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BIOTECHNOLOGY AND IPR: THE IMPORTANCE OF PATENT IN THE INDIAN PERSPECTIVE BY AMIYA KUMAR PATI & ANKIT SINHA *

INTRODUCTION

The biotech policy of India is continuously evolving but its basic concepts have been settled for creating a vibrant industry. The Indian biotechnology industry was slow to start but gained momentum and is now booming following the software sector. The current share in the global market in the global market is just 1.1%, but the Indian industry has the necessary ingredients to become a prominent player in the global biotech market.[1]

India's biotech sector is today among the top five in the Asia pacific region. India shows immense potential not only as a destination for new generation pharmaceuticals, biotech products and diagnostics but is also becoming an important hub for outsourcing of clinical traits and contract research.

Though India is yet to introduce a novel biotechnology product, it has strong science support and the potential to generate revenue of $5 billion and a million jobs by 2010. Over the past two decades, the Indian biotech sector has witnessed a number of scattered and sporadic initiatives on the academic and industrial front.[2]

Biotechnology patent applications experience numerous restrictions, due to the undefined scope and complex nature of the technology. The biotech IP scenario changed in the US through the involvement of an Indian Scientist, Ananda Chakrabarty whose oil-eating bacteria became the first micro-organism to be patented. The non-patentable status of living organisms in India changed with the landmark decision on January 15, 2002 when the Kolkata High Court granted a patent to Dimminaco AG for an invention involving lyophilized micro-organism. Deciding the scope of patent protection for biotechnological inventions is a difficult task, as it raises a number of technical and ethical issues.[3]

PRODUCT PATENTS

Before 1995, the patent regimes in India provided protection for processes rather than products. After becoming a member of TRIPs on January 1 1995, India promulgated an ordinance amending the Patent Act 1970 to receive product applications in the field of pharmaceuticals and agrochemicals (Mailbox applications) and also to grant Exclusive Marketing Rights (EMR) for these product for five years. This Ordinance lapsed but the Patent Office continued to receive the product applications. In March 1999 the patent (Amendment) Act 1999 was enacted and came into force with retrospective effect from January, 1995 with the provisions of the ordinance. This Act regularized the filing of mailbox

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[1] http://www.mondaq.com/india/x/247410/Life+Sciences+Biotechnology/Biotechnology+And+Allied+Sciences+Patent+Provisions+In+India, last visited on 28.08.2014

[2] Krishna M. Dronamraju, Emerging Consequences of Biotechnology (World Scientific 2008)

[3] http://dbtindia.nic.in/uniquepage.asp?id_pk=56, last visited on 28.08.2014

applications. Once India had started receiving the mailbox applications for product patents, it immediately received 1,312 applications for patents on pharmaceutical products, becoming the second country behind only the US. The patents (Amendment) Act 2005 was enacted in April 2005 and came into force with effect on January 1, 2005. Accordingly, in 2005 the mailbox applications were opened for examination.

The product patent applications other than the mailbox applications, which were filed between January 1, 1995 and December 31 2004, were not considered as patentable after January 1, 2005 as per the instructions of the Controller General.[4] However, in Auguron Pharmaceuticals Inc vs. Controller of Patents, the Honourable High Court of Kolkata held that an application for a patent prior to January 1 2005 has to be considered in accordance with the patents Act 2005. Pursuant to this order, the Controller General in September 2005 withdrew his earlier instructions and ordered that all applications filed and pending before January 1, 2005 containing product claims shall be examined in accordance with the Patents Act 2005 as per the directions of the Court.

The Swiss drug maker F Hoffmann-Roche became the first pharmaceuticals company in India to receive product patent under the new patent regime in 2006. The Patent Office granted the product patent to Roche for Pegasys, a new generation Hepatitis therapy drug, for an application filed under the mailbox facility. This necessarily means that no other company will be allowed to launch a generic version of the drug in India for 20 years from May 15, 1997. This development should now see more companies getting their technically complex products patented under the new patent rules.[5]

ROLE OF GOVERNMENT IN BIOTECHNOLOGY SECTOR

The national science and technology policy of the government and the Vision Statement on Biotechnology has been issued by the Department of Biotechnology (DBT) to provide a framework and give strategic direction to different sectors to accelerate the pace of development of biotechnology in India.

