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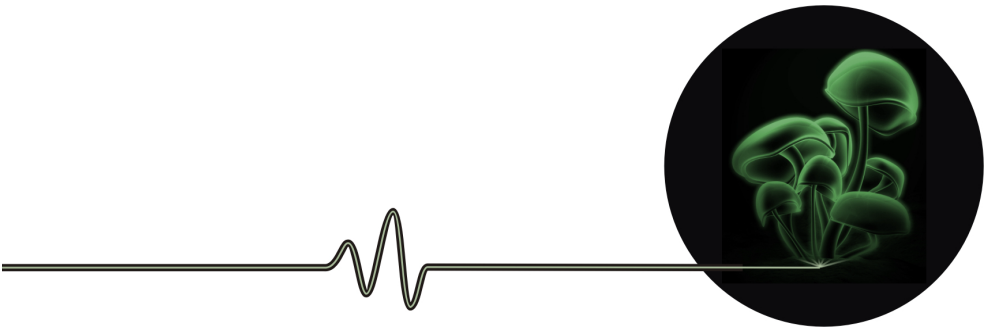
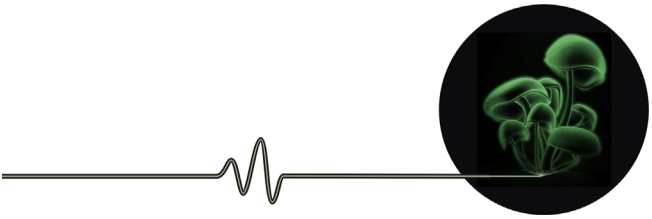


Biotechnology

- Legal & Ethical Issues

June 2005 Edition



Biotechnology
- Legal & Ethical Issues

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Nishith Desai Associates (NDA) is a research based, multi-disciplinary international law firm based in Mumbai and Silicon Valley. NDA specializes in globalization of Indian corporates, information technology, international financial and tax laws, corporate and securities laws, media and entertainment laws and telecom laws. It has structured and acted for a large number of private equity funds for India. It recently acted as underwriter's counsel in Infosys Technologies and Satyam Infoway's American Depositary Receipt (ADR) offerings in the USA. It also represented Wipro, Rediff.com and Silverline Technologies in their ADR listings. Amongst others, NDA was involved in the first cross-border stock swap merger out of India - that is, BFL's acquisition of MphasiS, besides Silverline's recent acquisition of Seranova Inc in an ADR stock swap deal. The firm has also worked on the acquisition of IMP Inc. by Teamasia and PMC Sierra's acquisition of SwitchOn Network. NDA was awarded "**Indian Law Firm of the Year 2000"** and "**Asian Law firm of the Year (Pro-bono)-2001**" by the International Financial Law Review, a Euromoney Publication. NDA has also been ranked as having a leading practice in Private Equity, Media and Entertainment and IT and telecommunications law for 2001-02 by the Global Counsel 3000.

Content

APPROACH AND METHODOLOGY

Project Biotech (the "**Project**"), commissioned by NDA was undertaken in the year 2001 by the Strategic Initiatives team of the firm. The objective of the project is to capitalize on the significant role that NDA can play in assisting biotechnology companies meet the complicated legal challenges involved with this fast growing sector of the Indian economy. The project aims at understanding the fundamental applications of biotechnology, analyzing the impact of the biotechnology industry, globally and in India, identifying potential areas of growth and building competence within the firm in the legal, ethical and regulatory issues connected with the industry.

The project has been approached in an attempt to consolidate the scientific and legal aspects of the biotechnology industry and is headed by a qualified surgeon, with inputs from members of NDA with expertise in intellectual property, information technology, medical laws, legal liability, corporate finance and venture capital funding.

This report is a consequence of Phase I report published in the year 2002 which included the creation of an extensive knowledge base on the biotechnology industry, the legal and regulatory issues connected therewith and the identification of the broad parameters, which will form the basis of detailed research and analysis. This report gives the feel of the Biotech industry in India, trends and opportunities in India with reference to the world as well as the guidelines on structuring in India and various tax, legal and regulatory issues.

EXECUTIVE SUMMARY

The growth of technology is revolutionizing the way we conduct our lives and is challenging established legal principles, which are struggling to adapt to rapid technological advances. Biotechnology is not a new science. It has existed in some form or the other for centuries. However, the advent of genetics has opened exciting opportunities in this sector, because of its numerous applications, which range from improvement of human health and food production to reduction of environmental damage. These opportunities are also coupled with controversies that not only challenge the laws within which our society functions, but also our ethical and religious beliefs.

The biotechnology revolution is gaining momentum all around the world and reports have indicated that the Indian biotechnology sector is estimated to grow faster than the robust Information Technology industry in India. "India's bio-vision" in the future years involves the building of a $5 billion biotechnology business segment and developing a $4 billion export market. This could provide employment to 1million scientists and engineers, besides throwing open a $1 billion business segment for outsourced research and development. The estimate appears to be somewhat over-optimistic, but is certainly indicative of the Indian potential. Further, the Indian market is at a very nascent stage, thereby making it difficult to give a quantitative estimate. Biotechnology companies, as well as the investment community in India are still in the process of identifying areas with potential. Some of the areas which are likely to witness immediate growth are (i) contract research, due to the low cost of research and development in India and (ii) bioinformatics, due to an established information technology sector with a vast pool of talented and skilled man power and its capabilities in developing sophisticated data management and analysis tools to mine data such as gene and protein sequences.

The biotechnology sector, unlike the information technology sector is highly regulated. Intellectual property, more specifically patents are the most valuable asset of a biotechnology company. The Patents Act, 1970 as amended in 1999 and 2002 governs patent law in India and the basic concepts of patentability have been often challenged when they are applied to life forms and biological material. The judgment by the Calcutta High Court in the *Dimminaco Case* has radically transformed the concept of patentability of life forms and has opened the door for the flurry of biotech related patent applications. Further, the decision of the Government not to go in appeal against the judgment of the Hon'ble Court has clearly underscored the intent of the Government to encourage such inventions. Pharmaceuticals and agro-chemical products are currently not patentable under Indian patent law and patents are presently restricted to the methods or process of manufacture and not extended to the substances/products themselves. With promulgation of the Patents (Amendment) Act, 2005 ("Third Amendment") India has complied with its commitment of introducing the product patent regime in India with effect from January 1, 2005. The agreement on Trade Related Intellectual Property Rights ("TRIPS") had allowed 10-year window to developing countries for introducing product patent regime. For developing countries, providing protection for pharmaceutical and agricultural chemical products has been a particularly controversial issue, and in recognizing the sensitivity surrounding this issue, TRIPS had provided for special treatment in respect of such products. The implementation of product patent regime is bound to be a boost for Multi National Companies, which have previously been reluctant to invest in India in the absence of product patent protection. In compliance with its obligations under the TRIPS

Agreement and the Convention on Biological Diversity, India has also enacted the Protection of Plant and Varieties and Farmers Rights Act, 2001, and has also enacted Biological Diversity Act, 2002.

Prior to launching its products in any country, a biotechnology company undertakes patent registration to protect its own interests. The next step involves acquiring the approval of the regulatory authorities. The existing drug approval process is governed by the Drugs and Cosmetics Act, 1940 and involves a complicated process of multiple clearances from various government departments, ministries and committees both at the state and at the central level. Further, the Drugs (Prices Control) Order, 1995 fixes the ceiling price of some active pharmaceuticals and formulations. The manufacture, import and storage of genetically modified organisms in India is regulated by the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Modified Organisms or Cell Rules, 1989 (made under delegated powers given by the Environment Protection Act, 1986). Under these rules six competent authorities were set up at a three tier level - national, state and district for regulatory purposes. However, the multi-body clearance system is time consuming resulting in numerous delays and needs to be revamped to curb the delay in clearing projects, which inadvertently affects the viability of upcoming biotechnology companies. Besides patents and regulatory approvals, several aspects of business law play a significant role in the functioning of biotechnology companies because drug discovery and innovations in biotechnology is risky, expensive and time-consuming. Companies are required to develop collaborations and strategic alliances, as the key commercial vehicles used to unlock the value in their intellectual property.

The rapid progress in certain controversial areas of biotechnology research has given rise for the need to frame appropriate laws to maximize the benefits of the new technologies, without compromising on ethics. Some of the significant areas of concern include human cloning, which emanated with the cloning of “Dolly” the sheep, in the year 1997. The ethical concerns about human cloning involve the risks and uncertainties associated with the current state of cloning technology, such as the possibility of genetic defects, development of designer babies and legal protection for cloned humans. The Human Genome project has led to fears regarding the privacy and confidentiality of genetic information, including questions of ownership and control of genetic information, human rights and consent to disclosure and use of genetic information etc. Stem cell research has been criticized because of the use of embryonic stem cells, which results in the destruction of the embryo. A majority of the concerns are due to deeply held religious and philosophical views, which give rise to the conflict between ethics and science. Gene Therapy is another tool that holds the prospect of great hope as well as the danger of the unknown, as researchers, scholars, doctors, and patients weigh the benefits and the risks of a medical treatment that is still in its infancy. Xenotransplantation, or the process of transplantation of body parts from animals to humans is another significant stepping stone in the advancement of biotechnology. Nanotechnology being a process of transition is perceived to have the potential of becoming the next biggest revolution since the infotech revolution, carrying with it the probability of giving rise to an entirely new legislation dealing specifically with issues relating to Nanotechnology. The threat of bioterrorism, especially since the September 11 attacks in the United States, has been omnipresent and also has been of considerable significance, as a result leading to diversify legal implications.

India has tremendous potential in the biotechnology sector, but one of the significant hurdles facing the industry is the current legal and regulatory framework. This includes the lengthy approval process for drugs and genetically modified organisms, import duties on raw materials for the sector, lack of protection for product patents, relatively weak patent enforcement and the need for well trained patent examiners. In order to ensure growth, cross licensing between biotechnology companies will be essential and companies will have to develop inter-dependencies. Biotech parks present a great opportunity for companies and academic institutions must network and develop ties with the industry to help fuel the growth of this sector. The current focus of companies is on strategies, because any future alliance they enter into will have to be in synchronicity with their long-term strategies. Biotechnology companies have to focus on developing effective patent strategies along with business models and with the required funding for innovative research and development and strengthening of government initiatives in framing effective policies and regulations, India is poised to emerge as a force to reckon with in the global biotechnology sector.

I. INTRODUCTION

1 Basics of Biotechnology

A. Origin & Development

"Biotechnology" is defined by the Convention on Biological Diversity as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Biotechnology has existed in various forms even prior to the dawn of civilization and has in many ways actually contributed to making human society conducive for taking the next quantum leap into a civilized world. Agriculture, is probably the earliest display of the use of biotechnology.

Over the centuries, mankind has learnt a great deal about the different organisms that our ancestors had been using so effectively throughout human history. The marked increase in our understanding of these organisms and their cells brought about the ability to control their many and varied functions. In the mid-eighties and early-nineties it became possible to transform (genetically modify) plants and animals that are necessary for food production. "Transgenic"[1] animals and plants, including cows, sheep, tomatoes, tobacco, potato and cotton have now been obtained.[2] Today, biotechnology has wide-ranging applications, from agriculture to cloning of living organisms and altering life forms.

Genetics and biotechnology offer a door to a new era in the history of mankind. The first genetically engineered products were medicines designed to combat human diseases. Insulin, used to treat diabetics, and as a blood clot-reducing enzyme for heart attack victims is now produced easily and cheaply as a result of biotechnology.

There is little doubt that the applications of modern biotechnology will increase rapidly in India and around the world. It holds great potential for providing solutions to improve the health of people and their quality of life, significantly improving agricultural productivity along with supplying more nutritious food and improving the quality of environment by ensuring sustainable development.

B. Brief History

Since the year 1859, when Charle Darwin published his work to Mendelian theory and discovery of molecular structure of DNA in 1953 by Crick and Watson and their theory of recombination and replication of gene which made them noble laureate, Biotechnology is expanding its wings to various fields widening the spectrum of applications.

It has rapidly progressed over the years and in the year 1990, a coordinated Human Genome project began with the objective of sequencing the human genome consisting of 3 billion base pairs. In the year 2001, Celera Genomic Corporation, a US Based firm completed the project.

C. Classification of Biotechnology

Biotechnology can be loosely classified into four types, namely Green biotechnology (Agricultural applications), Red biotechnology (Medical and health applications), Blue biotechnology (use of Bioluminescent microorganisms for sea water) and White/Grey biotechnology (Industrial processes applications).

[1] The term "Transgenic" was first introduced by J.W. Gordan and F.H. Ruddle in 1981 and refers to animals in which there has been a deliberate modification of the genome - the material responsible for inherited characteristics - in contrast to spontaneous mutation, *CCAC guidelines on: transgenic animals, 1997*, at http://www.ccac.ca/english/gdlines/transgen/transge1.htm (accessed on January 4, 2002).

[2] Arizona State University, *Introduction to "Biotechnology"* at http://photoscience.la.asu.edu/photosyn/courses/BIO_343/lecture/biotech.html (accessed on August 30, 2002).

D. Applications of Biotechnology

Biotechnology functions like a fruit on a tree having roots of biological sciences, microbiology, genetics, molecular biology and biochemistry and trunk of chemical engineering. So, it is indeed difficult to define the precise scope and extent of the applications of biotechnology. The introduction of biotechnology to produce new products or molecules poses various challenges, which may be technical or ethical. Biotechnology has numerous applications, with the potential to affect every facet of our lives in numerous ways.

Some of the various applications of biotechnology are as follows:

1. Genetic Engineering
2. Gene Cloning
3. Gene Transfer Mechanism
4. Plant Cell & Tissue Culture
5. Immunology
6. Animal Cell Culture
7. Agriculture
8. Industrial
9. Health Care
10. Environmental

2 Biotechnology Boom

The biotechnology revolution is gaining momentum all over the world and India is no exception. India has been a forerunner among the developing countries in promoting multi-disciplinary activities in this area, recognizing the practically unlimited possibilities of their applications in increasing agricultural and industrial production and in improving human and animal life. Some of the new initiatives include developing techniques for gene mapping, conservation of biodiversity and bio-indicators research, special biotechnology programs for the benefit of the scheduled castes and scheduled tribes and activities in the area of plantation crops. Presently there are about 5000 biotech companies worldwide. It is estimated that long-term product sales are expected to grow at an average annual rate of 12%, from a base of more than US$16 billion in 2000 to nearly US$50 billion in 2010. The number of companies in the Asia Pacific region is up 11 per cent to 667.

India is emerging as one of the 5 emerging biotech leaders in Asia Pacific; the others being Singapore, Taiwan, Japan and Korea, with Mainland China catching up quickly. India is currently ranked 3rd in the region based on the number of biotech companies (96), trailing behind Australia (228) and China, including Hong Kong (136). (Source: E &Y Biotech reports 2004)

“India’s position as a biotech player is assuming greater eminence as it continues to build critical mass in terms of skills and capabilities. An analysis of the year’s events clearly indicates that Indian biotech companies are getting their fundamentals firmly in place, business models are maturing, and product commercialization capabilities are improving,” says Rajiv Memani, CEO and Country Managing Partner, Ernst & Young India. In the report. India is expected to generate $ 5 billion in revenues and create more than one million biotech jobs over the next five years. This growth is expected to come on the back of increased partnering activity, transition to a product driven model, growth in the biogenerics market and government initiatives to encourage investment and expansion.. The Indian biotechnology sector is

booming with an average of 700,000 postgraduates and 1500 PhDs qualified every year in the biosciences and engineering fields. The market size of biotechnology products (medical, agriculture, functional food/nutritionals, research products, and services), which was estimated to be US$ 1.7 billion in 1999, is projected to grow up to US$3-5 billion by the year 2005.3 The estimate appears to be somewhat over-optimistic, but is certainly indicative of the Indian potential. Further, the Indian market is at a very nascent stage, thereby making it difficult to give a quantitative estimate.

II. BIOTECHNOLOGY INDIA & WORLD

Indian Statistics

The Indian Biotech industry can be divided into different segments. Following is a review of largest and the fastest growing segments of the Biotech industry in India.

Medical Biotech Segment

The Indian pharmaceutical market is growing very rapidly. According to a study by Mckinsey, Indian Pharma industry is expected to grow to an innovation-led US $25 billion industry by 2010 with a market capitalization of almost US $150 billion from the current US $5 billion generic based drug industry. The vaccine market is expected to grow by roughly 20%.

Agri Biotech Segment

India being the second largest food producer, offers a huge market for biotechnology products, especially agri-biotech products. India has an excellent scientific infrastructure in agriculture, rich bio-diversity and skilled and low cost human-power. In a report by Ernst & Young it is expected that the Nutraceuticals market is roughly US $532-638 million presently and growing. With its 8000 kilometer of coastline including Andaman & Nicobar and Lakshwadeep islands, India has a rich aqua culture and its Marine resource development holds great potential.

