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THE CONSERVATIVE PATH TO BIOTECH PROTECTION

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India has come a long way in protecting biotech inventions in the past decade. But, argue Sanjay Kumar and Deepa Kachroo Tiku of Remfry & Sagar, more progress is needed

"You can patent a table that you build from a tree, but you cannot patent the tree itself"
William Haseltine, president of Human Genome Science

According to the OECD, biotechnology is the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services. The biotechnology industry is one of the fastest growing knowledge-based industries in India. Investment touched $2.8 billion in the financial year 2007-08 and is forecast to reach about $13 billion to $16 billion by 2015, according to Cybermedia. The top 10 biotech companies in India are listed in table 1.

Protection of intellectual property provides encouragement for breakthrough innovations. It is, therefore, important that a strong IP regime be in place. With the objective of becoming a global player, India has transformed its patent law to enhance protection of inventions relating to biotechnology/life sciences.

Table 1: Top 10 Indian biotech companies

Rank 2008	Company	Biotech revenue in million rupees				Change over 2006-07
		2007-08	2006-07	2005-06	2005-04	
1	Serum Institute of India	9870.0	9509.5	7300	5050.0	4%
2	Biocon	9120.0	8490.0	6890.0	6610.0	7%
3	Panacea Biotec	6779.8	7011.3	4378.2	2172.9	-3%
4	Nuziveedu Seeds	3030.0	2264.2	625.2	-	385%

5	Rasi Seeds	2932.8	3333.3	3094.9	868.7	-12%
6	NovoNordisk	2600.0	2220.0	1750.0	1400.0	17%
7	Novozymes South Asia	2250.0	1000.0	830.0	690.0	125%
8	Indian Immunologicals	1960.0	1579.0	1022.0	830.0	24%
9	Mahyco	1700.0	1106.9	1177.6	1660.0	54%
10	Syngene International	1600.0	1320.0	980.0	660.0	21%

Source: Biospectrum – Able Biotech Industry Survey, 2008

PRE-1995 PATENT LAW

The Patents Act, 1970 came into force on April 20 1972. Under the Act, an invention was defined as "any new and useful art, process, method or manner of manufacture, machine, apparatus or other article, substance produced by manufacture and any new and useful improvement of any of them". No product patents were available for substances intended for use or capable of being used as a food, drug or medicine as well as for products of chemical processes. Needless to say, living organisms and biologically active material including recombinant DNA and the processes for preparing them were also not patentable.

Patentability of inventions relating to biological inventions was largely governed as per the office instructions of the Controller General of Patents, Designs and Trademarks dated July 15 1991, which provided:

1. Inventions relating to organisms or biological material per se viz (a) living entities of natural or artificial origin such as animals, plants and microorganisms, biological material such as plasmids, viruses, genes, recombinant DNA, bacteria, fungi, algae and other materials having self replicating properties and parts thereof, (b) naturally occurring substances from living entities, biological materials and also processes for their production, were not patentable under the Act.
2. Inventions relating to process or method of production of tangible and non-living substances like enzymes, antibiotics, insulin, hormones, interferons, alcohols by bioconversion or using such microorganisms or by utilizing the above referred biologically active substances as well as chemical substances produced by using genetically engineered organisms or such existing substances made more economically by use of biotechnology and/or microbiology were considered patentable under the Act.

India, thus, generally had narrow patent protection, especially in the area of biotechnology. This was contrary to the fundamentals of the World Trade Organisation TRIPs Agreement, to which India became a signatory effective from January 1 1995.

POST-TRIPS PATENT LAW

India being a developing country, a transition period of 10 years was accorded to it under TRIPs to comply fully with its provisions. Consequently, the Act was amended in three stages: effective March 26 1999 with retrospective effect from January 1 1995; May 20 2003 and January 1 2005.

The Patents (Amendment) Act, 1999 provided a scheme for filing applications for product patents in the areas of pharmaceuticals and agro-chemicals as Black-Box or Mail-Box applications. However, these applications were to be examined only after December 31 2004.

The Patents (Amendment) Act 2002, which came into force on May 20 2003, introduced Section 3 (j) to the Act, which was a landmark amendment in terms of broadening the scope of patentability of inventions relating to biotechnology/life sciences, in particular living organisms. Section 3(j) precludes the patentability of "plants and animals in whole or part thereof *other than microorganisms* but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". However, to ensure that only microorganisms prepared by human intervention were allowed to be patented, Section 3(c) was amended to include a bar on patentability of "discovery of any living thing or non-living substance occurring in nature".

Importantly, the 2002 amendment also said that "chemical processes" included "bio-chemical", "biotechnological" and "microbiological" processes. Thus, processes relating to biotechnology inventions became patentable. In 2005, after rigorous debate in both Houses of the Indian Parliament, the Act was further amended and a fully fledged product patent regime came into force on January 1 2005.

