

AN INTRODUCTION TO BIOTECH PATENTS

P. Padmapriya* and R. Kumaravenkatesan

Article History

Received: 12.04.2023

Revised and Accepted: 16.05.2023

Published: 19.06.2023

<https://doi.org/10.56343/STET.116.016.004.005>

www.stetjournals.com

ABSTRACT

Our traditional treatises in medicine such as Ayurveda and Siddha are still prescribed by medical practitioners at par with the modern medicine. Our intellectual efforts, investments and creations need legal protection. Intellectual Property offices are the authority created by government to regularise, register, protect and promote the intellectual property. Intellectual property rights are bundle of rights which include Patent right, Trade mark, Copy rights, Industrial designs, Integrated circuits and layout designs, trade secrets, the protection of plant varieties and farmers rights and geographical indications. In India the Intellectual Property Rights are administered by the Controller General of Patents Designs and Trademarks. Patent right is an exclusive right granted to a person who has invented a new and useful article or an improvement over an existing article. The right enjoyed by the inventor over his/her invention is Patent right. It is a monopoly right granted for a limited period of time and is territorial in nature. The protection, promotion and administration of rights associated with patents in India are regulated by the Patents Act, 1970. The Patent owner can commercially exploit his right by manufacturing, selling or licensing the patented article or technology. Patentability is the ability of the invention to make itself eligible for a grant of

patent. The criteria of patentability are novelty, inventive step, industrial applicability and utility. Patent system promotes technology and aids in transfer and dissemination of technology to the mutual advantage of producers and users.

Keywords: IPR, Invention, exclusive right, Patent, Patentability

INTRODUCTION

We can proudly say India is in the forefront of the developing countries in its race towards modernization and sustainable development. Today India has become the Intellectual entrance to the developing world. We are occupying a prestigious position in the world due to our remarkable achievements in the field of Science and Technology. The research and developments in Science and Technology lead to a many fold expansion in the horizon of its application and evolution of new inventive concepts. New disciplines in Science and Technology were emerged out from the basic sciences. The concept of mastering or gaining specialization in any selective or particular field has gained momentum in the recent years. The field of research has become more specific and result oriented. Huge Investments in R&D were made by manufacturers anticipating commercial gains through new inventions and devising new technologies. All these intellectual efforts, investments made and infrastructure necessitated a worldwide system to protect and promote them.

P. Padmapriya

PG and Research Department of Biochemistry, STET Women's College (Autonomous), Sundarakkottai, Mannargudi - 614 016, Thiruvavur (District), Tamil Nadu, India.

e mail: ppadmapriya724@gmail.com

Intellectual Property Rights

Intellectual Property Rights shortly termed as IPR. Intellectual means capacity, creativity, idea or knowledge. Property means one which is owned, registered or under ones possession. Right is one

which is claimed, exercised. Precisely, these are the right associated with the idea or creation of mind which is applied over a system to perform a particular task or results in a creation which can be legally owned and exploited by the creator or inventor. 'All that, what is produced or originated by the human skill, intelligence, labour and efforts' is intellectual property (Chandrasekaran, 2004). These are immaterial products arise out of human brain and they must be treated as valuable as his lands or goods. It includes anything that would result from the human intellect (Philips, 1986).

Administration

The WIPO (World Intellectual Property Organization) at Geneva is the governing body to frame the rules and regulations concerning to Intellectual Property Rights to the member countries. Besides WIPO every member country is having their own offices to protect and promote intellectual property within their country. In India the Intellectual Property Rights are administered by the Controller General of Patents Designs and Trademarks, which is under the department of industrial policy and promotion in the ministry of commerce and industry.

Patents

Among the intellectual property rights Patents are of significant importance due to their scientific and commercial impact over the industry and mankind. Since IPR is a wide subject, I limit my discussion in this article only to Patents.

A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application (www.wipo.net/patents/en/).

A patent is a form of intellectual property. It consists of a set of exclusive rights granted by a government to a true and first inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention. Patent is an exclusive right granted to a person who has

invented a new and useful article or an improvement over an existing article. With the increase in awareness of Intellectual Property Rights (IPR) in specific in patents, researches are being geared up towards making 'patentable inventions' rather than mere inventions. The protection, promotion and administration of rights associated with patents in India are regulated by the Patents Act, 1970. A granted patent is valid for a period of twenty years only thereafter it came to public domain.

Patent right

The right enjoyed by the inventor over his/her invention is Patent right. It is an exclusive right (monopoly) granted for a limited period of time and is territorial in nature. A patent granted by a patent office is applicable within the geographical boundaries of that country only. These are assignable, licensable, and transferable rights. These are Proprietary right which can be legally enforceable and to be registered before a competent authority. The Patent owner can commercially exploit his right by manufacturing, selling or licensing the patented article or technology.

Why Patents?

Following are the intention and consideration behind granting patents.

- Encouragement and inducement to the inventor.
- Possibility of working of the invention in India on commercial scale to the full extent without delay to help the society.
- Promotion of technology, transfer and dissemination of technology and mutual advantage of producers and users.
- Social and economic welfare of the nation as an Instrument to promote public interest.
- Availability of the patented invention at reasonably affordable prices to the public.
- To encourage healthy competition.
- Reveal the intellectual capability of the inventor/company to the world.