Services Segment[4]

With increasing number of pharmaceutical companies finding it difficult to conduct entire drug discovery process-in-house they are looking for ways to minimize costs. India has become a very attractive base as the cost of infrastructure is relatively lower compared to other nations. Foreign companies also benefit from cheaper qualified workforce available in India. India produces enough qualified graduates each year thus companies looking to expand their operations can easily do so without facing a shortage in labor.

It is estimated that vaccines, contract research, agriculture and human health sectors comprise as much as two thirds of the total market. It is further estimated that health care products would dominate the Indian biotech market, roughly 40% of the total market by the year 2010 followed by agriculture of about 30%. It is also estimated that contract research and bioinformatics would pick up and account for as much as 25% of the biotech market. An estimation by CII shows that the Agri-Biotech would see growth rates of as much as 60%, Diagnostic and Therapeutics of about 25% and Vaccines of about 15%. These figures clearly indicate the prospects of the Biotech industry in India.

[3] Amiya R. Nayak, *Biotech industries and business opportunities in India*, at http://www.assocham.org/features/btoppindia.asp (accessed on August 30, 2002).

[4] (Source: Confederation of Indian Industries)

India Market Highlights

Biotechnology in India is an emerging industry with a highly educated community of scientists and researchers, strong government support and a growing infrastructure base. There are as many as 800 companies active in the market; up to 96 of those companies work on advanced biotechnology applications. The industry was valued at $3.7 billion and is expected to grow to $6.7 billion by 2010. Approximately 60% of the industry is devoted to human health applications, 10% to agricultural biotechnology and 30% to industrial applications, bioinformatics and genomics.

Market Summary

The biotechnology industry in India is an emerging industry with significant promise for growth. There is a solid base of expertise in the country and strong government support for the industry at both national and state levels. India has the largest number of English-speaking scientists in the world outside the United States, and a highly educated and skilled workforce.

There are approximately 800 companies working in the biotechnology sector in India, with between 30 and 50 companies working on advanced biotechnology applications. Key areas of expertise include research and production of vaccines, diagnostics, enzymes and bio-pesticides.

The industry was valued at $3.7 billion2 in 2001 and employed approximately 20 000 people. Growth is expected to top $6.7 billion by 2010. Sales of biotechnology products for both human and animal healthcare totaled $115 million in 2000 and are expected to grow to almost $200 million by 2005.

Approximately 60% of companies and research centres in the Indian biotechnology market work in health-related industries. Of the balance, 10% work in agriculture and 30% work in industrial applications, bioinformatics and genomics.

The Indian biotechnology industry is focused in the southern state of Karnataka (especially in Bangalore), with other clusters of activity in the states of West Bengal, Maharashtra, Andhra Pradesh, Hyderabad and Kerala. Bangalore is branding itself as a "biocity" and is promoting convergence and growth between its successful information technology industry and biotechnology-the result of which is a growing bioinformatics industry. All the states mentioned above are establishing tax incentive programs for biotechnology companies (domestic and international) and investing in the construction of biotechnology research parks.

There are a large number of government-funded research institutions in India that have established a solid research base in biotechnology. The national government has invested more than $750 million in biotechnology since 1985.

Both the federal and state governments are encouraging more jointly funded private and public research initiatives on commercially viable projects.

Venture capital for biotechnology in India is limited but growing. ICICI Venture Funds Management Co. Ltd. is India's largest venture capital company. It announced the creation of the ICICI Biotechnology Incubator Fund in March 2002 with a target size of $32 million. The company has already invested in local industry leaders, including Biocon and Avesthagen.

The Department of Biotechnology (DBT)3 has also announced venture funding for small and medium-sized biotechnology companies. While the size of the fund has not yet been announced, it will be part of the Technology Development Fund program.

The DBT and the Indian Council of Agricultural Research (ICAR) have stressed the importance of government funded research and development for biotechnology and are requesting $560 million from the federal government for the tenth five-year plan. The DBT is seeking $90 million for 2002-2003, but has so far received $58 million. The budget will be used for ongoing programs in vaccine

research, genomics, transgenic plants and animals, and technology transfer. The DBT is also looking to support state governments in building biotechnology parks and research centres.

Particular strengths in the Indian biotechnology industry include expertise in pharmaceutical manufacturing and fermentation technologies, skills in handling microbes and animal cells, experience with plant and animal breeding, growing expertise in bioinformatics and solid infrastructure at numerous research centres.

Challenges for the industry will be to focus publicly funded research efforts on particular strengths, increase intellectual property protection and improve the regulatory systems for both medical and agricultural products. Critics accuse the government of supporting research in areas that have already been perfected in other parts of the world and of conducting unnecessary regulatory reviews of products already approved in Europe and North America. This "re-inventing the wheel" has slowed progress for product approvals and in niche sectors of research that are particular strengths for India, including bioinformatics, pharmacogenomics and seed research.

The All India Biotechnology Association (AIBA) has called for revisions to the regulatory system to make it less bureaucratic and more transparent. The association claims that the system, as it now stands, does not encourage private-sector investment in the industry.

Medical Biotechnology/Pharmaceuticals

In the biomedical and pharmaceutical field, the Indian biotechnology industry is dominated by generics manufacturers. Because of limited intellectual property protection in India-patents are issued on the process but not the product-companies are able to work backward from the finished product to develop new processes and launch a similar product. As a result, many biotechnology companies in India have limited experience with drug discovery and development. However, this is slowly changing as companies begin to look to the future and see how a strong intellectual property regime can have a positive effect on the way they do business.

Given Indian strengths in producing generic medications, companies are looking to increase their capabilities in biotechnology processing and manufacturing in anticipation of a new series of biotechnology-based generic drugs. As drug patents on some of the earliest biotechnology drugs expire in the coming years, there will be a new market for biotechnology-based generics.

The pharmaceutical market (both biotechnology-based pharmaceuticals and traditional pharmaceuticals) was estimated at $8 billion and is expected to grow to $37 billion by 2010. There are approximately 250 large, research-based pharmaceutical companies in India, with as many as 3000 companies active in pharmaceutical (particularly generics) manufacturing. The industry employs approximately 460 000 people and is the world's fifth-largest producer of medications by volume.

The Indian biotechnology industry is ranked third in the world in terms of stem cell research, primarily because both the government and private industry have invested heavily in research institutes studying human disease and searching for treatments. As well, the issues of embryonic stem cell research have not generated the same moral debate in India as they have in Canada, the United States, Britain and other countries. In fact, a bioethics committee has determined that human embryonic stem cells may be harvested, with full and informed consent from the donor, up to the 14th day of gestation.

Two research laboratories-the National Centre for Biological Sciences (NCBS) in Bangalore and Reliance Life Sciences-have been identified by the United States Institutes of Health Research as having cutting-edge embryonic stem cell research. Ten stem cell lines are eligible for funding under new guidelines in the United States restricting the use and application of embryonic stem cells. A total of 64 stem cell lines around the world have been identified.

Despite the advanced work in stem cell research, India has not yet formulated a policy on human cloning. The government has decided to study the issue more closely and does not feel there is a need to rush because the capacity to clone a human does not currently exist in India.

The vaccine market in India, valued at approximately $150 million, is a key component of the biomedical sector. The first biotechnology-based vaccine released in the Indian market was an rDNA hepatitis B vaccine produced by Shantha Biotechnics Pvt Ltd. Other biotechnology medications on the market include recombinant insulin, human growth hormone, alpha interferon, blood clotting factor VIII and medical proteins such as relaxin, rennin and interleukins.

The diagnostics market is valued at an estimated $75 million and is dominated by demand for monoclonal and polyclonal antibodies, tissue typing, clinical assays and contract research.

The Indian biotechnology industry is becoming an international hub for contract research and manufacturing. With a high level of expertise, low research and development costs and attractive incentives, many large pharmaceutical and biotechnology companies are establishing agreements with India companies and research institutions.

Small Indian biotechnology companies are currently focused on contract research as a way to build capacity prior to establishing drug discovery divisions.

Agricultural Biotechnology

More and more companies are interested in the agricultural biotechnology sector in India because there are perceived to be fewer government restrictions and financial investments are not as heavy. However, lack of a strong regulatory infrastructure, limited subsidies available and ignorance on the part of many farmers about the benefits of genetically modified (GM) seeds has delayed growth of the industry.

India is the world's largest producer of fruits and vegetables, but only accounts for 1% of total world exports. Indian agriculture is often inefficient and plagued by pests. The potential of agricultural biotechnology to feed the people of India and increase export markets for Indian products is significant.

India is the world's third-largest cotton producer in terms of area, but with yields of approximately 300 kg per hectare, the country produces far below the global average of 650 kg per hectare. To date, only a small number of companies and research institutions have been allowed to conduct field trials on GM crops. Trials have been (and are currently) conducted on rice, maize, cotton, tomatoes and cauliflower. In 2001, approximately 4000 hectares of GM cotton were found to be growing illegally and were ordered destroyed. U.S.-based multinational Monsanto has partnered with Maharashtra Hybrid Seed Company Ltd (Mahyco) to research and produce a genetically engineered cotton for the Indian market.

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 (a fourth is still in field trials and likely to be approved before the end of 2002). Five years of field trials were conducted by Mahyco prior to receiving approval.

Conditions for the three-year approval period include the stipulation that fields of Bt cotton must have a surrounding planting, or refuge, of the same non-Bt variety that is at least five rows deep or 20% of the total areas sown in GM cotton. As well, the seeds may only be sold in specific areas of the country and must adhere to certain labeling and packaging instructions. Experts predict as much as 150 000 hectares of the new GM varieties will be planted in the first year. The move to approve GM cotton has seen some resistance from the Communist Party of India as well as environmental groups and other non-governmental organizations. In general, however, the Indian people are receptive to the new crop, particularly because it is not intended for consumption and

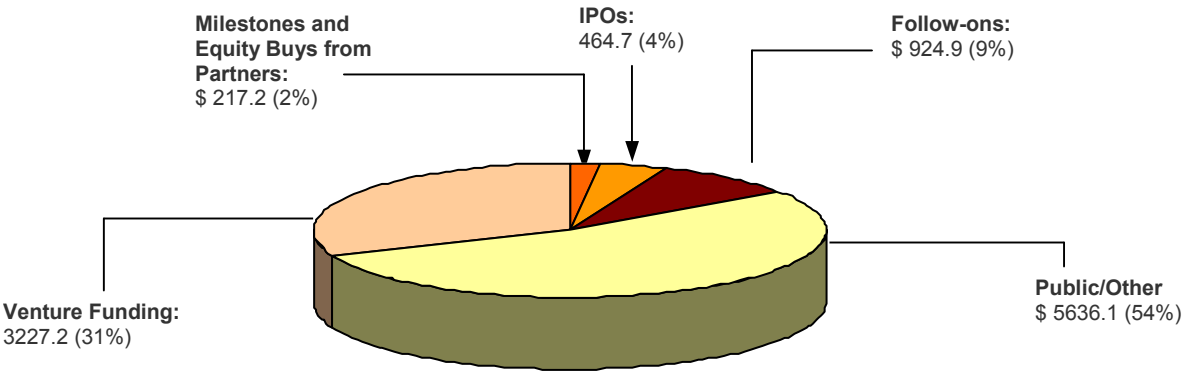
the potential benefits to the cotton and related textile industries are enormous. The biotechnology industry also holds potential for the Indian textile industry with the development of novel fibers, improved processing methods and more effective and environmentally friendly dyes. Now that the first GM product has been approved for commercial release, India is expected to approve other crops, including mustard, soybeans, corn and potatoes, in the near future.

Focus areas for future growth in agricultural biotechnology in India will be biofertilizers and biopesticides.

There is also market demand in India for biotechnology-based animal health products including vaccines, diagnostics and technologically advanced animal feed.

Trends and Opportunities

The Biotechnology sector presents a tremendous business opportunity and a potential for fresh investment of Rs. 7 to 8 billion in India, which, if realized could result in a turnover of Rs. 9 to 10 billion over the next 5 to 7 years5. This, in turn, could contribute towards import substitution, augmentation of local production and introduction of new products in the global markets.



As in other technology–oriented segments, there exist both short term and long-term opportunities for companies within the biotechnology sector. Indian biotech companies can counter the intrinsically long time-frame of a typical research and development ("R&D") exercise in a product development cycle in this field by adopting a two – pronged approach, wherein the short term goals could include exploiting 'service related' opportunities in contract research and exploitation of developed products commercially. The long-term goals can include a greater R&D focus, with a view to develop newer products.

The opportunities in the biotechnology sector of India can be sub-divided into (i) domestic as well as (ii) international opportunities.

Domestic Opportunities

Pharma potential

India's enormous population with a large and diverse gene pool makes it conducive for the Pharmaceutical industry to exploit their business. There is a growing demand for 'new generation' and 'combination' vaccines in India and the expected growth by 2010 for domestic vaccines is thought to be 800 million doses. The recombinant therapeutic market is a major industry and has yet to been exploited in India. Therapeutic products such as insulin, hepatitis B surface antigen based vaccine, human growth hormones etc. are being imported at present. The setting-up of

[5] CII, *Report on "Investment Opportunities in India – Key Sectors".*

manufacturing facilities or establish cross-border licensing to develop these products will generate substantial revenues in the Indian market.

Agriculture potential

India is pre-dominantly an agricultural economy with more than a billion mouths to feed. The use of biotechnology in agriculture, in the form of improved drought and pest resistance properties, besides productivity and yields producing better quality food using fewer resources has an immense potential in India. The industry for hybrid seeds alone is thought to be a $1.5 billion industry in the next 5 years.

Genetically Modified Rice

In recent developments, India has achieved the cloning and sequencing of at least 6 genes, regeneration protocols for citrus, mangrove, coffee, new types of biofertilizers and biopesticide formulations. Research to develop new genetically improved (transgenic) plants for brassicas; mung bean and potato are already well advanced and headed for commercial viability. In fact, 2002 marked the release of the first transgenic crop, BT Cotton (bacillus thuringiensis cotton) for commercial cultivation. The Government of India's Genetic Engineering Approval Committee (GEAC) approved the production of three genetically modified BT Cotton i.e. BT Mech 12, BT Mech 162 and BT Mech 184 on March 27, 2002.6 Industries have also showed a keen interest and extended their support to field trials and pilot level productions.7 The successful tissue culture pilot plants in the country, one at TERI in New Delhi and the other at National Chemical Laboratories, Pune are already functioning as Micro propagation Technology Parks. However, the GEAC has not approved BT Mech 1958, a specific suitable variety of BT cotton, causing inconvenience to farmers in Punjab and Haryana. Farmers are of the opinion that the pace of regulatory approvals needs to be quickened. Practically speaking, a very small part of the cotton growing area in the country is likely to be sown with BT cotton as the seeds are in limited supply.9 Of the 400 locations for BT Cotton 'trials', Maharashtra has 180 trial locations, Karnataka has 89, Gujarat and Madhya Pradesh have 23 each, Andhra Pradesh 49 and Tamil Nadu 31, apart from 11 Indian Council of Agricultural Research ("ICAR") locations.10

"India is among the forerunners in biotechnology", says a recent report on biotechnology by Ernst and Young. It also envisages that the collaborations of Indian biotech companies with foreign and domestic firms would play a significant role in the future growth of Indian Biotech industry.11 The Government has taken a very pro-active approach in promoting the biotechnology industry and biotechnology parks are set up in Maharashtra, Gujarat, Uttar Pradesh, Madhya Pradesh, Andhra Pradesh, Karnataka, Tamil Nadu, Himachal Pradesh and Orissa in 2002.12 The Government of India announced a 5 to 10 year tax holiday for units in Software Technology Parks, making such

[6] Hari Ramachandran, *India: Government Approves Use of BT Cotton,* http://www.corpwatch.org/news/PND.jsp?articleid=2172 (accessed on August 26, 2002).
[7] Manju Sharma, *India: Biotechnology Research and Development*.
[8] Financial Express, *BT-less farming*, at http://www.financialexpress.com/fe_full_story.php?content_id=7361 (accessed on August 30, 2002).
[9] Soybean and Oilseed Industry News, *Inadequate seeds hamper Bt cotton cultivation*, at http://www.soyatech.com (accessed on June 24, 2002).
[10] Monsanto India, *News*, at http://www.monsantoindia.com/news/news.html (accessed on July 5, 2002).
[11] *Supra* n.27.
[12] Ashok B Sharma, C*irca 2002 likely to set the trend for biotech development*, The Financial Express, January 3, 2002.

unites eligible for the tax holiday up to 2010.13 This announcement will encourage R&D in knowledge-based industries, particularly in the pharmaceutical and biotechnology industries, as the 10-year tax holiday is proposed to be extended to R&D companies.14

Taking a look at recent trends of the biotechnology industry, experts predict that the Indian biotechnology industry, which is currently worth around Rs. 7.3 billion is expected to grow to about Rs. 10 billion by 2002-2003, and further, double by 2007.15 It is evident that the biotechnology industry is poised to play a significant role in shaping the future of the global economy. India has the potential of developing into a forerunner in the international biotechnology sector because of its rich biological diversity and large scientific talent pool, skilled manpower and a well-established global pharmaceutical industry. The future of the Indian biotechnology industry largely depends upon the strengthening of government initiatives, establishing linkages between the industry, educational and government institutions, framing effective policies and regulations and increasing funding for innovative research and development.

