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FACULTY OF AGRICULTURE SCIENCES AND ALLIED INDUSTRIES

(Principles of Biotechnology)

For

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Intellectual Property Rights – Role in Biotechnology

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.

Introduction

One of the main features of modern agricultural biotechnology (agri- biotech) is its increasing proprietary nature. Unlike the agricultural sciences of the past, which came out of publicly funded labs, new biotechnologies are protected by patents and other intellectual property rights (IPRs).

The ownership of IPRs in agri-biotech is now an issue in the development of products and the transfer of the technology to developing countries. Scientists now need to consider IPRs as an important factor in their research, especially where the aim is product development. Since the early 1990s, most major research organizations, whether public or private, are actively considering and/or implementing IPR policies.

Intellectual property represents products of the mind or intellect. They are ideas that, when converted to tangible forms, can be protected. Examples of intellectual properties include inventions, computer software, publications, videotapes, music, and plant varieties.

Developing such products usually requires a great deal of time and financial investment. Therefore, the inventor usually seeks a return

on his effort by acquiring IPRs. They allow the inventor to restrict the use of the intellectual property, i.e., no one is allowed to use, manufacture, grow, sell or offer to sell the invention without permission. Several forms of this protection exist and they include copyright, trade secret, trademarks, plant breeder's rights, and patents.

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, nanotechnology, bio-informatics and IT- enabled biotechnology, clinical biotechnology, environment and intellectual property and patent law.

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

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.

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 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.

Promoting Transfer of Agri-Biotech to Developing Countries

Developing countries frequently lack the required IP management capacity and resources to perform product clearance analyses and evaluations that facilitate the legitimate import, use and/or export of technologically advanced products. Thus, to help transfer of appropriate agri-biotech to developing countries, capacity building in

IPR management is of vital importance from both the donor and the recipient side.

This can involve the following:

Educate research staff and research administrators on the basic principles of IPR management Use different patent databases as well as scientific databases as information sources. Remain aware of the complexity of germplasm issues. Stress the importance of good laboratory records. Document what comes in and goes out of the lab. Establish clear lines of responsibility for negotiating, reviewing and signing Material Transfer Agreements (MTAs) and licenses. Manage and organize licenses and MTAs and the various documents and correspondence associated with them.

Plant Breeder's Rights

Plant breeder's rights (PBRs) are used to protect new varieties of plants by giving exclusive commercial rights for about 20 -25 years to market a new variety or its reproductive material. The variety must be novel, distinct, uniform, and stable. This protection prevents anyone from growing or selling the variety without the owner's permission. Exceptions may be made, however, for both research and use of seed saved by a farmer for replanting.

Patents

A patent is an exclusive right given to an inventor to exclude all others from making, using, selling or offering to sell the invention in the country that granted the patent right, and importing it into that country. In agricultural biotechnology, patents may cover, for example, plant transformation methods, vectors, genes, etc. and in countries that allow patenting of higher life forms, transgenic plants or animals.

Patents are the most critical form of protection for agricultural biotechnology and considered to be the most powerful in the IP system. Patents are temporary, generally about 20 years, and are country specific.

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.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.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.

In conclusion, 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.

Moreover, IPs generated by the public sector can be considered assets that can be exchanged for private sector-owned IPs or used as bargaining chips in technology transfer negotiations. Partnership between the private and public sectors in technology development through sharing of knowhow and IP can hasten technology transfer and acquisition on both sides.