

BIOTECHNOLOGICAL INNOVATIONS PATENT: A REVIEW

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ABSTRACT

This article evaluates patent protection as an incentive mechanism for biotechnology innovation in India. Recent enhancements to India's patent laws, a new acceptance of biotechnology patents. It analyses the international patenting trends, patents that have significant impact and countries active in patenting. It also examines Indian patenting activity and its comparison with international trends to assess the Indian efforts. The patentability of products is essential in the biotechnology field, for limited market exclusivity compensates biotech companies' investments in research and development. The biotechnology field also uniquely faces Federal Drug Administration (FDA) approval, which includes considerable additional expense and time issues a biotech company must address.

Keywords: Biotechnology, patents, proprietary right, patenting trends.

INTRODUCTION

Many Indian biotechnology companies have developed proprietary processes for manufacturing "bio-generics" or "bio-similar," i.e., copies or derivative forms of first-generation biologics such as recombinant human insulin and erythropoietin now coming off patent in the U.S. and elsewhere. Despite their success in process development, the Indian firms are not yet filing a significant number of patent applications in India. Data gathered for this article, limited to companies generating significant biotechnology revenues in India; reveal that they filed only a handful of Indian patent applications during that period. The anomaly in patenting biotechnological products arises because patent law was intended to satisfy the requirements of industrial technology¹. The advent of biotechnology necessitated that patent laws to be suitably modified to match the needs of science and technology. The traditional notions of adequate disclosure at the time of applying for a patent had to be altered to cater itself to biotechnological innovation.

The TRIPS-mandated term extension of Indian chemical (including biotechnological) process patents from seven to twenty years from filing, coupled with a shifted burden of proof for alleged infringements of process patents, will work in concert with the Indian biotechnology industry's desire to lead the world in supplying generic biologics. As multiple Indian companies compete to sell the same biotechnology product, each firm's need to distinguish itself by process development increases. Stronger process patent protection will facilitate competitive advantage among Indian biotechnology companies.

Patent: A patent is an exclusive right granted by the government to the patentee in respect of a new invention, which may be product or process. A patent is granted by the patent office in which you wish to protect your valuable invention. A patent covers every area of technology as pencil to helicopter¹.

Biotechnology: Biotechnology comprises any technology that uses living entities, in particular animals, plants or

microorganisms. According to the Organization for Economic Cooperation and Development (OECD) biotechnology includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses.

Biotechnology Inventions Classification:

(a) Inventions relating to an organism or material such as living entities of natural or artificial origin (animals, plants, and microorganisms), biological material (plasmids, viruses and replicas, and parts of organs, tissues, cells, and organelles), and naturally occurring substances from living entities, biological material and parts.

(b) Inventions relating to the process for the creation of a living organism or production of other biological materials.

(c) Inventions relating to the use of such organisms or biological materials².

Innovation: Innovation is a new way of doing something or "new stuff that is made useful". It may refer to incremental and emergent or radical and revolutionary changes in thinking, products, processes, or organizations. Following Schumpeter (1934), contributors to the scholarly literature on innovation typically distinguish between invention, an idea made manifest, and innovation, ideas applied successfully in practice. In many fields, something new must be substantially different to be innovative, not an insignificant change, e.g., in the arts, economics, business and government policy. In economics the change must increase value, customer value, or producer value. The goal of innovation is positive change, to make someone or something better. Innovation leading to increased productivity is the fundamental source of increasing wealth in an economy.

Patent Forms³:

Form 1- Application for grant of a patent.

Form 1A- Application corresponding to an international application for grant of a patent.

Form 2- Provisional/ complete specification.

Form 3- Statement and undertaking under Sec- 8.

Form 4- Request for extension of time.

Form 5- Declaration as to inventor-ship.

Form 9- Request for publication.

Form 18- Request for examination of application for patent.

Filing a Patent Application in India⁴:

Filing a patent application in India is required some important documents, which are important for granting a patent in India.

- a- Application form in duplicate (Form 1 or 1A)
- b- Provisional or complete specification in duplicate
- c- Abstract of the invention in duplicate
- d- Drawing in duplicate (if need)
- e- Priority document (if priority date is claimed) in convention application
- f- Declaration of inventor ship
- g- Power of attorney (if filed through patent agent)
- h- Fee (to be paid in cash/by cheque/by demand draft)

Patenting trends in biotechnology:

Indian patenting trend: Patents granted to Indian organizations during 1990-2002 in different sectors easily reveals the fact that chemicals and pharmaceuticals were the major areas in which Indian organizations had obtained patents. However, it can also be observed that Indian organizations also got patents in biotechnology. Majority of these were overlapping patents addressing other sectors (mainly pharmaceuticals). The main technological domains of patenting activity in biotechnology were in microorganism compositions; macromolecular compounds; and biocide and plant reproduction techniques.

Steady increase in patenting activities in biotechnology can be observed from the different data available. Analyses of Indian patenting activity during 2003-04 again shows that in this period also, pharmaceutical and chemical sectors were the dominant areas of patenting activity. Pharmaceuticals had 213 patents (46 percent of total patents) during these two years while chemical sector had 125 patents (27 percent of total patents). Biotechnology sector was also well addressed with 48 patents granted during this period. Other major sectors contributed insignificant number of patents⁵.

International Patenting Trend: The US, Japan and the European Patent Office are the three major patent offices where international firms file patents. However, in the context of biotechnological inventions, the USPTO has a long tradition of firms filing their patents therein because of a number of factors such as emergence of firms from

the universities, venture capital investments, and landmark rulings. Thus, by observing patents granted by the USPTO, a good estimate of patenting activity in biotechnology can be obtained.

Patents granted by the USPTO in biotechnology in comparison to other sectors to some developed and developing economies have been illustrated in property right dates. It shows that patents granted to biotechnology inventions are relatively less than other sectors. However, they do contribute to substantial patents in the overall profile of developed economies. Firms in developing countries have dominated innovation in biotechnology with extensive patenting, but the US has clearly dominated patenting covering different application areas of biotechnology. These innovations have high degree of science linkages and joint partnership between industry and university^{6,7}.

Patentability of Biotechnological Invention⁷⁻¹¹:

Biotechnology in recent year has created unprecedented opportunities not only for the humankind but also industrial development. It has become the world fastest growing technology. Today a number of research institutes (public and private) are working in the area of modern biotechnology with strong scientific research system in country^{12,13}. But due to the emergence of modern biotechnology, one of the most important issues has been raised in legal characterization and Intellectual Property Protection (IPP). Invention such as genetic engineering, microbiology, medical invention and biotechnological invention that may be patentable by Indian patent law, 1970 can be categorized as-

A- The living entities of natural origin such as animal, plant in whole or any part thereof are not patentable in India.

B- Terminator gene technology and microorganisms are not patentable in India.

C- The biological materials such as organs, tissues, viruses etc and process of preparing thereof are not patentable in India. But biotechnological materials such as recombinant DNA, plasmid and process of manufacturing thereof are patentable.

D- Gene sequences, DNA sequences without having disclosed their function are not patentable. But the process relating to microorganism or producing chemical substances using such microorganisms are patentable^{14,15}.

E- The process of cloning human being or animals is not patentable¹⁵.

CONCLUSION

The study examined the field of biotechnology and identified some of the important areas in the context of patentability in this field. The article underscores the fact that patenting in biotechnology gives rise to complex issues as it involves patenting of living organisms, and how Indian patent provisions address the issue of patentability in this subject domain without violating the TRIPS Agreement. The study shows that Indian firms have been able to obtain a number of patents in

biotechnology during 1990-2004 by the US and Indian patent offices, particularly in the later period.

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