Global Opportunities

Contract Research

Currently the trend to outsource R&D in biotechnology is increasing. This provides an immense opportunity for Indian companies to pitch for contract research for overseas corporations. The global expenditure on outsourced R & D is around US$7 billion and this is expected to increase at 30% per annum for the next five years.16 A 2% share of the global outsourced business will constitute a $0.5 billion opportunity for India.17 Indian companies with excellent technical manpower are, thus, well suited to take up contract research on the same lines as the IT sub-contracting work. Some companies who have already begun and set-up contract-based research activities in drug discovery include: Aurigene, Avestha Gengrain, Bangalore Genei, Chembiotech International Limited, Gangagen, Genenquest, Genotypic technology, GVK bio, Reliance Life Sciences and Syngene.

Clinical Trials

India has a large population in rural areas that have not been subjected to any drugs. This is useful for drug companies that require such people to conduct their clinical trials. The large and diverse gene pool coupled with the substantially low cost of conducting clinical trials in India is a major incentive for large pharmaceutical corporations. For example, a study by Rabo India recently showed that the cost of trials in India is 50 per cent lower than the $20 million required in the US for the phase I study and 60 per cent lower than the $50 million required for the phase II study.

Bio Informatics

Another factor, which will play an instrumental role in the development of the biotech sector in India, is the strong software knowledge base, which is already present here. Together, the dynamic combination of software competence and low-cost R&D with a strong knowledge base has the potential to fuel tremendous growth of India's Biotechnology sector. This unique combination results in Bioinformatics, which is the application of computer technology to the management of biological information, wherein computers are used to gather, store, analyze and integrate biological and genetic information, which can then be applied to gene-based drug discovery and development. Major corporations such as Tata Consultancy Services, Satyam Computers and small startups like

[13] Tony Allison, *Software, the Arrowhead of India's IT weaponry,* Asia Times, at http://www.atimes.com/reports/BL07Ai01.html (accessed on July 5, 2002).
[14] "*Sinha gift-wraps Budget with tax largesse*", Economic Times, May 4, 2001.
[15] S. Mistry & K. Rajwadkar, *Indian Biotech Sector to Touch Rs.20 bn by '07*, Financial Express, February 24, 2002.
[16] Shilpa Puri, *And now, a revolution in biotechnology*, at http://www.projectsmonitor.com/detailnews.asp?newsid=2061 (accessed on August 30, 2002).
[17] *http://www.indiafdi.com/pdf/Report_Biotech.pdf*

Strand Genomics, Clinigene etc. have already taken the initiatives to set-up centers to exploit the potential of this industry.

With organizations like the Pharmaceuticals Research Manufacturers Association ("PhRMA") actively pursuing product patent protection in India and expected advent of this regime with effect from 2005, most multinationals are now gearing up for a post-2005 regime. The second Patent Amendment Act was passed in 2002 and it aligns Indian patent protection laws with the recommendations in the TRIPS.

There are several factors that appear attractive to global pharmaceutical companies looking towards India, some of which are set forth below:

- Healthcare spending is and will be on the rise with the middle-class investing more and more on branded medicines
- India is seen as a huge market not only for life saving drugs but also for lifestyle drugs
- Global pharma companies also see the tremendous potential for conducting research and development activities from India as India is known to have a vast talent pool of qualified PhDs. Outsourcing contract research to India is becoming quite common amongst global players
- India is also fast replacing Europe as the leader for sourcing active pharmaceutical ingredients (API) for the generic market where cost and speed to the market are important
- India is also seen to have a huge potential for conducting clinical trials and bioequivalence studies as costs are low for the same. Conducting a clinical trial in the U.S. or Europe would cost over USD 5000 a patient whereas in India it would cost only USD 3000 per person[18]. Global corporations like Glaxo and Pfizer are beginning to look at the possibilities of setting up their own clinical trial centers in India.
- Indian biotechnology companies have expertise in bioinformatics, manufacturing and genetics, as well as more traditional sectors of the industry including fermentation technology, industrial enzymes and vaccines.
- There are opportunities to partner with Indian companies at the drug discovery stage of research, and to use Indian companies for contract research and manufacturing.
- There are also opportunities to form joint-venture partnerships with Indian companies, or establish technology transfer agreements or strategic research partnerships with key research institutions.
- The Indian market represents opportunities to produce and sell vaccines and therapeutics that respond to the needs of the millions of poor in India.

III. BIOTECHNOLOGY IN INDIA

Entry strategy

1. Investment climate in India

By and large foreign direct investments are now permitted in almost all the sectors in India without obtaining prior regulatory approvals (i.e. under the "automatic route") barring some exceptional cases like defense, housing and real estate, print media, etc. (commonly referred to as the "negative list"). Under the automatic route, the details of the investments are required to be filed with the Reserve Bank of India ("RBI") within the prescribed time. However, if the

[18] Supra n.1. Page 27.

investment is not in accordance with the prescribed guidelines or if the activity falls under the negative list, prior approval has to be obtained from the Foreign Investment Promotion Board ("FIPB"). In the case of pharmaceutical companies, foreign direct investment is permitted to the extent of 100% under the automatic route provided that the activity does not attract compulsory licensing or involves the use of recombinant DNA technology and specific cell/tissue targeted formations. Any proposal for the manufacture of licensable drugs, pharmaceuticals and bulk drugs produced by recombinant DNA technology and specific cell/tissue targeted formulations will require the prior approval of the FIPB.

Further, while transfer of shares of an Indian company between two non-residents does not generally require any prior regulatory approvals, the transfer of existing shares from a resident to a non-resident and vice versa has been brought under automatic route. The Indian Government has, with a view to further liberalize foreign direct investment, notified vide Press Note No.1 dated January 12, 2005 that any new proposal for foreign investment or technical collaboration by a foreign investor, who has or had any previous joint venture or technology transfer / trademark agreement in the same or allied field in India, will be allowed under the automatic route. This route is however subject to the sectoral policies.

The said Press Note No. 1 has narrowed down the scope of the earlier Press Note No.18 (of 1998), which was applicable to the 'same' and 'allied' field. The Press Note No. 1 now requires prior Government approval only in cases where the foreign investor has an existing joint venture or technology transfer or trademark agreement in the 'same' field. The onus to provide requisite justification as also proof that the new proposal would or would not jeopardize the existing joint venture or other stakeholders would lie equally on the foreign investor or technology supplier and the Indian partner.

Even if the foreign investment is falling in the 'same' field, the Government has carved out following exceptions, for which no prior Government approval is required:

- Investments are made by Venture Capital Funds registered with the Securities Exchange Board of India.
- The existing joint-venture investment by either parties is less than 3%.
- The existing joint venture or collaboration is defunct or sick.

Hopefully, the changes envisaged through the implementation of Press Note 1 would create the balance in achieving a liberalized environment in India and at the same time protecting to the joint-venture partners to safeguard their interests.

2. Form of the Indian entity

A foreign company can establish its presence in India either as a liaison office ("LO"), branch office, or a limited liability company. Some of the important regulatory and tax requirements under each of these options are discussed hereunder:

Liaison Office

A foreign company can establish a LO in India only with the prior approval of the RBI. Such approvals are granted on a case-by-case basis provided the activities of the LO are restricted to acting as a communication channel between the foreign company and entities in India. Further, the LO is not permitted to generate any income on its own account and the cost incurred by the LO for its operations are required to be reimbursed by its parent. The liaison offices are currently under attack from tax departments. They are often being treated as 'Permanent Establishment' and being taxed on their deemed profits.

Branch Office

A foreign company can set up a branch in India only with the prior approval of RBI. Such approvals are granted on a case-by-case basis and provided the activities of the branch are restricted to the permitted activities which interalia include export/Import of goods; rendering professional or consultancy services; rendering services in Information Technology and development of software in India; etc.

In the event that a foreign company is looking at manufacturing pharmaceuticals in India or having an operation of a reasonable size, a branch or an LO may not suit its purpose. In such a case it would be advisable for the foreign company to set up a limited liability company in India which could be in the form of a joint venture with an Indian partner or a wholly owned subsidiary of the foreign parent.

Subsidiary

A subsidiary of a foreign company is treated at par, in almost all respects, with a company having resident Indian shareholders. Establishing a WOS in India is generally preferable vis-à-vis setting up of a branch in India as generally there is more flexibility in relation to the activities that can be carried on in India by the WOS and a branch of a foreign company may not be eligible for certain tax incentives currently available in India.

The WOS could be incorporated under the Indian Companies Act, 1956 ("Companies Act") either as a private limited company (which has to have a minimum of two shareholders but not more than fifty shareholders) or a public limited company (which has to have a minimum of seven shareholders). However, in the case of a private company there are restrictions on transfer of its shares and number of members and a total prohibition on invitation to the public for subscription to its shares and acceptance of deposits from outsiders.

Furthermore the Indian company would have to get registered with other regulatory authorities e.g. under the Shops and Establishments Act which governs the terms of employment, the Income Tax Act, the Provident Funds Act, the Director General of Foreign Trade, the Factories Act etc.

Corporate governance issues in India

Most global pharmaceutical companies would adhere to their corporate governance policies, which are usually formulated on a worldwide basis. Some global corporations have faced difficulties in India due to the vast difference in business practices in India and the country in which these companies have a principal place of business. For instance, unlike the United States, which makes bribery of foreign government officials a criminal offence, India does not have the equivalent of the Foreign Corrupt Practices Act ("FCPA"). However, it is an offence to give bribe to government official. There are no exceptions for "small-time" expenses under Indian law as there are under the FCPA.

This scenario is changing slowly with India completing a decade of liberalization entailing the removal of the license raj, reduction of tax rates and relaxation of exchange controls, all of which have significantly reduced the potential for bribery and corruption and have brought about greater transparency in the governmental and regulatory systems.

Overview of the Indian Tax Laws

The scope of taxability of any entity in India depends on its residential status. A resident taxpayer is taxable in India in respect of its global income. A company incorporated in India or wholly controlled and managed from India is regarded as a resident of India and thus would be chargeable to tax in India on its global income. A foreign company is taxed in respect of its Indian source income. Thus income of a branch and foreign company will be taxed in India. Recently, Liaison

offices and foreign companies (though generally not taxable) have been targeted by the Indian tax department.

Corporate tax rate

Domestic companies are currently taxed at the rate of 35%. The rates mentioned in this paper are exclusive of currently applicable surcharge at the rate of 2.5%, unless specified otherwise. The Finance Bill, 2004 ("Finance Bill") has also proposed Education cess of 2 % on the total tax. Foreign companies and a branch of a foreign company [which would be regarded as a Permanent Establishment ("PE") of its parent in India] would be chargeable to tax at the rate of 40%.

Deduction for expenditure on research and development

In-house research and development:

Companies engaged in the business of biotechnology or in the business of manufacture or production of any drugs, pharmaceuticals, chemicals, etc. and who have incurred any expenditure on scientific research (not being expenditure in the nature of cost of any land or building) on in-house research and development facility as approved by the Department of Scientific and Industrial Research, are allowed a deduction of 1 ½ times of such expenditure.

Expenditure on scientific research includes expenditure incurred on clinical drug trial, obtaining approval from any regulatory authority under any Central, State or Provincial Act and filing an application for a patent under the Patents Act, 1970.

Contributions made to other institutions:

The Indian Income Tax Act ("ITA") confers a deduction of 1¼ times of sums paid to any scientific research association (having as its object the undertaking of scientific research) or to any university, college or other institution to be used for scientific research.

Capital expenditure:

The whole of any expenditure on scientific research (other than expenditure on acquisition of any land) being capital in nature, incurred after March 31, 1997 is allowed as a deduction. Further, capital expenditure on scientific research incurred three years immediately prior to the commencement of business is allowed as a deduction in the year in which the business is commenced.

Dividends

As per The Finance Bill dividends distributed on or after April 1, 2003 are exempt from income tax in the hands of all shareholders, irrespective of their residential status and the company distributing the dividends will pay a dividend distribution tax of 12.5 % (excluding the proposed surcharge of 2.5 %).

Interest

Under the domestic tax laws of India, interest received by a non-resident on foreign currency loans is generally taxable at the rate of 20%, which can be reduced to 15% under some of the tax treaties signed by India with other countries. As in the case of dividends, tax is required to be withheld at source by the resident payer. Further, interest is a tax-deductible expense for the Indian resident (i.e. wholly-owned subsidiary), only if the applicable tax has been withheld before making the payments to the non-resident.

Royalties / Fees for technical services

Payment towards royalty and Fees for Technical Services ("FTS") currently attract a withholding tax of 20 per cent, on a gross basis. Under the various tax treaties that India has entered into with other countries this rate generally gets reduced to 10 per cent.

Further, most of the Indian tax treaties contain a provision that, if such payments are effectively connected to a PE in India then such payments would be taxed as business profits in accordance with the provisions of the domestic law. However, under section 44D of the ITA, which contained a non-obstante clause, such payments would be taxed on gross basis. This led to great hardship to the taxpayers.

The Finance Bill has proposed that if the payments towards royalty and FTS are effectively connected to a PE in India then such payments would be taxed as business profits on 'net income' basis.

Capital gains

Currently, capital gains are classified into short-term capital gains and long-term capital gains under the ITA. Shares of a company, securities listed on a recognized Indian stock exchange if held for more than 12 months are treated as long-term capital assets. In other cases, a long-term capital asset is one that is held for a period of more than 36 months. Long term gains on sale of listed securities on the floor of stock exchange are exempt or taxed currently subject to tax at a concessional rate of 20 per cent in the hands of a company while short-term capital gains are taxed at normal rates i.e. 40% in the case of a foreign company.

The Finance Bill has proposed to exempt long-term capital gains on sale of equity shares of a company listed on a recognized stock exchange in India and purchased between March 1, 2003 and March 1, 2004.

Minimum Alternate Tax

Where the tax payable by a company is less than 7.5 per cent of its book profits, the tax will be deemed to be 7.5 per cent of such book profits as Minimum Alternate Tax ("MAT"). This is to ensure that every company pays a tax of at least 7.5 per cent of its book profits.

Transfer pricing

India has enacted transfer pricing regulations and thus any international transactions between two associated enterprises would have to be on an arm's length basis.

Structuring the investment into India

Investing in the Indian company through an intermediate holding company in a favorable jurisdiction offers various tax advantages. It helps in pooling offshore investments and also helps in globalization or restructuring at a later stage. India has favorable treaties with quite a few countries including Mauritius, Cyprus and Netherlands. It may be worthwhile considering a higher debt: equity ratio as there are no thin capitalization rules in India.

Indirect taxes

Customs duty

It is levied on the import of goods/equipment into India. Import duties are prescribed by the Customs Tariff Act. Specified life saving products can be imported at zero duty. The Finance Bill has proposed removal of restriction of minimum export obligation of Rs 200 million for availing exemption from customs duty for specified equipments used in R&D by biotech and pharmaceutical companies. The Finance Bill has also extended the concessional duty of 5% to all importers of Pharmaceutical Reference Standards.

Sales tax

Sales tax is levied on the sale of movable goods by respective States. The Central Sales Tax Act regulates inter-State sales while intra-State sales are regulated by the local sales tax of the

respective State. Sale in the course of import and export are exempt from the levy of sales tax under the Central Sales Tax Act. The local sales tax is calculated as a percentage of the sale price and such percentage varies from 4-13% depending on the type of product being sold and the State which has jurisdiction to tax such a sale.

Value Added Tax

India proposes to shift to the Value Added Tax ("VAT") system from April 2005. The imposition of 12.5% VAT in lieu of sales tax is estimated to result in a 3-5% increase in the price of medicines19.

Service tax

It is currently levied at the rate of 5% on specified services like management consulting services, consultancy or technical services by a consulting engineer, etc. The Finance Bill has proposed to hike the service tax rate to 8% and has added 7 new services within the tax net including "business auxiliary services" which could cover the back office processing services. The exemption from service tax in relation to payments received in convertible foreign exchange has also been withdrawn.

