

Intellectual Property Rights and Biotechnology

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Abstract: India's biotech policy is constantly changing, but its basic principles for creating a vibrant industry have been developed. The Indian biotechnology industry was slow to launch, but has gained traction and the software sector is now booming. The current market share in the global market is only 1.1 percent, but to become a leading player in the global biotech market, the Indian industry has the requisite ingredients. The biotech sector in India is one of the top five in the Asia Pacific region today. India not only shows tremendous potential as a destination for new-generation pharmaceuticals, biotech products and diagnostics, but is also becoming an important outsourcing center for clinical features and contract research. Though India has yet to launch a new biotechnology product, it has strong support for science and the potential to create \$5 billion in revenue and a million jobs by 2010. The Indian biotech field has witnessed a number of dispersed and intermittent initiatives on the academic and industrial front over the last two decades. The rapid development of technology has opened up a wide variety of options for us. Some big advances have once been seen in engineering, which was limited to machines and other associated abiotic segments, and now we can alter or genetically manipulate living organisms.

Keywords: Biotech, Intellectual Property, Organism, Outsourcing, Product.

INTRODUCTION

Its increasing proprietary character is one of the key features of modern agricultural biotechnology (agri-biotech). In comparison to past agricultural sciences, which originated from publicly funded laboratories, modern biotechnologies are protected by patents and other intellectual property rights (IPRs). Would these mainly private-sector IPRs contribute to the monopolization of plants, research instruments, and even knowledge? Are they going to promote research and development by offering investment incentives and by encouraging access to innovations created elsewhere? [1]. Ownership of agri-biotech IPRs is now at stake in product production and the transfer of technology to developing countries. In their research, scientists now need to consider IPRs as an important factor, especially where product development is the target. Most major research organizations, whether public or private, have been actively considering and / or implementing IPR policies since the early 1990s [2].

Products of the mind or intellect are intellectual property. They are thoughts that can be covered when translated to physical forms. Inventions, electronic software, publications, videotapes, music, and plant varieties provide examples of intellectual properties. Typically, producing such goods requires a lot of time and financial investment. Hence, by obtaining IPRs, the inventor typically seeks a return on his effort. They allow the inventor to limit the use of intellectual property, i.e., without permission, no one is permitted to use, create, develop, sell or offer to sell the invention. There are many types of such protection, including copyright, trade secrets, trademarks, rights of plant breeders, and patents [3].

Role of Government in Biotechnology Sector

The Department of Biotechnology (DBT) has released the government's national science and technology policy and the Biotechnology Vision Statement to provide a structure and strategic direction for various sectors to accelerate the pace of biotechnology growth in India. Furthermore, this strategy aims to pave the way for advancement in sectors such as agriculture and food biotechnology, industrial biotechnology, therapeutic and medical biotechnology, regenerative and genomic medicine, diagnostic biotechnology, bioengineering, nanotechnology, bioinformatics and IT-enabled biotechnology, clinical biotechnology, environmental and intellectual property and patent law [4].

Patenting Biotechnology Inventions in India

The Indian Patent Office considers that biotechnological innovations apply to living organisms of natural origin, such as animals, human beings, including parts thereof, living organisms of artificial origin, such as microorganisms, vaccines, transgenic animals and plants, to biological materials such as DNA, plasmids, chromosomes, vectors, tissues, cells, replicas, processes linked to living organisms, Under Section 3 of the Indian Patent (Amendment) Act 2005, the cited biotechnological inventions are not considered as patentable [5].

Living beings of natural origin, such as animals, plants, plant types, seeds, species, genes and micro-organisms, in whole or in part. Any manufacturing or processing process relating to such living entities. Any treatment method, such as medicinal, surgical, curative, diagnostic and therapeutic prophylactic, human or animal treatment, or other treatment of a similar nature. Any living entity of artificial origin, or any part thereof, such as transgenic animals and plants. Biological materials, such as muscles, tissues, cells, viruses, and their entire preparation process. In essence, biological processes for the development of plants and animals, such as crossing or breeding methods.

