

## INTELLECTUAL PROPERTY RIGHTS AND THEIR SIGNIFICANCE IN BIOMEDICAL RESEARCH

Vipin Mathur\*

\*Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India

\*Corresponding Author: [vipinmathur75@gmail.com](mailto:vipinmathur75@gmail.com)

This article is available online at [www.ssjournals.com](http://www.ssjournals.com)

---

### ABSTRACT

The term intellectual property (IP) refers to a number of distinct types of intangible assets created by the human intellect. These intangible assets may be in the form of an invention, an industrial design, a literary work etc. Intellectual property once created can be protected under certain laws of the country. The owner of the intellectual property acquires a set of exclusive rights, called as Intellectual Property Rights (IPRs) over his/ her IP assets under these laws. Common types of IPRs include patent, trade secret, industrial design, trade mark, geographical indication, plant varieties and copy right.

Due to globalization and increased market competition, the importance of IPRs has increased manifolds in all fields of technology. In the current scenario it is imperative for all the researchers and scientists to acquire the basic knowledge of IPRs to avoid any potential losses of their IP rights. This paper throws light on various forms of Intellectual Property Rights and their significance in biomedical research.

**Keywords:** IPRs; patent; design; trade mark; copy right

---

### 1. INTRODUCTION

Research in biomedical field is very expensive, time consuming and unpredictable in nature. The outcome of the biomedical research that has certain commercial value is termed as the intellectual property (IP) of its creator or the researcher. Intellectual property refers to creations of the mind<sup>1</sup>. It can be protected in the form of various Intellectual Property Rights (IPRs) under certain laws. Like any other property intellectual property is also an asset and can be bought, sold, mortgaged, licensed, exchanged or gifted to others. The owner of intellectual property has exclusive monopoly rights over their intellectual property, which means nobody else can lawfully use their intellectual property without their permission. IPRs provide compensation and reward to the authors and researchers for their creative efforts<sup>2</sup>.

Although IPRs can be held simultaneously in many countries, but all IPRs are territorial rights and thus can be enforced only in the

geographical area of the country granting the right. All IPRs have fixed term, except trademark and geographical indications and they can be maintained for an unlimited term by paying the official fees. Most IPRs have to be renewed for keeping them in force during their term of protection except in case of copyright and trade secrets. Copyrights have limited term and it can not be renewed beyond that. Trade secrets have an infinite life and they do not have to be renewed.

Discussion on various types of IPRs and their significance in biomedical research has set forth in the following paragraphs in this paper.

### 2. Types of Intellectual Property Rights

Intellectual Property Rights can be broadly divided into two categories viz. Industrial Property Rights and Copyright<sup>3</sup>.

**2.1 Industrial Property Rights:** Industrial property rights are the IP rights that relates with some industrial activities. Patent, Trade Secret, Trade Mark, Industrial Design,

Geographical Indication and New Plant Varieties are the main industrial property rights.

**2.1.1 Patent:** Patent is an exclusive right granted by the government for an invention. It offers technical solution to a technical problem. Patent is a contract between an applicant/ inventor and the government, wherein the government provides right to protect the invention after full disclosure of the invention by the applicant/ inventor. Thus, patenting provides a strategy for protecting inventions without keeping the invention secret.

An invention may be in the form of a product or a process. Patent is granted only to those inventions which satisfies certain conditions known as criteria of patentability viz. newness, inventive step and industrial applicability<sup>4</sup>.

Patent is the right to exclude others from unauthorized making, using, offering to sale, selling or importing the invention. Patent is not a right to make, use or sell the invention, but it includes right to license others for the purpose of making, using or selling the patented invention. The right to use or practice the invention is subject to country's regulatory conditions such as new drug product approval prior to its launch in the market. The right to use the invention is also subject to any prior rights that others may have to the related inventions. For example, if company "A" has a patent on "drug X" and the company "B" has a patent on "extended release formulation of drug X", then "A" can prevent "B" from using "drug X" in the extended release formulation and "B" can prevent "A" from making "extended formulation" of drug X.