IV. ADVANTAGE INDIA

Potential & Opportunities

- India itself a huge market for biotech products. Estimated consumption to be USD 4.27 B by 2010
- Investment opportunity - India among the top 4 attractive countries in Asia Pacific region (Frost & Sullivan)
- Alliances for R & D – Big Pharma cos. with smaller biotech co.
- Marketing Tie-Ups
- Drug Discovery
- Contract R & D (Outsourcing)
- Bioinformatics – India's strength strong IT sector
- Clinical Trials
- Good market/R&D prospects for bio-pesticides and bio-fertilizers, bio-remediation products/processes, bio-fuels, bio-indicators, and bio-sensors.
- Export of Pharma / Biotech Machinery to India
- Facilities Planning Consultancy

The Pharmaceutical industry in India provides excellent facilities. It has quality producers and regulatory authorities in the United Slates of America and the United Kingdom approve many units.

Factors Aiding Growth

It has an educated work force and English is commonly used. It has a solid legal framework and strong financial markets. Professional services are easily available. It has a pool of personnel with high managerial and technical competence, as also skilled workforce. There is already an established international industry and business community. It has a good network of world-class

[19] ICICI Securities, January- March 2003, Q4 FY 2003, Equity Research Group. P. 120.

educational institutions and established strength in Information Technology. The country's commitment to free market economy and globalization has given it an added advantage. Above all, it has a 70 million middle class market, which is continuously growing. The Pharmaceutical industry in India provides excellent facilities. It has quality producers and many units are approved by regulatory authorities in the United Slates of America and the United Kingdom.. It provides a wide variety of bulk drugs and exports sophisticated drugs.

The Advantages

The availability of a large drug-naïve patient population and well-trained medical professionals, coupled with sophisticated technological infrastructure have made India an attractive destination for conducting global clinical trials

- Vast pool of talented & skilled manpower.
- Several leading R & D institutions
- Lower operational costs and technologies
- Complementary competencies in BT and IT - India well positioned to exploit the bio-informatics wave
- Large and diverse gene pool - plant and human
- Presence of big Pharmaceutical companies
- Well established industrial base
- English as the accepted business language

Changes for the Better

- Establishment of unified, single window Regulatory System
- Rationalization of procedures, transparency
- Expedited Product Review
- Availability of loan guarantees and low interest loans
- Setting up of dedicated VCs by govt. & industry
- Tax incentives to investors through tax holidays & Capital gains concessions including pass through status for VCs
- Lower import duties
- Expedited enforcement of new laws
- Effective IPR enforcement & change of perception about IPR protection in India
- Protection of India's traditional knowledge
- Data Exclusivity in terms of Article 39.3 of TRI

V. OVERVIEW OF LEGAL ISSUES

The race between science and the law is centuries old. It has greatly intensified with the rapid progress in science and technology. In the early days, science and law came into conflict because scientific theories and the prevailing concepts of law were immeasurably divergent. Today, the issue is not whether scientific postulates that are contrary to rule of law should prevail, but the extent to which law and government, should influence scientific progress. The law is no longer stagnant and is incessantly attempting to stay abreast with the rapid pace of progress and development. Governments will continue

to strive towards establishing a balance between the extremes of scientific innovation and the established rules of law. The powerful benefits that arise from biotechnology carry with it a tremendous responsibility. The scientific advances have brought along with them a multitude of controversial legal issues that require a multidisciplinary approach to arrive at a possible solution.

The legal issues in the biotech industry relate to discoveries in genetics, such as the patentability of genetic information, the conduct of clinical trials involving gene therapy, the approval process for new drugs, proteins and other biological components and cloning. Other issues include tissue engineering, foetal tissue research, confidentiality of patient health information, bio-engineered food and conflict of interest disclosure requirements for researchers.

The law will play a significant role in steering our ever-changing society to its most rational direction to ensure the development of medical sciences, the sustainability of environmental resources, and continuous economic growth through technological advances. The complex and controversial nature of biotechnology attracts and challenges a myriad of established laws and legal principles.

The establishment of the World Trade Organization ("WTO") has led to a major metamorphosis for global trade in the new millennium. The adoption of the TRIPS Agreement in 1994, to which India is a signatory, has accelerated changes in intellectual property laws, with profound implications in the area of pharmaceutical patents.

India is entering into global markets, where she has to compete with international quality standards and prices. Although R&D is an important factor to compete effectively, this is greatly dependent on IP protection. With the advent of product patent regime, patent enforcement will have to be stepped up to global standards to reap the benefits of the tremendous potential of Indian indigenous industry. Further, in order to ensure a competitive edge in the international arena, Indian pharmaceutical companies will have to acquire patents in potential markets around the world.

Provided below are some of the key laws and regulations that have a direct impact on the biotechnology industry in India.

IP Protection for Biotechnology

IP is the most valuable asset of any biotech company. Company's most valuable asset is frequently its technical edge or unique process. IP rights enable the company to recover its R & D cost and stimulate further risk taking investments. The biotech industry is capital intensive and most biotech companies depend on external sources of funding, which are greatly influenced by factors such as the nature and value of the IP owned by a company and the potential of IP that is under development.

IP is likely to emerge as the most challenging aspect for the biotech industry. Areas such as genomics are still emerging in the country. The emergence of new technologies (e.g. Nanotechnology, convergence between biotechnology and information technology etc) will also have implications on IP protection, which may go beyond the issues currently being debated in the biotech sector. The potential of the biotechnology sector is boundless, and the extent of IP protection accorded will play a critical role in shaping India's role in the biotechnology revolution.

Protection through patents, copyright, trade secrets, plant breeder's rights are vital for biotech industry.

Patents

In return of the exclusive right granted through patent protection the inventor discloses the invention to the public, and that disclosure enables other scientists and interested parties to use the invention in their own research. In due course, that research could lead to further innovation, with the intent to benefit society. Patent documents also act as source of valuable scientific and technical data and information.

In India's continued efforts to comply with it's commitment under TRIPS, the Patents Act has been amended thrice since 1995 by the Patents (Amendment) Act, 1999 ("1st Amendment"), the Patents (Amendment) Act, 2002 ("2nd Amendment") and Patents (Amendment) Act, 2005 ("Third Amendment"), respectively. The legislation is supported by the Patents Rule, 2003, ("Rules"). The Third Amendment has introduced a much awaited product patent regime in India, which is discussed in detail later.

Invention

The term Invention is defined under Section 2(1) (j) of the Patents Act as "a new product or process involving an inventive step[20] and capable of industrial application[21]."

In India, the patent rights in respect of any invention are created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Rules. India follows declarative system in respect of patent rights. India grants the patent right on the first to apply basis. The application can be made by either (i) the inventor or (ii) the assignee[22] or legal representatives[23] of the inventor.

Convention Application

India has published a list of convention countries under Section 133 of the Patents Act and is also a member of the Paris Convention. The convention application has to be filed within one year from the date of priority and has to specify the date on which and the convention country in which the application for protection (first application) was made. Priority document has to be filed with the application. Since India is a member of the Patent Co-operation Treaty, a National Phase Application could be also filed in India.

By the 2nd Amendment Act the following have been added to the innovations, which are not inventions within the meaning of the Act:

- plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals ;
- an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.".

Recent Amendments

The Patents Act has been amended to include the following provisions of TRIPS Agreement:

- The term of the patent has been extended to 20 years from 14 years;
- As required by TRIPS, by virtue of the 1st Amendment (which had retrospective effect from January 1,1995) pending the introduction of the product patent regime, the Patents Act had a provisions for:

[20] *Section 2(1) (ja) of the Patents Act: "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

[21] *Section 2(1)(ac) of the Patents Act: "capable of industrial application in relation to an invetion means that the invention is capable of being made or used in an industry."*

[22] *Section 2(1) (ab) of the Patents Act: "Assignee includes an assignee of the assignee and the legal representative of the deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person".*

[23] *Section 2(1) (k) of the Patents Act: "Legal representative means a person who in law represents the estate of a deceased person."*

- Acceptance of product patent applications. Such applications were to be kept in what is known as the "Black Box" until January 1, 2005, when such applications would be examined for the granting of a patent.
- Pending such grant, the applicant could apply for the grant of exclusive marketing rights24 ("**EMRs**") with respect to the invention disclosed in the product patent applications.

- In infringement suits over 'process' patents the 'burden of proof' is reversed.
- The Third Amendment has deleted Section 5 of the Act, which barred patent being granted in respect of substances:
- intended for use or capable of being used as food, medicine, or drugs; or,
- prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds).

Thus, product patents will now be allowed in India. The black box applications for product patents will be examined beginning January 1, 2005. The provisions for Exclusive marketing rights (EMRs) have been removed effective January 1,2005. The applications for patent in respect of which EMRs were granted will be examined for the grant of patent immediately on the commencement of the Third Amendment. All suits relating to infringement of the EMRs granted before January 1, 2005 will be dealt with in the same manner as if they were suits concerning infringement of patents under the Patents Act.

Section 3 of the Act, carves out certain exceptions from the patentable inventions. Under Section 3 (j) Plants and animals in whole or any part thereof (other than micro-organisms) including seeds, varieties and species and essentially biological processes for the production of plants or animals – cannot be patented. This is in line with Article 27.3 of TRIPS. Thus microorganisms, which satisfy the patentability criteria, may be patented in India.

Section 3(d) as amended by the Third Amendment clarifies that mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is not an invention and therefore not patentable. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy. Therefore, Swiss Claims will not be allowed in India.

Exclusive Marketing Rights granted

On September 5, 2003, Controller General of Patents, Designs and Trade Marks granted the first ever EMR in India to United Phosphorous for sale of its fungicide. On November 11, 2003 Novartis India, an Indian subsidiary of Swiss drug manufacturer became the second company and the first pharmaceutical company to be granted an EMR. Novartis was granted an EMR on 'Gleevec', its breakthrough anti-cancer drug.

Some of the other amendments are discussed herein below:

Infringement

If a patented invention is made, constructed, used sold or imported 'solely' for uses reasonably related to the development and submission of information required under any law (Indian or

[24] *EMRs entitle the holder to possess the exclusive rights by himself, with his agents, or with his licensees to sell or distribute in India the article or the substance on and from the date of approval granted by the Controller for a period of five years, or until the date of the patent application's grant or rejection, whichever is earlier.*

foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the Bolar provision will gain importance in view of introduction of the product patent regime in India. Bolar provision allows manufacturers to begin the research and development process in time to ensure that affordable equivalent generic medicines can be brought to market immediately upon the expiry of the product patent.

Parallel Imports

Import of patented products in India from a person authorized by the patentee to sell or distribute the product does not amount to an infringement.

Protection of generic manufacturers

Product patents granted in pursuance of black box applications have been treated differently to protect the interests of generic manufacturers. Enterprises which have made significant investment and were producing and marketing the concerned product prior to January 1,2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, are protected and the patentee cannot institute infringement suits against them but would be entitled to receive reasonable royalty from them. It is not clarified as to how the reasonableness of royalty would be determined. This provision would prejudice the rights of a patentee in respect of exploitation of its patent.

Enforcement

The global community has been viewing India as a 'poor patent enforcement' territory. Two provisions have been introduced that are likely to give a fillip to the patent enforcement mechanism. First being insertion of Section 104A, which is a "reversal of burden of proof" provision, in compliance with Article 34 of TRIPS. This is an exception to the normal rule, that is, the person who makes any claim or allegation has to prove it. In 'process patent' infringement suits, the defendant will have to prove that he has used a process different than the 'patented process' to arrive at an identical product produced by a 'patented process'. Second, an amendment to Section 108 of the Act will enable the court to order seizure, forfeiture or destruction of infringing goods and also materials and implements, used for creation of infringing goods.

Compulsory License

One of the most controversial amendments has been on compulsory licenses ("CL"). Now, CL can be also granted if the invention has not been worked in India or if the invention has not been worked in India on a commercial scale due to imports into India. New grounds for grant of CL have been inserted, that is, circumstances of national emergency; a circumstance of extreme urgency; a case of public non-commercial use, public health crises, relating to AIDS/ HIV, TB, malaria or other epidemics. With the advent of the product patent regime, the number of applications for CL is likely to rise and the real impact of the new CL provisions will then be realized. Due to existence of compulsory license provisions, MNCs will be forced to work their inventions in India in case they obtain Indian patent. In the event for a period of more than 3 years if the patented invention is not worked within the territory of India (e.g. the product is only imported in India and not manufactured in India), the patent would be open for compulsory license. Thus India industry as a whole is likely to benefit.

A new provision25 has been inserted in the chapter of Compulsory License. The provision provides for grant of license to manufacture and export the patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems provided a compulsory license has been granted in that country or if such

[25] *Section 92A*

country has allowed importation of the patented pharmaceutical products from India. The amendment seeks to implement the agreement on Para 6 of Doha Declaration on TRIPS and public health. The amended provision will allow Indian companies to produce and export AIDS drugs to African and South East Asian countries.

Change in the Procedure for grant, publication and opposition of patent as amended by the Third Amendment:

- All the applications would be published after expiration of 18 months, except on the grounds of secrecy or when the application is abandoned or withdrawn. The applicant could make an application for earlier publication.
- The stage of acceptance and advertisement of the application for opposition has been replaced by the stage of grant of patent.
- The new provisions allow both pre-grant and post-grant opposition. The pre-grant opposition can be filed anytime after the publication of the patent application but before a patent is granted. The post-grant opposition can be filed within a period of one year from the date of publication of the granted patent. The grounds on which pre-grant opposition and post-grant opposition can be filed are similar.

Rights prior to the Grant: From the date of publication of the application until the date of the grant of a patent, the applicant has the like privileges and rights as if a patent for the invention has been granted on the date of publication of the application. However, applicant is not entitled to institute any proceedings for infringement until the patent has been granted. Prior to the Third Amendment, only upon acceptance of the application did the applicant enjoy like privileges and rights.

Secrecy Provisions[26]*:*

Any person resident in India is not allowed to apply for grant of patent for any invention unless either of the following two conditions is satisfied:

- Obtaining written permission of the Controller of Patents. The Controller is required to obtain consent of the Central Government before granting such permission for invention relevant for defense purpose / atomic energy. The application is to be disposed of within 3 months. OR
- Patent application for the same invention has been first filed in India at least six weeks before the application outside India and there is no direction passed under Section 35 for prohibiting /restricting publication/ communication of information relating to invention.

This section is not applicable in relation to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India. In spite of this exclusion, this provision is likely to delay the filing of US applications since US applications are required to be filed by the inventors and not assignees of the inventors.

Data Exclusivity

The Government has rejected pharma MNC's plea for insertion of 'data exclusivity' provisions in the Patents Act.

When the Indian government was in the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, the MNCs had approached the Government with the recommendation to introduce a data exclusivity provision in line with Article 39.3 of TRIPS. However, the

[26] Sections 35 to 43 of the Patents Act; Can you keep a secret? <eco-times/2005/Can-you-keep-a-secret-Feb-14-2005.htm>, February 13, 2005

Government had refused to accede to such a request. The Mashelkar panel has also suggested introduction of provisions for data exclusivity, preventing reliance on the original inventor's data by others. Article 39.3 of Trade Related aspects of Intellectual Property rights (TRIPS) provides as following:

> *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."*

Price Hike

To provide affordable drugs to the Indian public and to foster the growth of an indigenous domestic pharmaceutical industry India had disallowed patents for drugs and pharmaceuticals under the Act. With introduction of product patent regime a primary concern being voiced from various quarters is the expected hike in price of drugs.

Typically the patentee would try to recover huge expenses incurred by him in the research and development of the patented product and therefore, price the product at a very level. However, the situation will not be as grim as it is made out to be. In the first place, a majority of the drugs, which are already available in the market, would not come under the purview of the product patents if no patent applications in respect of the same have been filed. Further, most of the patent products would have unpatented alternatives available in the market, though they may not be as effective. Considering the drugs that might see a price hike, the current health consciousness amongst humans would not make the high price a discomfort to them. There is a view that states that product patent regime would encourage introduction of new drugs, either by directly encouraging invention in India or through newly invented protected imports or through foreign investment in production and research in India.

There are a good number of checks and balances in place that would provide a cushion to the common man who has to bear the burden. In such circumstances, the Indian Government could intervene either under the Indian law or even under the TRIPS. TRIPS, for example, provides vide Article 8 that in formulating or amending the laws and regulations, a State may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. Such intervention by the Government could be in the form of regulating the prices by making use of Drug Price Control Order (DPCO) in relation to essential drugs, or using compulsory licensing under the patent laws or Article 31 of the TRIPS.