This policy further aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, therapeutic and medical biotechnology, regenerative and genomic medicine, diagnostic biotechnology, bio-engineering, nano-technology, bio-informatics and IT-enabled biotechnology, clinical biotechnology, environment and intellectual property and patent law.[6]

For the sector of IP rights, the key strategic actions include: increasing scientific manpower, which encourages science graduates to pursue law for a better understanding of IP-related issues and inclusion of these in the curriculum of law colleges to facilitate filing of international patents, license negotiations and dispute resolution; and a budget allowances of Rs 50 crore in the Innovative Development Fund to enable research scientists at a academic laboratories to develop scientific innovations from a concept from a concept to a form that is

[4] Sachin Chaturvedi, Dynaimcs of Biotechnology Research and Industry in India: Statistics, perspectives and Key Policy Issues, 35-62 (Organisation for Economic Cooperation and Development, 2006)
[5] http://www.nature.com/nbt/journal/v32/n2/full/nbt.2809.html, last visited on 28.08.2014
[6] David Castle, The Role of Intellectual Property Rights in Biotechnology Innovation (Edward Elgar Publications 2009)

licensable. The creation of biotechnology parks is another initiative of the Indian Government to promote biotechnology.

The Small Business Innovation Research Initiative (SBIRI) scheme through the Department of Biotechnology is to be instituted to support small and medium sized enterprises through a grant/loan. Companies with up to 1000 employees will be eligible for financial support. The recommendations of the Swaminathan Committee on the regulation of agri-biotech products and of the Mashelkar committee on recombinant pharma products demonstrate the active role of government in these areas.[7]

The Indian Patent Act provides for the provision of parallel importation as well as compulsory licensing. Parallel import is a mechanism that helps in price control. Compulsory licenses are granted if the reasonable requirements of the public have not been satisfied, or a patented invention is not available at a reasonable affordable price or the patented invention is not worked in India. It is worth noting here that though the grant of a patent provides the right of importation of the patent invention, importation is not considered as the working of a patent. Accordingly patents that are not worked in India are attracted by compulsory license provision[8]

A compulsory license on notification by central government for public interest is permitted in exceptional circumstances such as national emergency; extreme urgency; and public non-commercial use. There is also a provision for the grant of compulsory licenses to manufacture and export patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product. This is an exceptional provision to address public health problems, provided the country has granted a compulsory license or has by notification or otherwise allowed importation of the patented pharmaceutical product from India.

The government recognizes that the development if capabilities for the effective management of IP is an important element In securing the benefits of public and private sector research in the field of pharmaceuticals and biotechnology.

PATENTING BIOTECHNOLOGY INVENTIONS IN INDIA

The Indian Patent Office considers biotechnological inventions to be related to living entities of natural origin, such as animals, human beings including parts thereof, living entities of artificial origin, such as micro-organisms, vaccines, transgenic animals and plants, biological materials such as DNA, plasmids, genes, vector, tissues, cells, replicons, processes relating to living entities, processes relating to biological material, methods of treatment of human or animal body, biological processes or essentially biological processes.[9]

The following biotechnological inventions are not considered as patentable under Section 3 of the Indian Patent (Amendment) Act 2005:

[7] http://www.nistads.res.in/indiasnt2008/t5output/t5out12.htm, last visited on 29.08.2014
[8] Ashok K.Chauhan, A Textbook of Molecular Biotechnology (I.K. International Pvt. Ltd. 2009)
[9] T. Ramakrishna, Innovation, Invention in Biotechnology and Intellectual Property Rights Law: Can India Catch The Bus? (3rd Edition, 2008)

- Living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organisms.
- Any process of manufacture or production relating to such living entities
- Any method of treatment such as medicinal, surgical, curative, prophylactic, diagnostic and therapeutic, of human beings or animals or other treatments of similar nature
- Any living entity of artificial origin such as transgenic animals and plants, or any part thereof.
- Biological materials such as organs, tissues, cells, viruses and all the process of preparing them.
- Essentially biological processes for the production of plants and animals such as method of crossing or breeding
- Any biological material and method of making it which is capable of causing serious prejudice to human, animal or plant lives or health or to the environment including the use of those that would be considered contrary to the public order and morality such as terminator gene technology.
- Processes for cloning human beings or animals, processes for modifying the germ line, genetic identity of human beings or animals, uses of human or animals embryos for any purpose are considered to be against public order and morality.
- Any invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components.