In India the governing law for patent protection is the Patents Act, 1970. The term of patent is 20 years from the date of filing the patent application<sup>5</sup>.

**2.1.2 Trade Secret:** A trade secret is any information that has commercial value and that one takes reasonable efforts to keep secret. This information may be in the form of a formula, practice, technique, process, design, instrument, pattern, program device, method or compilation of information. Customer lists, business information, employee details, financial records, data compilations, business

plans and strategies, designs, drawings, algorithms etc. all amount to trade secrets<sup>6</sup>. Trade secret is the only intellectual property right where ideas can be protected and the owner can hold the right for an indefinite term. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) lays down the following general standards which are referred to in Art. 39 for trade secrets:

- i) The information must be secret (i.e. it is not generally known among, or readily accessible to, circles that normally deal with the kind of information in question).
- ii) It must have commercial value because it is a secret.
- iii) It must have been subject to reasonable steps by the rightful holder of the information to keep it secret (e.g., through confidentiality or non disclosure agreements).

It is important to note that a trade secret need not be something that is novel nor should it have any real or intrinsic value to be protected. The only important requirement is that it must be a secret<sup>7</sup>.

There is no specific law in India that protects trade secrets and confidential information. Nevertheless, in India it is possible to contractually bind a person not to disclose any information that is revealed to him/her in confidence. The remedies available to the owner of trade secrets would be to obtain an injunction preventing a third party from disclosing the trade secrets, return of all confidential and proprietary information, and compensation for any losses suffered due to disclosure of trade secrets

One of the most famous examples of a trade secret is the formula for Coca-Cola. The formula, also referred to by the code name "Merchandise 7X," is known to only a few people and kept in the vault of a bank in America.

**2.1.3 Trade Mark:** Like how a name identifies an individual the trade mark provides the identity and origin of a product. A trade mark is a mark capable of being represented graphically. The main function of a trade mark is to enable customers to identify a product of a particular company so as to distinguish it from other identical or similar products provided by

competitors. As per the Trade Marks Act, 1999 a mark is a device, brand, heading, label, ticket, name, signature, words, letter, numerals, shape of goods, packaging or combination of colors or any combination thereof. The initial term of the trade mark is 10 years that can be extended every 10 years thereafter for an indefinite period by paying the prescribed fee<sup>8</sup>. Customers who are satisfied with a particular product or service are likely to buy or use it again in the future. Thus, if properly advertised, trade mark becomes an effective instrument to attract and acquire goodwill of the customers. Estimates of the value of some of the world's most famous trademarks such as Coca-Cola or IBM exceed 50 billion dollars each.

There are two primary types of marks that can be registered viz. trade marks and service marks. Trade marks are used by their owners to identify goods, whereas service marks are used by their owners to identify services. Becosules, Combiflam, Coca Cola, Sony, Bajaj, Samsung etc. are examples of trade marks, whereas ICICI, LIC, BSNL etc. are some examples of service marks.

Rights related to trademark are equitable rights, mean these rights come into existence as soon as the mark is used in commerce for the first time. After registration the rights becomes statutory rights. Benefit of registering a trademark is that a statutory right is a *prima facie* evidence of ownership of the right. A mark should be original and distinctive to get registered. The registration of a trade mark gives the proprietor of the trade mark the exclusive right to the use of the trade mark in relation to the goods or services in respect of which the trade mark is registered and to obtain relief in respect of infringement of the trade mark.

**2.1.4 Industrial Designs:** Any product or article is not only distinguished by its technical characteristics but also by its visual appearance or design. An industrial design relates to the aesthetic or outward appearance of the product. It is what makes a product attractive or appealing to customers. It belongs only to the external features of an article and not to its technical and functional characteristics. The

owner of a registered design has an exclusive right over the use of the design.