Impact of TRIPS on the Indian Pharma and biotech Industry

Erstwhile patent law endorsed reverse engineering that allowed expensive drugs available in the foreign market to be reproduced cheaply and made available to the Indian public. Though Indian pharma majors like Dr. Reddy's and Ranbaxy have already started investing in research and development, smaller Indian firms who relied mainly on reverse engineering are likely to bear brunt of the new law. Smaller firms fear that they will be at a disadvantage as they have limited capital and technology to invent new drugs that can be patented and exploited by them.

Currently, major structural changes are taking place at global drug development and production arena. This is happening mainly due to exponential increase in the cost of drug development, shortening of product life and stiff competition from generic drugs.

All these factors would lead the Indian firms to shift of paradigm of functioning. The Indian firms will be required to change their thinking, planning and focus of functions.

It is very difficult to predict the future. Only certain broad trends can be pasteurized. Indian industry will obviously face stiff competition from the MNCs.

The trends that are likely to evolve with respect to Indian players are:

- Some of the big Indian players are likely to spend more on R & D, which will lead to the development of new drugs. Some promising players may also benefit by foreign investments.
- Indian companies may not be able royalties, which the MNCs may demand in respect of their patented molecules. Indian companies which are currently manufacturing certain molecules will be required to cease their activities once the patents are granted in respect of the same molecules (applications for which were pending in the black box.)
- Since MNCs are now assured of protection of their IP in India, they would be willing to transfer technology to Indian players. There will be inclination towards collaboration between Indian industry and the MNCS in the following areas:
    - Contract Manufacturing outsourcing where MNC would transfer its technology to Indian manufacturer and get the drugs manufactured in India. It is estimated that the contract manufacturing market for global companies in India will touch $900 mn by 2010.
    - Licensing: Indian firms will have to capitalize on the opportunity which might be created to obtain license to produce drugs as global pharma companies that do not have any significant stake in Indian market will not hesitate to give license to Indian firms. However, MNCs with subsidiaries in India are likely to introduce patented drugs only through their subsidiaries. Further, the in licensing of partially developed product to Indian companies and in turn out-licensing of fully developed product by such Indian companies to MNCs would be on the hike.
    - Contract research: India is all set to become the hub for R&D activities considering the cost effectiveness and presence of skilled human resource and fast developing infrastructure. India is already seeing an inflow of funds into research and development, both from local investors and multinational organizations.
    - Clinical trials to be carried out in India by international companies. There is strong possibility of Indian pharma industry seeing many partnerships, collaborations and acquisitions. The large patient pool and low cost investigators too would be playing a major role in this space. It is estimated that the outsourced clinical research market in India will increase to $500 mn by 2010. Quintiles, a leading pharmaceutical service provider, and other such CROs are an example of establishment or research organizations.

Due to existence of product patent regime, and existence of factors such as availability of skilled manpower at lower costs, India has a potential of emerging as a major exporter of new pharmaceuticals. However, in the initial stage MNCs are likely to be apprehensive of extent of and speed at which they may be able to protect their IP in India. As discussed earlier, MNCs may increase their focus on India by creating subsidiaries or entering collaboration or licensing arrangement with Indian companies. At the moment the choice of MNCs has been to establish fully owned R&D subsidiaries in India for their activities in India.

Considering the above trends, the need of the hour is to create favorable conditions and environment for contract enforcement and effective protection and enforcement of IP within the country.

The basic concepts of patentability have often been challenged, when they are applied to life forms and biological material. The primary reason being that living matter is capable of reproduction and issues such as the extent to which patented plant and animal species can be infringed by biological reproduction remain controversial.

In view of the politically and ethically sensitive nature of the subject matter, this has become a debate with repercussions far beyond its technical aspects. The biotechnology field is one that requires more capital than the computer software field did. It also has a longer gestation period for returns. However, the accrual from a real patent could be so high that its value is unparalleled.

Patentability of Biological Inventions

A biotechnological invention would commonly include products, compositions, processes or methods. Biotechnological products would generally consist of a body of microorganisms such as bacteria and fungi, one part of microorganism; plasmids etc., allied products such as antibiotics and enzymes derived from recombinant DNA, antigens, monoclonal antibodies, hybridoma, artificial organs and novel microorganisms obtained as a result of discovery.[27] Broadly, patentability of biotechnological inventions would fall under two heads, patentability of plants and that of life forms.

- **Plant Patents:** The advent of plant genome sequencing efforts has resulted in the patenting of plant DNA sequences by the plant biotechnology industry and public research institutions.[28] DNA sequences are patentable only when the gene has been isolated and a utility for it demonstrated.[29] Plant Patents in the U.S. are granted to any person who "invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, subject to the conditions and requirements of Title 35"[30]. Further, all the provisions applicable to patents for inventions also apply to patents for plants unless otherwise provided by the statute.[31]

  Similarly in the United Kingdom, the law is clear that just because a product consists of or contains biological material or even if it is a process by which the biological material is produced, processed or used, it is not to be considered as unpatentable.[32] Fundamentally, if an invention relating to, or using biological material is novel, involves an inventive step and is industrially applicable, it will be eligible for patent protection. In UK, plant varieties, in particular, may be protected under the Plant Varieties Act 1997 or under Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.[33] It must be noted, however, that inventions, which concern plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. Again, genetic sequences, whether full or partial, may be patentable as long as they satisfy the aforementioned criteria, which mean amongst other things, that the industrial application of the sequence must be disclosed in the patent application. The Patent Regulations, 2000 amended the Patents Act, 1977 and the basic rationale behind the patenting of plant varieties in the UK is that inventions concerning genetic

[27] Giant Group, *The Invention Patent of Biotechnology*; at http://www.giant-group.com.tw/ep&t/ep&t4.htm (accessed on August 30, 2002).
[28] *Id.*
[29] *Id.*
[30] Title 35, US Code, Chapter 15, Section 161.
[31] *Id.*
[32] Intellectual Property, *What is patentable in the biotechnology area?* at http://www.intellectual-property.gov.uk/std/faq/patents/biotech.htm (accessed on August 30, 2002).
[33] *Id.*

manipulation of plant and animal tissue may be patentable and rights can extend to the products of this genetic manipulation.

The TRIPS Agreement allows its member countries to exclude plants and essentially biological processes for the production of plants from patentability, but at the same time provides for the protection of plant varieties either by patents or by an effective *sui generis* system or a combination of both.[34] The Paris Convention permits governments of signatory countries to manipulate the patent system to suit their needs but creates an obligation of uniform application of such law to its own citizens and foreign nationals reciprocally.[35]

In India, the Patents Act excludes from the purview of 'inventions', plants in whole or any part, seeds, varieties and species and essentially biological processes for production or propagation of plants.[36] Microorganisms are patentable in India.

- **Patenting of Life Forms:** Formerly there existed a general doctrine related to patenting, known as the "product of nature" doctrine, which prescribed that products of nature could not be patented. Subsequently, this doctrine was laid to rest after the landmark decision of 1980, the case of Diamond v. Chakrabarty37 wherein it was held by the US Supreme Court that a live, human-made microorganism was patentable subject matter under Section 101 of Title 35 of the US Code38, and that the respondent's microorganism constituted a "manufacture" or "composition of matter". This ruling shed light on the fact that microorganisms being alive, were without legal significance for the purposes of the patent law, also manifestly declaring that anything under the sun that was created by man was eligible for a patent. This was a clear indication to the chemical and pharmaceutical industries that the world's most commercially important patent regime was open to patenting any and all forms of life.

  Most industrialized countries allow the patenting of microorganisms,[39] as long as they meet the criteria of patentability, such as novelty, utility and non-obviousness. The question shrouding patentability of life forms, again, may be directed towards different kinds of life forms right from microorganisms to clones of animals and humans. The TRIPS Agreement vide Article 27(3)(b) allows signatory member nations to incorporate patenting of microorganisms under their respective patent laws. The United States Patent and Trademarks Office granted the first animal patent in 1988 to Harvard University for the '*Onco-mouse*'[40], a transgenic non-human eukaryotic animal. The same onco-mouse however, was initially disallowed from grant of patent protection in Europe, as it the principle behind it was contradictory to the provisions of the European Patent Convention, but on appeal, the decision was reversed.[41] The current situation in the US is however, no less than chaotic, on the question as to whether 'life' is patentable. Forty-six percent of all biotech patents challenged in US courts have been overturned.[42]

[34] Article 27 (3)(b), TRIPS Agreement.
[35] Dr. Harriet Strimpel, Patents *promote the useful arts in a free market*.
[36] Section 3(j) Patents Amendment Act 2002.
[37] 447 U.S. 303 (1980).
[38] Title 35, U.S. Code § 101- Inventions patentable: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".
[39] Mona Ashiya, *Intellectual Property Rights in Biotechnology*; at http://www.cid.harvard.edu/cidbiotech/bioconf/text3.htm (accessed on August 30, 2002).
[40] U.S. Patent no. 4,736,866.
[41] Judy Erratt & Konrad Sechley, *The European Biotechnology Directive and the Patentability of Higher Life Forms,* at http://www.contactcanada.com/articles/article86.html (accessed on August 30, 2002).
[42] ETC Group, *Patenting Elements of Nature*, at http://www.rafi.org/article.asp?newsid=308 (accessed on August 30, 2002).

Broadly speaking, the situation as it exists today, sees most countries disallowing patents on animal varieties *in specie*, but genetic manipulation of animal tissue may be patentable and rights can extend to the products of this genetic manipulation.[43] Patentability of life forms raises questions from various dimensions and this is where the ethical issues arise. Opponents of patents for inventions relating to biotechnology and life forms have been more concerned with the ethical, moral and safety issues surrounding the research, development and use of such inventions rather than the issue of allowing patents for them. A few arguments that have been laid down against the allowing of patents for certain biotechnology inventions (specifically genetic material and life forms) include: [44]

- Genetic alteration of life forms is immoral, and allowing patents for these inventions leads to the ownership and commercialization of life, and reduces life forms to 'products of manufacture';
- Human, animal and environmental safety might be compromised in the development and subsequent use of these inventions;
- Allowing patents for certain life forms and genetic material may lead to unauthorized exploitation of a country's natural resources;
- Allowing patents for certain life forms and genetic material may be insensitive to the beliefs of indigenous populations and may exploit their knowledge; and
- It also discourages disclosure of information and collaboration between researchers.

Most countries currently accept patent applications for biotechnology related inventions provided they meet the novelty, non-obviousness and capability of industrial application criteria of the patent system the Intellectual Property Office of New Zealand ("**IPONZ**") for instance, is one such example.[45] It is significant to note that DNA or raw human genome information cannot be patented because they are discoveries and not inventions, and one of the essences of patentability is that the object under consideration must be an invention. Inventions relating to gene therapy are currently not patentable in Canada, although they are allowed in the U.S.[46] another significant issue is the patentability of stem cells. The US granted a patent (no. 6,200,806) in March 2001 on embryonic stem cells derived from Primates. Looking at the situation from the light of the TRIPS Agreement, animals other than microorganisms and essentially biological processes for the production of animals other than non-biological and microbiological processes may be excluded from patentability by the member nations, under Article 27(3)(b).

In relation to India, on January 15, 2002 Calcutta High Court delivered a landmark judgment in *Dimminaco AG v Controller of Patents and Designs & Others,*[47] which is set to change the landscape of patents and life forms in India, just as the *Diamond* v. *Chakrabarty* did in US. Dimminaco AG had filed a patent application for the process of manufacture of a vaccine. The end product contained living organisms in the form of a virus. Under the Patents Act, 1970 life forms cannot be

[43] The U.K. Patent Office, *Patents for Biotechnological Inventions - Frequently Asked Questions*, at http://www.patent.gov.uk/about/ippd/faq/biofaq.htm (accessed on August 30, 2002).
[44] Shelley A. Rowland, *Patents and Biotechnology-Issues Around Patenting of Life Forms*, at http://www.piperpat.co.nz/resource/life.html (accessed on August 30, 2002).
[45] *Id*.
[46] UNIVERSITY OF SASKATCHEWAN TECHNOLOGIES INC., *What is Patentable in Biotechnology?*, at http://www.usask.ca/ust/IP/biotech.html (accessed on August 31, 2002).
[47] IP World Online, *Case Comment–India: Patentability of biotechnology*, at http://www.google.com/search?q=cache:MPbgI8_17g0C:www.ipworldonline.com/IPW/articles/ipwc02.htm+Dimminaco&hl=en&ie=UTF-8 (accessed on August 20, 2002).

patented, but the Court held that the process of manufacture was patentable, merely because the end product contained a live virus did not inhibit the process of manufacture from being patented. The Court held that there is no statutory bar to accept a manner of manufacture as patentable even if the end product contains a living organism.[48] The applicant for patent stated that since there was no statutory definition of the word 'manufacture' the dictionary meaning should be attributed to the word, taking this into account, Justice Mr. Ashok Kumar Ganguly observed that "if the end product is a commercial and vendible entity, and for that, presence of living virus/microorganism in the end product cannot be a bar to its patentability".[49] On April 10, 2002 the Controller of Patents finally accepted Dimminaco's application. Subsequently, the Government decided against filing an appeal against the Calcutta Judgment. This should provide a breakthrough for the filing of patents by the biotech industry[50] and will be a crucial factor for the growth of the biotech sector.

With regards to the Patents Amendment Act 2002, Section 3(b) provides that an invention, the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment, is not to be regarded as an invention at all, in other words, is not patentable. The Act also excludes from patentability, animals in whole or any part, other than microorganisms.[51]

In order to bring about an effective growth in the biotechnology sector, the industry will have to change its orientation and stress the protection of IP. India's patent protection will have to be stepped up to global standards to reap the benefits of the tremendous potential that exists within the biotechnology sector in the country. Further, in order to ensure a competitive edge in the international arena, Indian companies will have to acquire patents in potential markets around the world. The Government has been encouraging in this regard, by taking appropriate steps to provide for biotechnology patents. This is reflected in the Government's decision to sign the Budapest Treaty on Microorganisms on July 20, 2001, which will give the country the advantage of depositing patentable microorganisms for protection. The establishment of an international depositary in India will help facilitate the patenting of microorganisms that are new and are created using inventive steps.

- **Plant Varieties:** Under TRIPS India was obligated to put sui generis plant varieties protection ("PVP") legislation in place.[52] In the year 2001, the Indian Legislature passed the Protection of Plant Varieties and Farmers Rights Act, 2001 ("PVP Act").

  The PVP Act is designed to include farmer's rights over his seeds. It also has a provision for a national gene fund for sharing the benefits to the traditional conservers of the variety. The concept of plant breeders' rights arises from the need to provide incentives to plant breeders engaged in the creative work of research which sustains agricultural progress through returns on investments made in research and to persuade the researcher to share the benefits of his creativity with society.[53]

[48] *Id.*
[49] Mohan Padmanabhan, *Govt not to appeal against ruling on biotech patent,* at http://www.blonnet.com/2002/04/26/stories/2002042600570200.htm (accessed on August 29, 2002).
[50] *Id.*
[51] Section 3(j), Patents Amendment Act, 2002.
[52] Article 27.3(b) of the TRIPs agreement, which states that members shall provide for the protection of plant varieties whether by patenting or by an effective sui generis system or by any combination thereof.
[53] http://www.sikkiminfo.com/gtimes/June19-25/india_is_determined_to_protect_p.htm (accessed on January 4, 2002).

The law provides mechanisms for the protection of the rights of farmers at the level of village and local communities, promoting the growth of domestic seeds industry and attracting investment for R&D. The PVP Act recognizes the farmer not just as a cultivator but also as a conserver of the agricultural gene pool and a breeder who has bred several successful varieties. It makes provisions for such farmers' varieties to be registered, with the help of non-government organizations so that they are protected against being scavenged by formal sector breeders. Apart from the right to sell non-branded seeds of protected varieties, the rights of farmers and local communities are protected in other ways too.

The PVP Act also ensures availability of high quality seeds and planting material to the farmers, while providing for an inbuilt mechanism for the protection of breeders' rights. Further, it acknowledges the efforts of rural communities towards conservation and maintenance of diversity and innovation, and provides them a system of rewards.

Biodiversity

India has a rich and varied heritage of biodiversity, encompassing a wide spectrum of habitats from tropical rainforests to alpine vegetation and from temperate forests to coastal wetlands. Two of the world's 18 hot spots of biodiversity are found in India: the Eastern Himalayas and the Western Ghats. In addition, India has 26 recognized endemic centers that are home to nearly a third of all the flowering plants identified and described to date.[54]

As a signatory of the Convention on Biological Diversity ("**CBD**")[55] India has the responsibility of protecting the country's sovereign rights over its biodiversity, which would be the raw material for the biotechnology industry. Further, it also has to see that there has to be equitable sharing of the benefits from the biodiversity use with those commodities that protected it over generations.