Gene sequences and DNA sequences without their function disclosed are considered to be not patentable for lack of inventive step and industrial application. Bioinformatics can play a role in characterizing the gene sequences and thereby increasing their chances of patentability.[10]

However, according to the Indian Patent Act 2005, living entities of artificial origin such as microorganisms and vaccines are considered patentable. Biological material such as recombinant DNA, plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention. The processes relating to microorganisms or producing chemical substances using such microorganisms are also patentable.

If biological material is used in the invention is disclosed in the patent application the source or geographical origin of that material must be mentioned in the specification.[11]

MEDICAL BIOTECHNOLOGY

In India, the pharma industry is one of the first to reap the benefits of biotechnology. Human health biotechnology products account for about 60% of the domestic market, while biodrugs, vaccines and diagnostics have significant market shares as well. Consequently, Indian pharma is beginning to harvest the benefits from enhanced IP protection of their products. An example is Ranbaxy's NDDS for Ciprofloxacin licensed to Bayer for $65 million plus royalties. Other Indian research based companies have

[10] http://www.jurisnotes.com/IP/articles/patentsbio.htm, last visited on 29.08.2014
[11] Janice M. Mueller, Biotechnology Patenting in India: Will Bio-Generics Lead a 'Sunrise Industry' to Bio-Innovation? (No. 2, 2008 ed. University of Missouri-Kansas City Law Review 2008)

earned about $70 million from R&D milestone payments. CSIR has also earned revenues by licensing its patents to the industry.

The Indian Patent Office received 15 applications for the grant of Executive Marketing Right (EMR). Of these, three have been allowed, four rejected and the remaining eight are pending. The Patent Office has become more open to the grant of EMR's. Novartis was the first company in India to be granted an EMR by the Indian patent Office for a blood cancer drug, GLIVEC. Smithkline Becham challenged the order in a writ petition before the Delhi High Court. This writ was dismissed for want of territorial jurisdiction. However, Novartis won a stay from the Madras High Court restraining six drug companies from manufacturing and distributing Imatinib Mesylate – the active ingredient in Novartis' Glivec. The EMR provision is no longer in force from January 1 2005.

Medical biotechnology offers a good possibility for Indian industry to establish a strong pharmaceutical sector, a growing number of small and medium biotechnology companies, a large network of universities, research institutes and medical schools and low cost of product evaluation.

CLINICAL BIOTECHNOLOGY AND CLINICAL RESEARCH

India has made tremendous progress in clinical biotechnology over the past few years and has the potential to be a key player in this highly remunerative area. There is also an exciting opportunity of conducting longitudinal studies in disease segments for prospecting new biomarkers and novel pharmacogenomic information – both yielding high value intellectual property.[12]

With the global pharmaceutical companies looking outward to reduce their ballooning research costs, India is in a good position to tap the new business opportunities. Due to the emphasis on outsourcing to cut costs and retain competitiveness, India is being considered as a destination for contract research in the pharma sector.

Data exclusively is a prerequisite of research efforts, decisions on where to conduct clinical trials and the amount of foreign investment in the pharmaceutical and biotech sectors. India is yet to comply with the TRIPs requirement of providing data exclusively[13]. The IP environment needs to be upgraded to have a mechanism or standard for contract sharing. Industry needs to collaborate with academia and a code of conduct for biotech members has to be designed. Further, the regulatory issues are all in a very naïve stage such as the draft guidelines for stem cell research by ICMR.

The clinical trials/contract research industry in India gets a boost due to the presence of a Bolar provision in the Indian Patent Act 2005. Under this provision the patented invention can be used for the purpose of collecting data such as the clinical trial data, for approval from the appropriate authority. This ensures that hen the term of the patent

[12] HS Chawla, Patenting of Biological Material and Biotechnology, 44-51 (Journal of Intellectual Property Rights 2005)
[13] http://www.teriin.org/index.php?option=com_ongoing&task=about_project&pcode=2008GL02, last visited on 29.08.2014

expires, the manufacturer need not wait for clinical trials/DCGI approvals etc., and straightaway go for manufactures.[14]

BIOINFORMATICS

Bioinformatics has proved to be a powerful tool for advanced research and development in the field of biotechnology. As the full genome sequences, data from micro arrays, proteoics as well as species data at the taxonomic level became available, integration of these databases requires sophisticated bioinformatics tools. Organizing these data into suitable databases and developing appropriate software tools for analyzing them are major challenges. India has the potential to develop such resources.