The prevailing law relating to the registration on Industrial Designs in India is the Designs Act, 2000. The primary object of the Act is to protect the shape of an object and not its functional aspects. Design means the features of shape, configuration, pattern, ornament or composition of lines or colors or a combination thereof. Following can be registered as a design under the Act<sup>9</sup>:

- i) three-dimensional features, such as the shape of a product;
- ii) two-dimensional features, such as ornamentation, patterns, lines or color of a product;

iii) a combination of one or more such features

For the purposes of the registration of designs, articles are classified into 32 classes. The classification is based on the International Classification of goods and is specified under the third schedule to the Designs Rules, 2001. Any person claiming to be the proprietor of the new or original design that is not previously published anywhere in the world and that is not contrary to public order or morality may apply for the registration of the design in the prescribed manner. The term of industrial design protection is 10 years from the date of registration which may be extended further for a second period of five years. The maximum period for design protection is 15 years.

#### **2.1.5 Geographical Indications:**

Geographical Indications (GIs) identify the place of origin of a particular product. It is an indication which identifies the agricultural, natural or manufactured goods, originating from a definite territory, region or locality, where a given quality, reputation or other characteristics of the goods is essentially attributable to its geographical origin and in case of the manufactured goods one of the activities of production, processing or preparation of the goods takes place in such territory, region or locality. GI can be any name, geographical or figurative representation or combination of them, conveying or suggesting the geographical origin of goods to which it applies. GIs are given the status of an Intellectual Property because the name of a particular place when attached with the name

of the goods increases the commercial value of the goods. Darjeeling Tea, Basmati Rice, Nagpur oranges, Kanchipuram sarees etc. are some examples of goods protected under Geographical Indications.

A GI can be registered for goods belonging to any or all of the 34 classes of goods specified under the fourth schedule to the Geographical Indications of Goods (Registration and Protection) Rules, 2002<sup>10</sup>.

Any association, organization or authority that represents the interest of the producers of the concerned goods, who are desirous of registering a GI in relation to such goods, can apply in writing along with the prescribed fees for the registration of such GI. The initial term of GI protection in India is 10 years from the filing of the application. Registration can be renewed every 10 years thereafter for an indefinite period by paying the prescribed fee.

Registration of the GI gives the registered proprietor and the authorized user, the rights to obtain relief in respect of infringement of the GI and the exclusive right to the use of the GI in relation to the goods in respect of which the GI is registered.

**2.1.6 New Plant varieties:** For the protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants The Govt. of India enacted The Protection of Plant Varieties and Farmers' Rights Act, 2001. Under this Act farmers and plant breeders get exclusive rights to produce, sell, market, distribute, import or export the protected plant variety. A variety is eligible for registration if it essentially fulfills the criteria of Distinctiveness, Uniformity and Stability. The term of protection for a variety varies from 6-18 years depending upon certain conditions<sup>11</sup>.

**2.2 Copyright:** Copyright is a right given by the law to creators of literary, dramatic, musical and artistic works and producers of cinematograph films and sound recordings. Copyright is a bundle of rights including, *inter alia*, rights of reproduction, communication to the public, adaptation and translation of the work. Copyright is an equitable right that becomes statutory right after the registration. Copyright come into existence as soon as the work is created or published. Copyright

protects skill and labour employed by the creator in the production of his work. Computer programmes, books, poems, paintings, music, sound recording etc. are works in which copyright subsists<sup>12</sup>.

Use of copyrighted material without the consent of the author is permissible solely for the purpose of research or private study, for criticism or review, for reporting current events, in connection with judicial proceeding, performance by an amateur club or society if the performance is given to a non-paying audience, and the making of sound recordings of literary, dramatic or musical works under certain conditions.

The Copyright Act, 1957 is the governing law of copyright in India. The term of copyright is up to sixty years after the death of the author.