- If the inventor does not get the patent rights over his invention and introduce his product/process in the market, anybody can copy his invention and exploits it commercially against interest of the inventor.

Who can apply for a patent?

Persons entitled to apply for patents in India,

- 1) A true and first inventor
- 2) Assignee of the true and first inventor
- 3) Legal representative of any deceased person who immediately before his death was entitled to make such application

Rights of a Patent owner/Patentee

- a) Right to manufacture the patented product
- b) Right to offering for sale, selling or importing the patented product or product made by the technology in to India for sale
- c) Right to prevent others from make, use, sell, import the patented product / patented process within the country during the term of the patent and commercially exploiting the patent.
- d) Assign, transfer and issue license and surrender the patent.
- e) Sue in case of infringement
- f) Claim remedies upon proving the infringement.

The industries concerned with patents includes, all the fields of engineering and technology, Fertilizers, pesticides, insecticides, chemicals, bulk drugs, drug formulations, Food products and nutritional supplements. The stages of development of a successful invention are:

- I. Identification of a problem that needs to be solved.
- II. Study the existing solutions (prior art) to the problem
- III. Inventing a new / improved solution to the problem, which works.

- IV. Developing a prototype to demonstrate the invention to prove it's workability.
- V. Filing a patent application to protect the invention
- VI. Arrange for the manufacturing and marketing of the patented invention and commercially exploiting the Patent.

Pharmaceutical Patents

Besides Patents in the field of engineering which shares to a high proportion of total patents, pharmaceutical Patents became one of the important segments in patents. Both the product and processes can be patented in pharmaceutical products, when novelty is there in the product as well as in the process. The Active Pharmaceutical Ingredients and Formulations are getting patented. Pharmaceutical Patents includes allopathic drugs and formulations, herbal drugs based on research and development besides biotechnological products. We are one among the very few countries in the world endowed with a traditional system of medicine which is, still in our active practice and widely prescribed. Our traditional treatises in medicine namely Siddha and Ayurveda were recognized widely by the scientific community as economic and easily available system with minimum side effects.

Biotech Patents

Among the recent developments in Pharmaceutical and health care segments, the biotech inventions are gaining attention due to their scientific importance besides their commercial impact. Bio pharmaceuticals and bio pesticides are occupying a sizable share in the market. We can't deny the fact that besides commercial gains, the evolution of new inventions aids in dissemination of technology, benefit to mankind. Number of lifesaving drugs, medical devices and technology has been offered to the mankind through the developments in Medicine and biotechnology. To be precise, any further development in the field of biological sciences cannot proceed without the application of techniques of biotechnology. Even though

biotechnology has gained importance, there are no clear guidelines in the legislation governing patents upon 'patentability' of biotech inventions. Today, the techniques such as Genetic engineering and Tissue culture have emerged as effective tools in the hands of researchers to unfold the secrets of life in animals and plants. Pharmaceuticals, food products and fertilizers are the industries, largely depends on the field of biotechnology for their further research and development. Unlike the inventions in the field of engineering, there is no specific guideline in patenting the process or products arising out of research in biotechnology and still it is a matter of discussion and controversy even in the patent offices of developed countries.

Who owns your genes? Do you own them if they are inside your body, but someone else can own them if they have been removed? Are isolated human genes man-made, patentable inventions or unpatentable products of nature? These were the issues before the nine justices of America's highest court in *Association for Molecular Pathology v Myriad Genetics* earlier this year (www.wipo.int/wipo_magazine/en/2013/04/article_0007.html).

Once the basic patentability criteria are met, as for any other technological invention, living matter can be patented. The relevance between invention and products of nature was not between living and inanimate things, but between products of nature and man-made inventions (Li westerlund, 2002).

It is appropriate here to indicate the recommendations of the Report of the Technical Expert Group on Patent Law Issues (Report of the technical expert group on Patent Law Issues, 2009) under the chairmanship of Dr. R.A. Mashelkar, Director General Council of Scientific and Industrial Research New Delhi (Revised, March 2009) on biotech industry states that, "Biotech industry is one of the fastest growing industries in the world, including in India. India being one of the bio-diversity rich countries, it would, thus, be prudent for us to protect biotechnological inventions as that would help Indian biotechnology research compete globally attracting collaborations, FDI, contract R&D, etc.

to the best advantage of the Indian R&D and biotech industry. India needs to reap the due benefits from its rich bio-resources with an enabling provision for protection of intellectual property in bio-technological innovations and inventions."

Conclusion

The research and development in biological sciences such as biotechnology and molecular biology and genetics are aimed at, encouraging and enabling new inventions in medicine and innovative techniques in treating the ailments to render the society free of disease. High degree of ingenuity, investment and labour are involved in the research. The intellectual efforts put forth by the inventor in his invention, is to be given due credit and appreciation. In the near future India should not be neglected kept and behind other countries in its intellectual race for want of appropriate legislation to grant biotech patents. So, taking in to consideration the public health and ensuring availability of life saving drugs at economical prices to the public in near future, India should come up with clear guidelines to enable the products of biotechnology as patentable subject matter.

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