authority in partnership with the industry.

**B. Department of Biotechnology is inviting proposals under INDO-US Collaborative Expansion of Vision Research. For details, please check <http://dbtindia.nic.in>**

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For any queries, please contact:

Mehrnoosh Khorshidchehr,  
Commercial Assistant  
Consulate General of India  
San Francisco  
[com@cjisf.org](mailto:com@cjisf.org)