In India, Informatics for life sciences is an emerging sector: the market size is still quite limited.[15] India has strengths in chemistry and computer science, software, healthcare and biology.

However, bioinformatics may not constitute patentable subject matter since it would come under the purview of Section 3(k) and 3(n) if the Indian Patent Act. However, if the bioinformatics tool can be proven not to be a computer program per se, it may be patentable.

AGRICULTURE BIOTECHNOLOGY

To comply with the TRIPs agreement, India adopted a sui generis system for plant variety protection. The Indian Parliament enacted the protection of Plant Varieties and Farmer's Rights Act of 2001 in order to spur the development of new varieties of plants by providing protection for developers of new plant varieties.[16] But the protection available through patents is also available for various plant related/derived products.

A study by TIFAC shows that in India 484 applications have been filed specifically referring to plants between November 1994 and December 2003. These applications include 89 convention applications and 132 PCT applications. The top applicants were CSIR, Avestha Gengraine, JB Chemicals and pharma ltd., ICAR, Aventis Corp Science GMBH and Novartis. The most important thing to observe is that patents are possible for many aspects of a plant and its utilization except the plant per se. The applicant should look at multiple forms of protection and not just think in terms of protecting plant per se.[17]

With respect to infringement of registered seeds under the Seeds Act, there are been important decisions to protect them with help of biotechnology. In Emergent Genetics India Pvt Ltd. Vs. Shailendra Shuvam[18], the Delhi High Court applied the principles of the law of confidentiality in giving protection to hybrid cotton seeds which are genotypically identical. Emergent owned a copyright in the unique DNA sequence if a hybrid variety of cotton seeds. A tort of breach of confidential information was found that

[14] Biotechnological Innovations Patent: A Review 131-135 (2nd Edition, ISSN 0976-044X Rishabha Malviya 2010)
[15] http://www.bananaip.com/sinapse-blog/2011/01/patentability-of-biotechnology.html, last visited on 29.08.2014
[16] Jayshree Watal, Indian patent Law on Biotechnological Inventions, 79-83 (4th ed. Asia Pacific Biotech 2000)
[17] http://biotechpatentattorney.wordpress.com/, last visited on 29.08.2014
[18] I.A. Nos. 388/2004 (U/S 39 R 1 & 2)

the ex-employee defendants received while employed by Emergent.[19] The Court restrained the defendant from marketing and selling the said cotton hybrid seeds based on the DNA fingerprinting results. The principles of the copyright law were applied to protect unique sequencing information locked inside genes of hybrid varieties of the plaintiff. This approach was necessitated by the fact that the Protection of Plant Varieties and Farmer's Rights Act had not been notified then.[20]

The Protection of Plant Variety and Farmer's Rights Act, 2001 along with the Rules, 2003 were notified in March, 2005, and are expected to come into force soon. The Protection of Plant Variety and Farmers Right Authority is being constituted and is expected to be active soon. The registration process would require DUS(Distinctness, Uniformity and Stability) testing of the plant varieties by the authorities. DUS testing centres have been identified based on the crop and area. Guidelines for DUS tests to be performed have also been prescribed for different crops. However, the guidelines to be followed for registration of transgenic plants are not clear. The biotechnological processes involved in producing the transgenic are patentable subject matter.

NATIONAL BIOLOGICAL AUTHORITY AND TRADITIONAL KNOWLEDGE

The Biological Diversity Act, 2002 has come into force and the National Biological Authority (NBA) has been established. The NBA lays down guidelines for access to biological resources, and for fair and equitable benefit sharing besides advising the central government on conservation of biodiversity. Section 21(2) of the Act contemplates a variety on monetary and non-monetary compensation for the benefit claimers including transfer of technology; joint ownership; location of research facilities within a certain area; the association of local scientists; and the setting up of venture funds.[21]

The Biological Diversity Act has no restrictions with respect to obtaining biological materials on local communities but implies limited restrictions on Indian Individuals/entities and stronger restrictions on foreign nationals and entities. Regarding the transfer of Information relating to research on bio resources, the restriction is applicable to all and for the application if IP rights, all parties are obliged to seek the approval of the NBA who may impose monetary or non-monetary benefit sharing.