Today, product patent protection is possible in all fields of technology including food, drugs, chemicals and biotechnology/life sciences. Additionally, plant varieties are given protection under the provisions of the Protection of Plant Varieties and Farmers' Rights Act, 2002. Table 2 shows the number of patent applications related to biotechnology/life sciences inventions filed and granted since the 2002 amendment.

Table 2: Lifesciences/biotech patents

Year	Number of applications filed	Number of patents granted
2003-2004	23	0
2004-2005	1214	71
2005-2006	1525	51
2006-2007	2774	89
2007-2008	4138	1626

Source: Annual Report, Indian Patent Office, 2007-08

Interestingly, no patent was granted for biotechnological inventions in the year 2003. However, from 2004 onwards, the data has been promising as it indicates a steady increase in the number of filings and grants in the field of biotechnology.

INDIAN PRACTICE

What is patentable?

- Biological materials such as DNA, plasmids and processes of manufacturing thereof.
- Micro-organisms and vaccines and processes related thereto.

- Expressed sequence tags (ESTs), gene sequences and DNA sequences provided their functions are properly and sufficiently disclosed in order to establish inventive step and industrial applicability.
- Biotechnological entities such as nucleotides and amino acid sequences, provided their functions are properly defined in the description and the full sequence listing (in soft copy) is filed at the Patent Office.

What is not patentable?

- Naturally produced antibodies and cells (including stem cells).
- Living entities of natural origin such as animals, plants in whole or any part thereof, plant varieties, seed, species and processes of preparation thereof.
- Biological materials such as organs, tissues, cells, viruses and processes relating thereto.
- Any biological material and method of making the same which is capable of causing serious prejudice to human, animal or plant life or health or to the environment including the use of which would be contrary to public order and morality (such as terminator gene technology).
- Essential biological processes for the production of plants and animals such as methods of crossing or breeding.
- Processes for cloning human beings or animals, processes for modifying germ lines or genetic identity of human beings or animals and any use of human or animal embryos for any purpose.

INTERESTING CASE LAW

Dimminaco AG v Controller of Patents & Designs and others (AID No 1 of 2001) is a landmark case in which Dimminaco, a Swiss company, applied for a patent for "the process for preparation of a live vaccine for bursitis" (bursitis is an infectious poultry disease and the invention involved a live (attenuated) vaccine to combat the disease).

The Controller of Patents refused to allow the application on the ground that a vaccine with a living organism could not be considered a substance and the process for preparation of the vaccine involved a living entity and thus could not be considered as "manufacture" under Section 2(1)(j) of the Act, which defines an invention as "any new and useful art, process, method or manner of manufacture, machine, apparatus or other article, substance produced by manufacture and any new and useful improvement of any of them".

However, on appeal, the Calcutta High Court rejected the Controller's finding. The Court held that there was no statutory bar to accepting a manner of manufacture as patentable, even if the end product contained a living organism. The Court also held that the dictionary meaning of the word manufacture did not exclude the process of preparing a vendible commodity which contained a living substance and in a case such as the one at hand, in the absence of a statutory meaning of manufacture, the dictionary meaning must be accepted.

In addition, it was stated that if the invention resulted in the production of some vendible items or improved or restored formal conditions of vendible items or had an effect on preservation and prevention from deterioration of some vendible products, then such an invention would pass the vendibility test. The court further held that since the claimed process for patent led to a vendible product, it was certainly a substance after going through the process of manufacture. Consequently, the order of the Controller was quashed.