India has enacted Biological Diversity Act, 2002 ("Biodiversity Act"). Biodiversity Act aims to ensure the conservation of biological diversity in India, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources.

The Biodiversity Act has provisions to regulate the flow of genetic material and the traditional knowledge of its use, with equitable benefit sharing with the local communities. It seeks to protect the country's biological resources from foreigners but gives Indians free access to these.

"Biological diversity" means the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems. "Biological resources" means plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.

NBA is required to regulate the commercial/other uses of biodiversity by both Indian and non-Indian entities. Prior to applying for any IPR in respect of biological resources the applicant will be required to obtain approval of NBA.

Under this Act, all foreign individuals, associations and organizations would be required to seek the prior approval of a NBA to access any biological resource, or the results of research occurring in India, for any use.

Indian citizens, local people and communities, including *vaids* and *hakims*, will have free access to biological resources for use within the country, for any purpose. But before seeking any form of

[54] Tata Energy Research Institute, *India's biodiversity*, http://www.teriin.org/biodiv/status.htm (accessed on August 31, 2002).
[55] India signed the CBD on June 5, 1992, at http://www.biodiv.org/world/parties.asp?lg=0 (accessed on August 31, 2002).

intellectual property right on an invention based on biological resources from India, the NBA's prior approval would be needed. NBA will have the power to impose conditions to ensure a share in the benefits accruing from the IP.[56]

The Regulatory Approval Process

India's ability to compete in the global markets is highly dependent on an efficient regulatory process, which results in the timely approval of pharmaceutical and biotechnology products.[57] The existing regulatory approval process involves a complicated process of multiple clearances from various government departments, ministries and committees both at the state and at the central level. Prior to launching its products in any country, a biotech company undertakes patent registration to protect its own interests. The next step involves acquiring the approval by regulatory authorities. Mostly the process for seeking approval is initiated alongside the patent registration process.

- **The Department of Biotechnology ("DBT"):** DBT was set up under the Ministry of Science and Technology in 1986 to give a new impetus to the development of the field of modern biology and biotechnology in India. In more than a decade of its existence, the department has promoted and accelerated the pace of development of biotechnology in India. Through several R&D projects, demonstrations and creation of infrastructure facilities it endeavors to create impact on this field. DBT has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry..[58]

  Pursuant to the abovementioned goals of the DBT, it has been issuing various guidelines from time to time. The DBT has issued guidelines including those for transgenic plants, recombinant vaccines and drugs. The guidelines are specifically are on safety, purity, potency and effectiveness of the product.

- **The Drugs and Cosmetics Act, 1940 ("Drugs Act"):** The Drugs Act and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 ("the Rules") regulates the import, manufacture, distribution and sale of drugs in India. It provides the procedures for testing and licensing new drugs. The main object of the Act is to ensure availability of standard quality drugs and cosmetics to the consumer. In order to achieve the objects of the Act, a drug is defined comprehensively to include substances in the definition of drug.59 The responsibility to enforce the Act is entrusted with both the Center and State. The Central Drugs Standard Control Organization, headed by the Drugs Controller General of India ("DCGI") is mainly responsible for coordinating the activities of the State Drugs Control Organization, laying down policies, and ensuring uniform implementation of the Act throughout India. The enforcement of the Act is the responsibility of the State Government**.**

  The procedures under the Drugs Act involve obtaining a series of approvals for the different stages at which the drugs are tested, before the DCGI grants the final license to allow the drug to be manufactured and marketed.

  New drug development is knowledge intensive, time consuming and risky. The development process could broadly be divided in two major stages viz. Pre-clinical and clinical. The objective of pre-clinical studies is to come up with a molecule that is effective against the disease vector and safe in animal testing. This is the Investigational New Drug ("**IND**") stage. This stage of investigation may take anywhere between 3 to 5 years and

[56] *Bill bars foreigners from using India's biodiversity*, The Times of India, 16 May 2000.
[57] "The Indian Pharmaceutical industry is poised to grow at a compounded annual growth rate at 19 % and touch $25 billion in revenue by 2010, says a survey conducted by McKinsey on behalf of FICCI. The current revenues of the industry is estimated at $5.5 billion", Economic Times, May 1, 2001.
[58] Department of Biotechnology, *About Biotechnology*, http://dbtindia.nic.in/overview.html (accessed on August 12,2004).
[59] Section 3(b) of the Drugs Act and Cosmetics Act, 1940.

cost between US$100-150 million overseas or about Rs.40-60 crore in India.[60] Pre-clinical investigations need an assembly of multi-disciplinary activities covering design and synthesis of new chemical compounds, bio-activity screening for both in-vitro and in-vivo testing, toxicity, pharmacokinetics, metabolism et al. Having established safety and efficacy in relevant animal models, the IND is administered to small population of healthy volunteers, in what is defined as Phase I of clinical trials. The purpose is to confirm safety of drugs in humans and establish a basis for progressing towards the next phase that would find out the efficacy of the drug in actual patients. The second phase clinical trials is carried out on a restricted population (numbers determined based on an approval protocol) and is used for proving efficacy in a disease category towards which the drug targeted. The following phase of clinical trials (Phase III) is used for statistical validation and observing the long-term effect of administering the drug on a larger set of patients.[61]

DCGI approval has to be taken at each stage and only when all three trial stages are successfully completed can the product be launched. If an IND passes through all these clinical studies the compound becomes a drug that could be marketed. The clinical studies take generally 6 to 8 years, depending upon availability of patients, complexity of the drug and adverse reactions encountered during the development of the drug.

2002 amendments to the Rules streamlined the procedures for manufacture and import of new drugs. According to the amended rules, institutions will be allowed to conduct clinical trials, whether for clinical investigation or experiment, for a new drug only after obtaining permission of the DCGI. Prior to this amendment, permission was mandatory only if the drug was sought to be marketed in India.

- **The Drug (Prices Control) Order 1995 ("DPCO"):** The Drug Price Control Order ("DPC Order") has been promulgated under the Essential Commodities Act, 1955 ("ECA")[62]. The DPC Order fixes the ceiling price of some active pharmaceuticals and formulations. The active pharmaceuticals and formulations, which fall within the purview of the legislation, are called scheduled drugs and scheduled formulations, respectively. The items in the schedule can be added or deleted. The authority set up under the legislation is the National Pharmaceutical Pricing Authority ("NPPA"),[63] which is responsible for the collection of data and the study of the pricing structure of active pharmaceuticals and formulations. Upon the recommendation of the NPPA, the Ministry of Chemicals and Fertilizers fixes the ceiling prices of the active pharmaceuticals and formulations and issues notifications on drugs, which are scheduled drugs and scheduled formulations. The NPPA arrives at the recommend prices for the scheduled drugs and formulations after collection and analysis of data on costing which includes data on raw material composition, packing materials, process losses, overhead allocation and apportionment, capacity utilization, technical data on manufacturing work orders and packing work orders. The government of India has the power under the DPC Order to recover the amounts charged in excess of the notified price from the company. There are also penal provisions for the violation of any rules and regulations under the ECA. Separate formulae have been prescribed for calculation of price for bulk drugs, drugs manufactured in India and drugs imported into India.

  The Government can exempt certain products from price control if they are new drugs discovered in India or bulk drugs produced from the basic stage by a new process discovered in India or drugs manufactured by small-scale industries (capital investment

[60] See, http://www.nic.in/cpc/pharma10_f1.htm (accessed on January 4, 2002).
[61] Sandhya Srinivasan, *Clinical trials: some ethical issues*, at http://www.healthlibrary.com/reading/ethics/apr98/clini.htm (accessed on August 31, 2002).
[62] Section 3 of the Essential Commodities Act, 1955.
[63] National Pharmaceutical Pricing Authority, at http://www.nppaindia.nic.in/

below a certain level) and sold under their own brand names. Price control does not apply to formulations under the Indian system of medicine or homeopathic medicines or items to which the Drugs Act does not apply.

- **The Environment Protection Act, 1986 ("EPA"):** The EPA authorizes the central government to protect and improve environmental quality, control and reduce pollution from all sources, and prohibit or restrict the setting and/or operation of any industrial facility on environmental grounds. The biotechnology regulatory approval process was developed within the framework of this act by way of 'Rules' made by the Ministry of Environment and Forests ("**MoEF**")[64] and Department of Biotechnology of the Ministry of Science and Technology.

- **Measures to Regulate Genetically Modified Organisms ("GMOs"):** Manufacture, import and storage of GMOs in India are regulated by the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Modified Organisms or Cell Rules, 1989 ("**Rules**"). These Rules are made under delegated powers given by the EPA. The rules are framed by the MoEF with the objective of protecting the environment, nature and health in connection with the application of gene technology and microorganisms. They came into force on 1 October 1993. The Rules define microorganisms to include all the bacteria, viruses, fungi, mycoplasma, cell lines, algae, protodones and nematodes indicated in the schedule and those that have not been presently known to exist in the country.

  The Rules set up following six competent authorities at a three tier level - national, state and district for regulatory purposes: [65]

  A. Recombinant DNA Advisory Committee ("**RDAC**") - to review developments in biotechnology at national and international levels and recommend suitable and appropriate safety regulations for recombinant research, use and applications in India from time to time.

  B. Review Committee on Genetic Manipulation ("**RCGM**")- This monitors safety related aspects in respect of "on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms." The Committee is empowered to lay down procedures restricting or prohibiting production, sale and importation of genetically engineered organisms.

  C. Institutional Biosafety Committee ("**IBSC**")- This Committee is required to be set up in research institutions etc. handling microorganisms/genetically engineered organisms.

  D. Genetic Engineering Approval Committee ("**GEAC**") - This Committee is to function under MoEF for approval of activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle.

  E. State Biotechnology Co-ordination Committee ("**SBCC**")- This Committee can be set up in States when necessary. It will review periodically the safety and control measures in various industries/institutions handling genetically engineered organisms/hazardous microorganisms. In fact it possesses powers to inspect, investigate and take punitive actions in cases of violations of statutory provisions.

  F. District Level Committee ("**DLC**")- This Committee is to work under the District Collectors to monitor the safety regulations in installations engaged in the use of

[64] Ministry of Environment and Forests, at http://envfor.nic.in/ (accessed on August 31, 2002).
[65] Section 4 of the Export and Storage of Hazardous Microorganisms/Genetically Modified Organisms or Cell Rules, 1989.

genetically modified organisms/hazardous microorganisms and its application in the environment. Import, export, transport, manufacture, process, use or selling of genetically engineered microorganisms is prohibited without the approval of the GEAC. Further, deliberate or unintentional release of genetically engineered organisms/hazardous microorganisms is prohibited. Moreover, the rules prohibit the production, selling or import of substances and products containing genetically engineered organisms or cells or microorganisms, without the approval of this Committee.

The legal framework to handle entry of new drugs in India is archaic and complicated. For a drug to reach the market in India, it has to go through three phases of clinical trials. In the US, permission from the monitoring authority, the Food and Drug Administration, is required only at the beginning. In India the DCGI is required to separately give permission for each stage of the trials and all genetically modified products have to be cleared through the above-mentioned regulatory committees for safety. There is an urgent need to develop a fast-track regulatory process for the evolving biotechnology industry in India. The present time-consuming, multi-body clearance-giving system needs revamping to curb the delay in clearing projects, which will inadvertently affect the viability of upcoming biotechnology companies.

VI. EMERGING LEGAL & ETHICAL ISSUES

The rapid progress in cutting edge areas of biotechnology research in recent years has led to widespread discussions on the need to frame appropriate laws to maximize the benefits of new technology, without compromising on ethics. Some of the significant areas of concern have been outlined hereafter:

Privacy and Data Protection

The advent of genetics has triggered the probability of sensitive personal material being exposed to the outside world by obtaining genetic material relating to a person. This probability has materialized into a reality and the information, which is now available, is such that if properly examined, it can reveal the entire life of a person, right from time of birth to his death. Probably as the technology advances into previously uncharted dimensions of biotechnology there will come a time when ever more complex revelations of the decoding of the human genome might reveal not only the cause of the death of an individual but also the reason why death might occur.

"Is genetic information unique? Should it be protected separately from other forms of information? There exist six arguments for considering genetic information different from other kinds of medical data: It reveals the health of family members; it reveals parentage, reproductive options, and future health risks; it goes to the essence of who and what an individual is; and it's regarded as unique by individuals and third parties, who often overuse it. Even if the public is satisfied that genetic information is unique, it should not necessarily be protected separately. This is so because firstly, people don't know exactly what genetic information is and secondly, it is probably impossible to segregate it from other information in a clinical record. Lastly, enacting a genetic-specific legislation may be self defeating because it further stigmatizes people with genetic conditions."

Currently, the Indian legal regime does not have a specific law for privacy and data protection. However, Indian courts have interpreted the right to privacy as an unarticulated fundamental right[66] against an action by the State. There are many spheres of social life wherein private information of a person obtained by using the biotechnological means, can be to the detriment of that person.

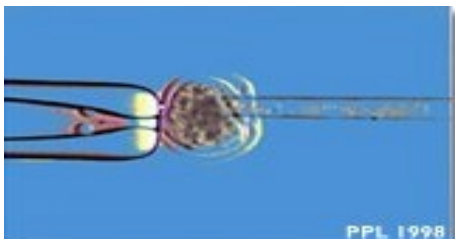
[66] See *Kharak Singh* v. *State of U.P.* AIR 1963 SC 1295; *Gobind* v. *State of Madhya Pradesh* (1975) SCC (Cri) 468; *People's Union of Civil Liberties* v. *Union of India* (1997) 1 SCC 318.

Insurance, employment, criminal law, personal-injury litigation, domestic relations, forensics, education and commerce are some of the non-medical uses of genetic information:

As seen above, there are so many uses of private information that are possible and the way in which the information might be used is also crucial. If for example a person goes to a hospital to get a routine blood test and the hospital authorities sell the records of that individual to an insurance company, it could lead to genetic discrimination. The insurance company which receives the information can get the analysis of that person done, with regards to his medical records, his chance of a premature death, etc. Thus, by studying these reports, the Insurance Company could give a lesser rating to that person, as a result of which he would have to pay a premium, which is higher than that of another person of a similar categorization as himself.

There is a need for policies that envisage the advancements in biotechnology and adapt to them accordingly. For instance in the insurance sector, there needs to be a legislation to prohibit insurance companies from using genetic information to deny coverage or raise health insurance rates, not only at the stage when symptoms are not showing, but also at a stage when symptoms appear the companies should not be allowed to quit. In the future there could be a uniform healthcare and insurance system or an absolutely discriminatory system where the culmination of the right genes will make your future and not the abilities that you hold. Like in the movie *Gattaca*[67] where the society is divided into the "Valids" (the persons with the "right" genetic makeup) and the "Invalids" (the persons who do not have the "right" genetic makeup), where the invalids are doomed to become the subject of discrimination by the 'Valids', third class citizens merely on the basis of their genetic makeup. It will not matter what you can do or who you are, but only what you are made of! We have to ask ourselves, whether we want such a world where the rule is discrimination? If not, then, there needs to be a lot of work done in this field to maintain the free world that we live in. Privacy and data protection needs to come at the forefront of socio-ethical issues in a country where patient records are being sold by the hospitals in bulk.

Human Cloning



In 1997, the entire world was shocked and captivated by the news that a cloned sheep called Dolly was brought into the world by a nuclear transfer of somatic cells. These concerns were not about Dolly, the now famous sheep, nor even about the considerable impact cloning may have on the animal breeding industry, but rather about the possibility of cloning humans. The ethical concerns about human clones involve the risks and uncertainties associated with the current state of cloning technology. This technology has not yet been tested with human subjects, and scientists cannot rule out the possibility of mutation or other biological damage.[68]

There exist numerous controversial issues involved with human cloning such as the possibility of deformed offspring, designer babies and the rights and legal protection for cloned humans. Further, concerns have been expressed regarding the possibility of premature aging of clones, especially since Dolly, the sheep contracted arthritis at an early age and scientists are yet to determine

[67] © Columbia Pictures ALL RIGHTS RESERVED
[68] *Genetic Encores: The Ethics of Human Cloning,* □ HYPERLINK "http://www.puaf.umd.edu/IPPP/Fall97Report/cloning.htm" □http://www.puaf.umd.edu/IPPP/Fall97Report/cloning.htm□ (accessed on September 30, 2002).

whether it was caused due to genetic defects.[69] Religious scholars from a wide range of faith traditions have contributed to a substantive and remarkably diverse literature on the ethics of human cloning[70]

However, on the other hand there exist concerns in certain scientific communities that the extent of legislation against human cloning might result in stifling research into human embryology that could lead to new treatments for disease. The potential benefits include the use of cloning by infertile couples wanting to create a genetically related child or those wishing to clone a lost loved one. It has been said that often the change in custom or practice in an emotionally charged area has always elicited a response from established custom and law of horrified negation at first; then negation without horror, then slow and gradual curiosity, study, evaluation, and finally a very slow but steady acceptance.[71] Many people viewed the birth of Louise Brown in 1978 as an aberrant and abhorrent event. Yet she was just the first of some 250,000 people conceived in the past 20 years through test-tube fertilization.[72] Now a generation later many people celebrate such technology as a gift, and even consider it as an option not to be denied to an infertile couple.