Medical Biotechnology

The pharmaceutical sector in India is one of the first to reap the benefits of biotechnology. Biotechnology products in human health account for nearly 60 percent of the domestic market, while biodrugs, vaccines and diagnostics still hold large market shares. Consequently, Indian pharmaceuticals are beginning to reap the benefits of their products' improved IP security. The NDDS of Ranbaxy for Ciprofloxacin licensed to Bayer for \$65 million plus royalties is an example. Other research-based Indian businesses have received around \$70 million from milestone payments for R&D [6].

Through selling its patents to the industry, CSIR has also gained revenues. 15 applications were received by the Indian Patent Office for the grant of Executive Marketing Rights (EMR). Three of these have been permitted, four have been denied and the remaining eight are pending. The Patent Office is more open to the granting of EMRs. The Indian Patent Office for a Blood Cancer Drug, GLIVEC, was the first company in India to issue an EMR to Novartis. Smithkline Becham challenged the order before the Delhi High Court in a written petition. For lack of federal authority, this writ was dismissed.

Novartis, however, secured a stay from the Madras High Court to restrict the manufacture and sale of Imatinib Mesylate, the active ingredient in Novartis 'Glivec, by six drug firms. As of 1 January 2005, the EMR provision will no longer be in effect. A strong pharmaceutical market, an increasing number of small and medium-sized biotechnology companies, a wide network of universities, research institutes and medical schools, and low product evaluation costs are a good opportunity for the Indian industry to develop medical biotechnology.

Promoting Transfer of Agri-Biotech to Developing Countries

Developing countries also lack the ability and resources needed for IP management to carry out product clearance analyses and assessments to promote the legal import, use and/or export of technologically advanced goods [7]. Therefore, in order to support the transition of suitable agri-biotechnology to developing countries, capacity-building on the donor and recipient side of IPR management is of vital importance. The following may be interested in this:

- Educate research workers and research managers on the core concepts of the management of IPR.
- Using various patent databases as well as science databases as sources of knowledge.
- Keep conscious of the importance of the problems with germplasm.
- Stress the value of good records in the laboratory.
- Document what comes in from the lab and goes out.
- Establish specific duty lines for negotiating, updating, and signing licenses and Material Transfer Agreements (MTAs).

- Manage and coordinate licenses and MTAs and the numerous related documents and correspondence.

Plant Breeder's Rights

In order to protect new varieties of plants, plant breeder's rights (PBRs) are used by granting exclusive commercial rights for approximately 20-25 years to sell a new variety or its reproductive content. Novel, distinct, uniform, and stable must be the variety. This defense prohibits someone without the permission of the owner from growing or selling the variety. However, exceptions can be made for both study and the use of seeds saved for replanting by a farmer.

Patents

A patent is an exclusive right given to an inventor to prohibit all others from making, using, selling or offering to sell and import an invention into the country in which the patent was granted. Patents in agricultural biotechnology which cover, for example, methods of transformation of plants, vectors, genes, etc., and in countries which allow higher life forms, transgenic plants or animals to be patented [8].

Biotechnology Companies in India

With a combined bioscience investment of more than \$500 million, India is home to over 300 biotech firms. Though this is a small share of the global biotech market, India's promise of industry growth is substantial. The domestic market for biotech products is expected to expand tremendously, with India reporting 8% of the world's biotechnology companies by 2010. Biocon, Serum Institute of India, Panacea Biotech, Nicholas Piramal, GlaxoSmithKline, Abbott, Ranbaxy and so on are the key players in the Indian industry [9].

Through various efforts and final revenue generated by them, the active position of Indian biotech firms has become visible. For example, ABLE, the Biotechnology Led Enterprises Association, is a forum for leading Indian biotechnology companies to establish a symbiotic interface between industry, government, research and academic bodies and national and international investors. At the inauguration of India's first biotech SEZ in Pune, the Serum Institute of India Ltd. recently announced an investment of Rs.1200 crore [10].

CONCLUSION

In conclusion, India has navigated the journey from a state of complete lack of IP knowledge to the current state of constructive IP pursuit in technology frontier areas. The time has now come to harness the immense strengths and energies of the countries in the biotechnology sector, having unleashed the IT capacity of India in the recent past. In addition, public sector produced IPs may be considered assets that can be traded for IPs held by the private sector or used as bargaining chips in agreements for technology transfer. Partnerships between the private and public sectors in technology growth will speed up technology transfer and acquisition on both sides by exchanging know-how and IP.

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