GOVERNMENT INITIATIVE

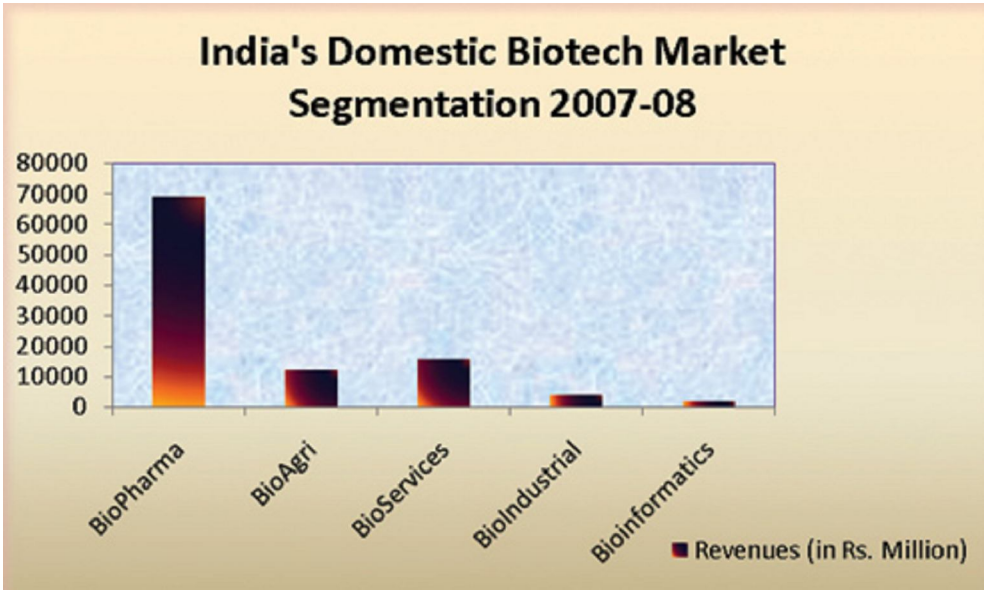
After the 2005 amendment to the Act, the government had set up a technical expert group (TEG) chaired by R A Mashelkar (the former director general of Council of Scientific & Industrial Research – CSIR) to evaluate (1) whether it would be TRIPs-compatible to limit the grant of a patent for a pharmaceutical substance to a new chemical entity or to a new medical entity involving one or more inventive steps; and (2) whether it would be TRIPs-compatible to exclude micro-organisms from patenting.

The revised report of the TEG concluded that excluding micro-organisms *per se* from patent protection would be in violation of TRIPs. The group pointed out as India is a country rich in bio-diversity, it would be prudent to protect biotechnological inventions as that would help Indian biotechnology research compete globally and attract collaborations, FDI, contract R&D etc. Further, it was stated that India needed to reap due benefits from its rich bio-resources with an enabling provision for protection of intellectual property in biotechnological innovations and inventions.

The report further added that there had been instances of patenting of Indian biological materials by other countries. It would, thus, be in India's interest to document, protect and modify new micro-organisms isolated from various parts of the country and find their new and improved industrial uses.

The government also set up a task force in July 2006 to recommend measures for increasing exports of pharmaceutical products which came out of its report in December, 2008. One of the terms of reference was to act as a think tank and make appropriate policy recommendations for boosting pharmaceutical exports. Encouragingly, biotech exports grew to Rs57.3 billion in 2007-08, biopharma accounting for 70% of the total. The Indian domestic biotech market segmentation *vis-à-vis* revenue (2007-08) is shown in figure 1. This data indicates that biopharma leads other segments by a long way.

Figure 1



Source: BIOSPECTRUM – Able biotech industry survey, 2008

Further, the Union Budget, 2009-10 has allocated a total of Rs6650 million ($137.5 million) to the biotech sector. Of this, Rs3410 million is for research and development, Rs2790 million is for autonomous R&D institutes and Rs450 million has been allocated to excellence and innovative programmes.

In addition, Kiran Majumdar Shaw, CMD, Biocon Limited, has noted that reduction in Customs duty and exemption from excise and countervailing duty on specified life-saving drugs/vaccines – such as those for breast cancer, hepatitis-B and rheumatic arthritis, bulk drugs thereof and certain heart devices – would help the biotech industry.

THE WAY FORWARD

Until now, India has been treading a conservative path in patenting life forms and there are still many lacunae in our policies and systems, which must be tackled to ensure robust growth for the biotech sector in the future. To this end, we recommend the following steps:

1. Provision of incentives for R&D, transfer of technology from laboratories and the creation of new firms by public researchers.
2. Setting up of specialised IP courts. Legal protection remains a very complex issue in general, and is especially sensitive in case of biotechnology, because of the involvement of technical and ethical issues.
3. A biotechnology directive with clear guidelines for patenting of biotechnological inventions must be framed to render uniformity to Patent Office decisions.
4. Organisation of training programmes for examiners and Controllers at the Patent Office to handle biotechnology-related inventions in keeping with international biotechnology guidelines.
5. Formation of a biotechnology think tank by the government to oversee contentious matters involving biotechnology/life sciences.
6. The draft Manual of Patent Law and Practice (2008) ought to be formalised as soon as possible.

Though the government continues to support biotechnology, it needs to be more proactive as India has the potential to be on the "to reckon with" list of countries in the coming years.

SANJAY KUMAR

Sanjay Kumar is a partner of Remfry & Sagar. He has a graduate degree in science and holds a masters degree in law. With 15 years in the profession, he has in-depth knowledge of patent law with extensive experience in patent prosecution and litigation. He is also actively involved in patent policy issues with the patent authorities in India. He is a member of several international IP associations and has authored numerous articles on patent law and practice.

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Deepa Tiku is a consultant with Remfry & Sagar and holds a PhD and masters degree in biotechnology. A registered patent agent with more than five years of experience in patent law, she

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