The cloning of human embryos has gathered tremendous attention in recent times due to the announcement made by Advanced Cell Technologies, a US based company that it had created a human embryo clone.[73] The company claimed to have cloned human cells by fusing their contents with the empty egg cells taken from a cow. In response to the critics, the company clarified that that they had no intention of trying to create a human clone and that they planned to try and grow organs and tissues in the lab for use in transplantation therapy.

Countries worldwide have reacted to the prospect of human cloning by lobbying for a ban on the creation of human clones. Representatives of several member countries of the Council of Europe have signed a protocol that would commit their countries to ban by law "any intervention seeking to create human beings genetically identical to another human being, whether living or dead." The U.S. House of representatives, on July 31, 2001 voted for a ban on human cloning, but according to recent developments, the US Senate, on June 18, 2002, blocked an effort to add an anti-cloning amendment to a legislation dealing with insurance against terrorism. In the United Kingdom, the High Court passed a ruling, in the year 2001 that cloning could not legally be banned[75], but earlier this year the UK Government won an appeal overturning the High Court's decision.[76] Although therapeutic cloning using cell nuclear replacement for research is not covered under the ban (in UK),[77] it can be regulated by the Human Fertilization and Embryology Authority, which was given the power to regulate therapeutic cloning experiments in the UK, by the House of Lords according to recent case law development.[78] New experiments in therapeutic cloning can prevent the immune rejection of transplanted tissue. However, scientists are of the opinion that the key ethical objection to therapeutic cloning could be undermined if the results of experiments on abnormal cloned frog

[69] CNN, *Cloned Dolly has arthritis,* at HYPERLINK "http://www.cnn.com" www.cnn.com, (accessed on January 4, 2002).
[70] S. Campbell, *Religious Perspectives on Human Cloning*, at HYPERLINK "http://bioethics.gov/pubs/cloning2/cc4.pdf" http://bioethics.gov/pubs/cloning2/cc4.pdf (accessed on January 4, 2002).
[71] Jennifer Rosenberg, *The World's First Test-Tube Baby: A Triumph in Medicine That Caused Fears for the Future*, at HYPERLINK "http://history1900s.about.com/library/weekly/aa043001a.htm" http://history1900s.about.com/library/weekly/aa043001a.htm (accessed on August 30, 2002).
[72] *How important is cloning of the human embryo?* The Economic Times, December 3, 2001.
[73] Helen Dewar, *Human Cloning Ban Sidetracked*, The Washington Post June 19, 2002, at HYPERLINK "http://www.washingtonpost.com/wp-dyn/articles/A7667-2002Jun18.html" http://www.washingtonpost.com/wp-dyn/articles/A7667-2002Jun18.html (accessed on August 30, 2002).

[75] The Queen v. Secretary of State for Health ex parte Eastside Cheese [1999] 3 CMLR 123.
[76] *Id.*
[77] Lord Phillips MR in *The Queen (on the application of Bruno Quintavalle on behalf of Pro-Life Alliance)* v. *Secretary of State for Health* [2002] EWCA Civ 29.
[78] Lord Phillips MR in *The Queen (on the application of Bruno Quintavalle on behalf of Pro-Life Alliance)* v. *Secretary of State for Health* [2002] EWCA Civ 29.

embryos are repeated in humans.[79] In other developments, a noted Italian fertility expert, Severino Antinori recently claimed that one of his patients was pregnant with a clone, which if true, would lead to the first pregnancy of a clone in November 2002.[80] But if even this baby is born healthy, experts are of the view that there could be a high risk of rare invasive womb cancer for the mother.

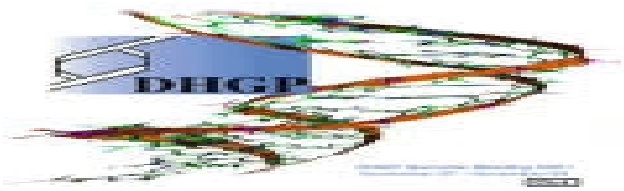
With regards to human cloning, we cannot "un-discover" what is discovered; neither can we "un-invent" what has been invented. Developments in the field of biotechnology have shed light upon the fact, that the day when a human can be cloned is not as incredible, or far off as it seemed. Until then we have time, but it is essential for society to be ready, educated, and open minded, so the law can act as required.[81]

The Human Genome Project ("HGP")[82]

The completion of the human genome project, and the sequencing of other organisms' DNA, is widely regarded as a turning point in biology and medicine. The elaboration of the human genome sequence is a major step in demystifying the evolution of the human species and the workings of the human body.[83] The possibilities that may result from the HGP seem endless. Geneticists are now able to identify genes that control diseases, aging, and other specific traits. This enhances the opportunity for the human race to rid itself of disease and unwanted genetic traits. However, the HGP has generated widespread interest in a large spectrum of questions regarding the ethical, legal, and social implications of the existence and use of human genetic sequences. The draft sequence of the Human Genome (US project) provides a scaffold of sequences across about 90% of the human genome, the remaining gaps anticipated to be closed and accuracy improved over the following 3 years to achieve a complete, high-quality DNA reference sequence by 2003, two years earlier than originally projected.[84] The new five-year plan of the US Human Genome Project involving human DNA Sequencing includes the following:

- Generate a working draft of 90% of the genome (2001).
- Obtain a complete, high-quality genomic sequence (2003).
- Make all data publicly available.

With the completion of the HGP, the emphasis is shifting to the protein compliment of the human organism, which has given rise to the science of proteomics.[85] The term 'proteome' refers to all the proteins expressed by a genome, and thus proteomics involves the identification of proteins in the body and the determination of their role in physiological and patho-physiological functions.[86]



Enabling technologies for proteomics have been in development for over 20 years. However, more recently, the field has become formalized by combining the techniques for large-scale protein

[79] New Scientist, *Clone pregnancy risks womb cancer*, at HYPERLINK "http://www.newscientist.com/news/news.jsp?id=ns99992148" http://www.newscientist.com/news/news.jsp?id=ns99992148 (accessed on August 31, 2002).
[80] *Id.*
[81] Opinions and Views, *Justification for Human Cloning?*, at HYPERLINK "http://www.redbrick.dcu.ie/~crashaid/opinions/cloning.html" http://www.redbrick.dcu.ie/~crashaid/opinions/cloning.html (accessed on August 31, 2002).
[82] Picture Source: HYPERLINK "http://www.life.uiuc.edu" www.life.uiuc.edu (accessed on August 31, 2002).
[83] Frank Gaglioti, *The human genome project: science, society and superstition*, at HYPERLINK "http://www.wsws.org/articles/2000/aug2000/geno-a15.shtml" http://www.wsws.org/articles/2000/aug2000/geno-a15.shtml (accessed on August 31, 2002).
[84] U.S. Human Genome Project 5-Year Research Goals 1998-2003, *Time Table Accelerated on U.S. Human Genome Project*, at HYPERLINK "http://www.ornl.gov/TechResources/Human_Genome/hg5yp/" http://www.ornl.gov/TechResources/Human_Genome/hg5yp/ (accessed on August 31, 2002).
[85] Altruis Biomedical Network, *E-Proteomics*, at HYPERLINK "http://www.e-proteomics.net/" http://www.e-proteomics.net/ (accessed on August 31, 2002).
[86] *Id.*

separation (two-dimensional electrophoresis) with very precise, high fidelity approaches to the analysis and characterization of the separated proteins (mass spectrometry).[87] Applications of proteomics are wide ranging and can be found within many disciplines, although one of the more developed fields that is examined here covers the arena of toxicological and pharmacological profiling.[88]

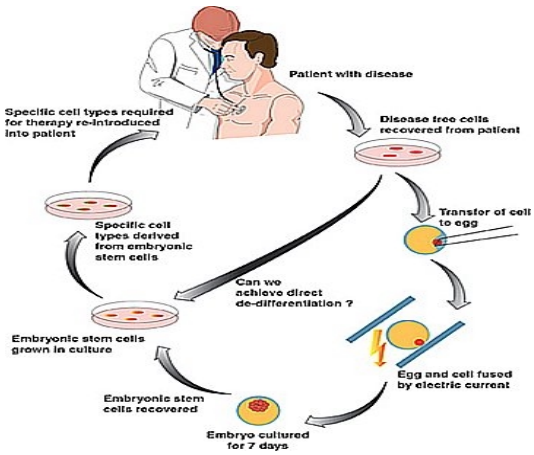
However, the HGP has led to fears regarding the privacy and confidentiality of genetic information, including questions of ownership and control of genetic information, and consent to disclosure and use of genetic information; these fears stem from issues such as privacy associated with medical information, which is currently a subject matter of great controversy. With genetic information being added to the information into medical files, there exist fears that such information could fall in the wrong hands. For example if a health organization is paying for the gene tests, and holds the view that it owns the information, it could be used to serve its corporate interests. There also exist questions regarding the right of third parties such as employers subjecting individuals to genetic testing to determine the likely future health status of the employee and insurers securing a detailed genetic profile of the insured.[89] Insurance Companies can grant or deny medical insurance if they know the possibility of a client having a genetic disease. While this may help the insurance company save money, it's denying the client insurance coverage and proper medical treatment.

The HGP has also led to certain concerns regarding human rights. The new ability to transform life that has resulted from advances in human reproduction and knowledge in the field of genetics led to the Universal Declaration on the Human Genome and Human Rights. This was adopted unanimously and by acclamation by the General Conference of UNESCO at its 29th session on November 11, 1997. It is the first universal instrument in the field of biology. The uncontested merit of this text resides in the balance it strikes between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research. The Declaration states that no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity. There is an urgent need to develop programs directed toward understanding the ethical, legal, and social implications of HGP data, to identify and define the major issues and develop initial policy options to address them.

Stem Cell Research

A stem cell is a primitive type of cell that can be coaxed into developing into most of the 220 types

Foetal Stem cell



of cells found in the human body (e.g. blood cells, heart cells, brain cells, etc). Some researchers

[87] Molloy M.P.; Witzmann F.A., "*Proteomics: Technologies and applications*", at HYPERLINK "http://www.ingenta.com" http://www.ingenta.com (accessed on July 1, 2002).
[88] *Id.*
[89] The Hon. Justice Michael Kirby, *Human Genome Project-Legal Issues*, at HYPERLINK "http://www.lawfoundation.net.au/resources/kirby/papers/19990710_humang.html" http://www.lawfoundation.net.au/resources/kirby/papers/19990710_humang.html (accessed on August 29, 2002).

regard them as offering the greatest potential for the alleviation of human suffering since the development of antibiotics.[90] Stem cells can be obtained from adults, but the stem cells that most researchers consider most promising come from embryos. Medical researchers hope to use stem cells to produce perfectly matched tissues to replace or repair organs that have stopped functioning, thus treating diseases including diabetes, heart problems and Parkinson's, and perhaps allowing the replacement of body parts/organs.

The concerns regarding stem cell research do not exist in researching these special cells, but the method by which researchers obtain the stem cells from embryos. The only way to harvest the cells is by killing the embryo. Those who believe that all human embryonic cells are human lives consider it immoral and unethical to use them in research. Stem cell research has, from the time of its conception, ignited a heated ethical debate among legislators and scientists. A viable alternative might be to use adult stem cells, taken from bone marrow or the brains of cadavers. Unfortunately, they are difficult to remove, are severely limited in quantity, and some experts say don't show the same promise that embryonic stem cells do. [91] The issue has become inextricably entangled with the politics of abortion and the difficulty in distinguishing between what material can or cannot be defined as having the potential to become a human being. Opinions are divided on whether or not such material can be said to deserve the same protections as a fertilized human embryo.[92]

The potential benefits for this research are abundant but there exists a debate arising from differences in deeply held religious and philosophic views which give rise to the conflict between ethics and science. The ethical issues of biotechnology are up for debate in our culture now. Developments are outpacing the public's awareness and ability to determine correct courses of action. If stem-cell research were allowed to develop further, advances in this field could ensure the treatment of numerous human diseases, such as Parkinson's disease, Alzheimer's disease, multiple sclerosis, heart disease, diabetes, and leukemia.[93]

As far as the legal position of stem cell research is concerned, in the US, a bill that purported to ban the cloning of human embryos for reproductive purposes or harvesting of stem cells was stalled on June 18, 2002.[94] In Norway, there exists a situation similar to that of Germany, where the current legislation does not allow the production of stem cells from fertilized eggs.[95] In contrast, the governments of Sweden, the Netherlands, and France have either already accepted the use of fertilized eggs as a source of stem cells or suggested that such use be accepted.[96] Further, a bank of stem-cell lines is currently being developed in Sweden.

In recent developments, the Indian Government has proposed to regulate stem cell sourcing and research, vide a comprehensive policy for the sector to be formulated by the Indian Health Ministry, which mandates permission from a national apex committee for existing as well as future players, in the private sector.[97] Further, since India is being viewed by global stem cell research firms as a low cost sourcing place, the Government also proposes to ban trading of human embryo, a stem cell

[90] Religious Tolerence.Org, *Human Stem Cell Research: All sides of the dispute,* □ HYPERLINK "http://www.religioustolerance.org/res_stem.htm" □http://www.religioustolerance.org/res_stem.htm□ (accessed on August 31, 2002).

[91] □ HYPERLINK "mailto:kp@wired.com?subject=Stem Cells: Killer or Savior?" □Kristen Philipkoski□, *Stem Cells: Killer or Savior?,* at □ HYPERLINK "http://www.wired.com/news/technology/0,1282,35947-2,00.html" □http://www.wired.com/news/technology/0,1282,35947-2,00.html□ (accessed on August 29, 2002).

[92] Leo Gough, *Investing in Biotech Stocks*, p. 20.

[93] The New England Journal of Medicine, *European Perspectives on Therapeutic Cloning, at* □ HYPERLINK "http://content.nejm.org/cgi/content/full/346/20/1579" □http://content.nejm.org/cgi/content/full/346/20/1579□ (accessed on August 29, 2002).

[94] *Supra* n.110.

[95] □ *Supra* n.128.

[96] □ *Id*

[97] K.G.Narendrath, *Govt. plans to regulate stem cells research*, at □ HYPERLINK "http://economictimes.indiatimes.com/articleshow.asp?artid=15798421" □http://economictimes.indiatimes.com/articleshow.asp?artid=15798421□ (accessed on August 29, 2002).

source, by in-vitro fertility (IVF) clinics and an accreditation system for domestic cell line repositories.[98]

Gene Therapy

Gene Therapy is a unique technology involving the usage of genes as therapeutic agents to treat hereditary genetic disorders. It is a novel approach to treat, cure, or ultimately prevent disease by changing the expression of a person's genes.[99] A gene is the fundamental physical and functional unit of heredity that is made up of tightly coiled threads or polymers of DNA.[100]

Ever since the first clinical trial was initiated in 1990, the area of gene therapy has held the promise of curing disease and improving the quality of life for millions.[101] Hemophilia, cystic fibrosis and cancer are some of the diseases that can be cured by gene therapy.

Moral and ethical issues arising within the framework of Gene Therapy are usually centered around the proposition that by way of Gene Therapy, man would be playing God, whereby the genes would be altered without having any knowledge as to the effects it would have on generations to come. It is believed by some, that the risk involved is much greater than the benefits that might accrue from the long-term research and testing involved with Gene Therapy. Further, the concept goes against the laws of nature in so far as alterations to genes without any knowledge as to the effects of such alteration might lead to serious implications, which gives rise to questions on various legal issues and legal rights.

Xenotransplantation

Since early times, man has made good use of animals and their body parts. He has eaten them, worn them and used them as tools, fertilizer and decoration. In 1995, doctors in California, USA, transplanted bone marrow from a baboon into an AIDS patient, via a highly controversial procedure, which involved the removal of an organ or tissue from an individual of one species and transplanted into an individual of another. This prompted the creation of strict guidelines for '*xenografts*'[102], by the consortium of US federal agencies that make up the Public Health Service, including the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control.