Eight out of India's 26 states have set up their own state biodiversity boards and the NBA has received 19 applications, five from foreign companies and nine related to collaborative research between Indians and non-Indians. However none of them has received approval yet because the NBA has held only 2 meeting. NBA is only a regulatory body and not a denying authority with a positive attitude towards biotechnology research. As long as the benefit derived is shared with the local community, sovereign rights are protected and the research does not damage the ecosystem or endanger biodiversity, the NBA will grant approvals for progress in biotechnology research.[22]

[19] http://spicyip.com/2011/12/debate-on-copyright-for-dna-sequences.html, last visited on 29.08.2014
[20] Biotechnology and Pharmaceutical Opportunities in India (3rd ed. UK Trade & Inv. 2011)
[21] http://fbae.org/2009/FBAE/website/our-position-ipr.html, last visited on 29.08.2014
[22] Biotechnology in India, 56-59 (3rd ed. CERNA, A.Maria, 2011)

In compliance with the BDA, Section 10(4) of the Patents Act 2005 creates an obligation to deposit and disclose the source and geographical origin of the biological material in the patent specification. Failure to disclose or wrong disclosure is a ground for opposition and revocation. The Patent Act 2005 also speaks of traditional knowledge as anticipating a patent.

The National Institute of Science Communication (NISCOM), New Delhi and the Department of Indian Systems of Medicine and Homeopathy (ISM&H), Ministry of Health and Family Welfare have come together to compile the Traditional Knowledge Digital Library (TKDL) which would document the traditional knowledge available in the public domain in a digitized format. Starting with the existing literature in Ayurveda, it would later cover unani, siddha, naturopathy, homeopathy and folklore medicine. In the first phase, a Traditional Knowledge Resource Calssification (TKRC) is prepared for 2147 medicinal plants.

There has been international acceptance of TKDL, with the World Intellectual Property Organization (WIPO) constituting a group of members from USPTO, China, Japan, the European Patent Office and India for discussing the findings of the TKDL Task Force. India's TKDL database has also been selected for pilot study by 170 member states of WIPO. When completed, TKDL would help patent examiners easily retrieve traditional knowledge-related information, thus avoiding the possibility of granting patents to unoriginal inventions. Further, a review process of patents already granted in light of the TKDL database would help in the cancellation of some patents.[23]

BIOTECHNOLOGY COMPANIES IN INDIA

India is home to over 300 biotech companies with a total bioscience investment of more than $500 million. Though this is a small share of the global biotech market, the promise of the growth of the industry in India is significant.[24] It is estimated that the domestic market for biotech products will grow tremendously and India may claim 8% of the world's biotechnology companies by 2010.

The major players in the Indian Industry include: Biocon, Serum Institute of India, Panacea Biotech, Nicholas Piramal, GlaxoSmithKline, Abbott, Ranbaxy etc. The active role of Indian biotech companies has become visible through various efforts and final revenue generated by them. ABLE, the association of Biotechnology Led Enterprises, for example, is a forum of leading Indian biotechnology companies to generate a symbiotic interface between the industry, the government, academic and research bodies, and domestic and international investors.[25] Recently, Serum Institute of India Ltd., has announced an investment of Rs.1200 crore at the inauguration of India's first biotech SEZ in Pune.

CONCLUSION

[23] http://duncanbucknell.com/2011/12/14/pharma-biotech-global-week-in-review-14-dec-2011-from-ip-think-tank/, last visited on 30.08.2014
[24] Katherine Linton, MIHIR Torsekar, Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China, 23-27 (Journal of International Economics and Commerce 2011)
[25] http://www.bananaip.com/sinapse-blog/2011/12/gene-sequences-not-copyright-worthy.html, last visited on 30.08.2014

India has sailed through the journey from a state of a total lack of IP awareness to the present state of proactive pursuit of IP in frontier areas of technology. Having unleashed India's IT potential in the recent past, the time has now come to harness the tremendous strengths and energies of the countries in the Biotechnology Sector.