In recent times, there has been an increase in the interest on using animal parts to save human lives, through the transplantation of whole organs, parts of organs or small numbers of cells from certain animals. Such a transfer or grafting of tissue from an animal of one species into an individual of another is called xenotransplantation, which also includes the process of transplantation of organs from genetically modified animals. A per the definition put forth by the US Food and Drug Administration[103], xenotransplantation is any procedure that involves the transplantation, implantation, or infusion into a human recipient of either:

(a) live cells, tissues, or organs from a nonhuman animal source, or

(b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs.

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98 *Id.*

99 Human Genome Project Information, *Gene Therapy*, at HYPERLINK "http://www.ornl.gov/hgmis/medicine/genetherapy.html" http://www.ornl.gov/hgmis/medicine/genetherapy.html (accessed on August 29, 2002).

100 Biotechnology Industry Organization, *Primer: Genome and Genetic Research, Patent Protection and 21 St Century Medicine*, at HYPERLINK "http://www.bio.org/genomics/primer.html" http://www.bio.org/genomics/primer.html (accessed on August 29,2002).

101 Biotechnology Industry Organization, *Gene Therapy*, at HYPERLINK "http://www.bio.org/bioethics/genetherapy.html" http://www.bio.org/bioethics/genetherapy.html (accessed on August 29, 2002).

Innovation, *Xenografts*, at HYPERLINK "http://www.pbs.org/wnet/innovation/html/glossary.html#xenograft" http://www.pbs.org/wnet/innovation/html/glossary.html#xenograft (accessed on January 4, 2002). 102

103 U.S Food and Drug Administration, *FDA Approach To The Regulation Of Xenotransplantation* HYPERLINK "http://www.fda.gov/cber/xap/xap.htm" http://www.fda.gov/cber/xap/xap.htm (accessed on August 29, 2002).

According to recent statistical reports, more than 62,000 people in the U.S. are waiting for organ transplants.[104] Since the number of human donors falls considerably short of this demand, scientists hope that the organs of genetically modified pigs will meet the shortfall. Tests carried out in the past have proven that transplant of organs from unaltered pigs have not been accepted by the human body due to immune rejection of the tissue.[105] The scientists are also apprehensive about the transplantation of the organs from 'knock-out' pigs (as the cloned pigs are referred to), since they are of the opinion that porcine endogenous retroviruses that exist in the pigs' organs might affect the human recipients adversely, as previous tests have shown. Human genes will need to be added to prevent rejection of the organ in the long run. However, a lot more study and research is necessary before organs from clones of pigs can actually be transplanted into humans, and as of now, it still remains uncertain as to whether xenotransplantation can be successfully implemented on humans.

The risks associated with xenotransplantation are innumerable. Firstly, the recipient of a xenotransplant is potentially at risk for infection with infectious agents already known to be transmissible from animals to humans; and secondly those infectious agents which may become transmissible only through xenotransplantation and which may not be readily identified with current diagnostic tools.[106] Infected xenograft recipients could then potentially transmit these infectious agents to their contacts and subsequently to the public at large.

The United States Public Health Service has laid down certain guidelines[107] on infectious disease issues in xenotransplantation, where they recommend the following:

i. recipients of xenotransplantation products should be informed that they and their intimate contacts should defer from donation of blood and other tissues.

ii. patients should also be informed that they have been treated with a xenotransplantation product and of the risks involved.

iii. patient samples such as blood etc., must be archived in a systematic manner, to allow future monitoring for potential infections.

iv. patients should be followed for their lifetimes and counseling may be carried out to issue warnings to be alert to any unusual symptoms.

v. samples of the xenotransplantation product must also be archived (i.e. non-human animal cells used for the co-culture process).

vi. Problems arising out of xenotransplantation in the long run can be tackled by educating people and increasing the number of voluntary donors.[108] In the future, therapeutic cloning can offer more solutions, making xenotransplantation a comparatively unattractive option.[109]

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[104] Emma Young, *Knock-out pig clones advance transplant hopes*, at HYPERLINK "http://www.newscientist.com/hottopics/cloning/cloning.jsp?id=ns99991737" http://www.newscientist.com/hottopics/cloning/cloning.jsp?id=ns99991737 (accessed on August 31, 2002).

[105] *Id.*

[106] U.S Department of Health et. al., *Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans*, at HYPERLINK "http://www.fda.gov/cber/gdlns/xenoprim.pdf" http://www.fda.gov/cber/gdlns/xenoprim.pdf (accessed on August 31, 2002).

[107] U.S Food and Drug Administration, *Information and Recommendations for Physicians Involved in the Co-Culture of Human Embryos with NonHuman Animal Cells*, at HYPERLINK "http://www.fda.gov/cber/infosheets/humembclin.htm" http://www.fda.gov/cber/infosheets/humembclin.htm (accessed on August 31, 2002).

[108] *Public concerns on biotech are soundly based: Mayer*, at HYPERLINK "http://www.economictimes.com/articleshow.asp?art_ID=209062506" http://www.economictimes.com/articleshow.asp?art_ID=209062506 (accesses on August 31, 2002).

[109] *Id.*

Bio-terrorism

Bio-terrorism is a criminal act, involving the intentional or threatened uses of viruses, bacteria, fungi, toxins from living organisms, or chemicals, to produce death or disease in humans, animals, or plants. Bio-terrorism can be described as the use, or threatened use, of biological agents to promote or spread fear or intimidation upon an individual, a specific group, or the population as a whole for religious, political, ideological, financial, or personal purposes.[110] The layperson definition of bio-terrorism would be, to create a sense of terror in a person's mind by utilization of biological techniques or weapons, as they are generally referred to as. The expenditure involved in conventional terrorism is by far much higher than that compared to bio-terrorism, hence bio-terrorism is a more convenient and an easier implemented form of terrorism.

Biological weaponry has been used to promote terror since time immemorial. The history of bio-terrorism traces right back to 6th Century BC, when the Assyrians contaminated their enemy wells with rye ergot, continues to the time when the Tartars catapulted the bodies of bubonic plague victims over the walls of the city of Kaffa, killing approximately 25 million people in medieval Europe, and brings us to the more recent September 11-related attacks in the US, the 'anthrax scare' being one of the most 'media-hyped' of all. Modern bio-terrorism may be carried out via agents such as anthrax, smallpox virii, Botulinum Toxin, plague or the Yersinia Pestis virus, Tularemia virus, Brucella virus or any other hemorrhagic fever viruses.[112]

Bioterrorism and the law

The threat of a bio-terrorist attack opens up many difficult legal questions; the nature of the issue, itself, is set in a unique legal environment.[113] The study of bio-terrorism and issues involved therein makes one delve into varied realms, such as public health, criminal law, national security, the environment and the rules of war, among others. Since it cannot be pigeonholed neatly into any single category, there is a need, at the domestic level, for the effective coordination of resources, personnel, training and equipment among all relevant authorities at the federal, state and local levels.[114] The problem is that the applicability of such resources and its entailing consequences have to be thought through thoroughly. Drawing from the (US) National Commission on Terrorism (otherwise known as the Bremer Commission), there are four components of the legal aspect of bio-terrorism:

- Foreign intelligence;
- Law enforcement;
- Military; and
- Public health.

By far, the United States of America has a well-defined set of guidelines to combat biological warfare and bio-terrorism. Title 18 of the U.S. Code, vide Sections 175[115], 1716 and 2332(a)[116]

[110] Arizona Department of Health Services, *Definition of Bioterrorism*, HYPERLINK "http://www.hs.state.az.us/phs/edc/edrp/es/bthistor1.htm" http://www.hs.state.az.us/phs/edc/edrp/es/bthistor1.htm (accessed on August 31, 2002).

[112] American Medical Association, at HYPERLINK "http://pubs.ama-assn.org/bioterr.html" http://pubs.ama-assn.org/bioterr.html (accessed on August 31, 2002).

[113] Suzanne Spaulding, "*Bioterrorism – Legal initiatives for prevention/deterrence*", at HYPERLINK "http://cns.miis.edu/cns/dc/041701.htm" http://cns.miis.edu/cns/dc/041701.htm (accessed on August 31, 2002).

[114] *Id.*

[115] Title 18, US Code, S. 175: "Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or

[116] Title 18, US Code, S. 2332(a): "A person who, without lawful authority, uses, threatens, or attempts or conspires to use, a weapon of mass destruction... including any biological agent, toxin, or vector...against any person within the United States, and the results of such use affect interstate or foreign commerce or, in the case of a threat, attempt, or conspiracy, would have affected interstate or foreign commerce; or...against any property that is owned, leased or used by the United States or

envisage comprehensive rules of punishment to be meted out to the '*bio-terrorist*'. Although India has the comprehensive Terrorist and Disruptive Activities (Prevention) Act, 1987, this Act does not make provision for 'bio-terrorism' as such. Hence keeping in mind the rising need for legislation to regulate this growing problem, India requires major re-vamping of the laws to tackle bio-terrorism, biological warfare and the related issues, *in specie*.

VI. BIOTECHNOLOGY & BUSINESS LAW

The complex nature of the biotechnology industry brings with it a multitude of corporate and finance issues, which require diverse legal expertise. Under the current regulatory framework drug discovery and innovations in biotechnology is risky, expensive and time-consuming. Success in the industry is largely dependant not only on the strength of research capabilities, but also on the emergence of methods of financing high-risk long-term biotechnology research until commercialization. Servicing the biotechnology industry requires a comprehensive understanding of the array of needs and challenges facing biotechnology corporations. A co-coordinated, multidisciplinary approach is required to provide legal services at every stage of development of a biotechnology company.

Collaborations and strategic alliances are some of the key commercial vehicles used by biotechnology enterprises to unlock the value in their IP. Because of the increasing costs of R&D, collaborations, with MNCs, and strategic alliances have become useful catalysts to share risk and get new ideas to market. Structuring, negotiating and drafting private placement, venture capital investments, as well as complex financing agreements for biotechnology companies play a significant role in maximizing ones potential. Any biotechnology company or start up seeking venture capital funding will be faced with a number of legal issues in addition to the negotiation as far as the business is concerned. The legal issues arise either at the stage of the parties documenting their intention or at the stage when some concrete decision to invest has been made.

Further, licensing strategies are critically important to a biotechnology company's growth and economic viability companies.[117] Licenses for biotechnology-derived products necessarily involve unique subject matter, sometimes not-so-obvious derivative products and the transfer of information to successfully implement biotechnology inventions. The most competitive biotechnology companies establish and maintain a dominant market position by using innovative licensing methods. Strategic licensing methods can be used to divide intangible property rights and yield maximum gain from product development, related technology, technological know-how, packaging, commercialization and commercial product use. Therefore, the essential factor in providing business law services to biotechnology companies is to draw upon the expertise of existing areas such as corporate law, tax etc., to provide clients with the best possible representation.

VIII. BIOETHICS

Science and technology have played an important role in improving the quality of mankind. However, they have also contributed to the deterioration of the social and natural environment due to the extensive and irrational utilization of natural resources. Biotechnology is more than just a scientific issue; some regard it as interfering with the workings of nature and creation. On one hand, we have the scientific community assuring us that biotechnology is innocuous, and promises tremendous advantages to humankind, even that it may be the key to our survival in an ever-changing world. On the other hand there exist a diverse array of arguments about the right of man to interfere in nature or God's process

by any department or agency of the United States, whether the property is within or outside of the United States, shall be imprisoned for any term of years or for life, and if death results, shall be punished by death or imprisoned for any term of years or for life.".

[117] Pamela Winston Bertani, *Tips for Licensing Biotechnology,* HYPERLINK "http://www.wirepaladin.com/biotip.htm" http://www.wirepaladin.com/biotip.htm (accessed on January 4, 2002).

and the dangers to the environment, the food chain and ultimately our own health.[118] Such issues are largely related to cultural backgrounds and levels of public perception and awareness. It is therefore necessary that decisions on the use of new technologies should respect socio-economic realities. Public understanding of biotechnology as a science and technology is important because the products of biotechnology and consequent benefits and risks are ultimately going to affect everyone. Biotechnology holds great promise as a tool to preserve and enhance environmental quality. Years of plant breeding show that genetics is the most cost-effective, environmentally safe way to address problems that reduce yields. But without public understanding, acceptance, and support, the role that biotechnology could play in solving environmental and food production problems could be stymied.

IX. GOING FORWARD

Partnering activity between industry and academia and foreign collaborations by Indian companies has received a major boost. These alliances involve contract research and manufacturing, co-marketing, technology transfer and joint Research & Development (R&D) agreements.

Explains Utkarsh Palnitkar, Health sciences Industry Leader, Ernst & Young India, " With the global industry's current focus on accelerating productivity, collaboration is the way forward for several American and European companies faced by resource constraints. With its abundant high quality-low cost technical manpower, India is emerging as a partner of choice. Though intellectual property protection in the country continues to be a bugbear, several Indian companies have managed to cross IPR hurdles to work with international partners through confidentiality and non-disclosure agreements. The effective implementation of the WTO mandated product patent regime on the anvil will give further impetus to a change in perception."

Partnering is equally an imperative for Indian companies as they are increasingly pursuing a resource-intensive, product-driven model for sustainable growth in the wake of the new IPR regime. Indian biotech companies had initially emulated the information technology sector's service based model to earn early revenues. "India's major biopharmaceutical companies are now accelerating efforts to get bio-equivalent versions of patented, well-characterized recombinant proteins onto the market before the window closes in 2005. The small biotech companies are focusing on innovative research, and are picking niches where there is little competition.

Other players benefiting from an intellectual property driven model are bio-informatics companies, " adds Utkarsh Palnitkar. The report also notes that the market for generic biotech products will increase over the next few years, as many products will be coming off patent. Asia-Pacific nations such as India and China are emerging as major players in the development of a global market for biogenerics. Both countries are positioned to take advantage of moves by Governments in the U.S. and Europe to create a regulatory framework for approving generic versions of successful protein drugs. Several new sources of capital and government policy changes will also benefit the Indian industry, says the report. These include allowing insurance companies to invest in biotech venture funds and the Indian government's decision to raise the cap for foreign investment. This will make it easier for foreign venture capitalists to invest in Indian biotech companies. Biotech has been relatively new ground for the Indian venture capital community, though there have been some initiatives like the APIDC fund launched last year and announcements by the Department of Biotechnology and the Technology Development Board to launch funds. A lukewarm capital market in 2003 deterred leading Indian biotech companies from holding initial public offerings.

Globally, a combination of smart business decisions and product advances has renewed investor interest in biotech stocks and financings. The biotech index, which includes US, Canadian and

[118] University of Melbourne, *Biotechnology Issues and Ethics: Industry and Alternative Perspectives*, at HYPERLINK "http://www.arts.unimelb.edu.au/amu/ucr/student/1996/b.schiemer/" http://www.arts.unimelb.edu.au/amu/ucr/student/1996/b.schiemer/ (accessed on August 31, 2002).

European companies, soared 60 per cent from March 2003 – March 2004, and outperformed the NASDAQ, Dow Jones and S&P 500 (all on an upswing). Many European firms and US experienced their second-best financing year in history. Venture funding in the US jumped 31 percent, but declined by 10 percent in Europe in 2003.

"Our analysis around the globe indicates that biotechnology is leading the new health economy _ in which hospitals, biotech, pharmaceutical and medical device companies form a network of health care innovation, working beyond borders through investments, data sharing, and product development collaborations, " notes Rajiv Memani. The benefits of collaborations at a global level were evident throughout 2003 as almost half of the 25-biotech drugs approved by the Food and Drug Administration (FDA) came from biotech-pharma collaborations. Global biotech revenues of public companies totaled $46.6 billion in 2003 ($ 39.8 bn in 2002). More than three fourths of this revenue continues to come from the US, with Europe contributing 16 per cent (21 per cent), Canada with 4 per cent (4 per cent) and Asia-Pacific 3 per cent (3 per cent). Though the Asia-Pacific share in global revenues is comparatively lower, the region outperformed Europe in revenue growth, R&D expenses and increases in the number of companies and employees

According to the report, "Biotechnology now has the potential to replace information technology as the engine of economic development for the Asia Pacific region. It is a region whose biotech engine is revving loudly, fueled by aggressive government funding, that likely will drive many nations over the next decade to surpass competitors in Europe and begin to challenge the U.S. for global dominance in production of biotechnology products."

Biotechnology has very good future in India. There is a lot that can be done to benefit India, using biotechnology. For example, new pest and drought resistant crops will help India in becoming a leader in rice and other crops. Potential business opportunities exist for foreign bioscience firms seeking research and business alliances with Indian firms. Other market segments are contract research and manufacturing services, research/ medical instruments, biomedical devices, research reagents, aquaculture, waste treatment and bio-fertilizer. A proper balance between strategic research, product planning and effective collaboration will help support biotech growth in India. Partnerships with global biotech industries have the greatest impact on India's own bio-business markets.