### **3. Significance of Intellectual Property Rights in Biomedical Research**

India being a WTO (World Trade Organization) member country signed TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights) in 1995. TRIPS laid down the harmonized minimum global standards of IPRs. The inception of WTO and TRIPS created a profound effect on the international business. It opened the doors for liberalization and globalization. In the prevailing competitive scenario sticking to global IP standards has become mandatory for the companies to get back adequate returns on heavy investments made in R&D and business promotion.

IPRs are rewards to the creator of the intellectual properties for the time, money, hard work and intellectual efforts which they put in carrying out the work. Since biomedical research is very expensive, time consuming and unpredictable in nature, it is imperative for the researcher to understand the basis concepts of IPRs in order to avoid any possible losses on the IP front.

Patenting system encourages innovation and research by permitting companies to recover Research & Development (R&D) costs during the period of exclusive right. Patenting system also facilitates transfer of technology. It compensates the researcher for the expenses which his research and experimentation leading to the invention entails.

The outcomes of the biomedical research are often documented in the form of research/ review articles or they can be published in books. The energy, creativity and intellectual efforts of the authors to produce such documents are protected under the Copyright. Copyright thus provides recognition and monetary rewards to the author that encourages the dissemination of the information to the full extent.

Trade marks play very crucial role in building the brand value of the products. The reputation built by a trademark on the basis of product's quality or performance increase the chance of product's acceptance by the customers on the long term basis.

Value of all other forms of IPRs like Trade Secret, Industrial Designs and Geographical Indications are also evident in biomedical research.

### CONCLUSION

With the increased globalization and R&D cost it has become imperative for every biomedical researcher to gain the basic knowledge of IPR. It is essential for the overall economic growth of the industries that the creative outcomes of the research shall be protected under the Intellectual Property Rights. It is through the judicial use of IPRs heavy investments poured in research and other business activities can be regained.

In India more efforts are needed to create awareness about IPRs amongst the business and scientific community. Onus lies on the Govt. of India to provide more simplified and user friendly environment and processes for acquiring IP rights. Training programmes shall be organized both at government and institutional level on regular basis to create more awareness on IPR in the country.

### REFERENCES

1. What is intellectual property?. WIPO Publication No. 450(E). Available at: [http://www.wipo.int/freepublications/en/intproperty/450/wipo\\_pub\\_450.pdf](http://www.wipo.int/freepublications/en/intproperty/450/wipo_pub_450.pdf). Data accessed: 12 Nov. 2011.
2. Andersen B. Introduction. In: Intellectual property rights: innovation, governance and the institutional environment. 1st ed. Cheltenham: Edward Elgar Publishing, Ltd.; 2006. p 6.
3. Introduction to Intellectual Property. Controller General of Patents, Designs & Trade Marks, India. Available at: [http://ipindia.nic.in/ipr/patent/patents\\_filing.pdf](http://ipindia.nic.in/ipr/patent/patents_filing.pdf). Data accessed: 23 Oct. 2011.
4. Durham AL. Patents Distinguished from other Rights. In: Patent law essentials: a concise guide. 2nd ed. Westport, USA: Praeger Publishers; 2004. p 13.
5. The Patents (Amendment) Act, 2002, No. 38 of 2002 (June 25, 2002).
6. Jorda KF. Trade Secrets and Trade-Secret Licensing. In: IP Handbook of Best Practices. 1st ed. Michigan: Thomson-Shore. Inc.; 2007. p 1043-1057.
7. Pianon A. Trade secret vs. open source: and the winner is ... *Er Law Eco. Rev.* 2004; 1: 47-75.
8. The Trade marks Act, 1999, No. 47 of 1999 (Dec. 30, 1999).
9. The Designs Act, 2000, No. 16 of 2000 (May 25, 2000).
10. The Geographical Indications of Goods (Registration and Protection) Act, 1999, No. 48 of 1999 (Dec. 30, 1999).
11. The Protection of Plant Varieties and Farmers' Rights Act, 2001, No. 53 of 2001 (Oct. 30, 2001)
12. The Copyright Act, 1957, No. 14 of 1957 (June 4, 1957)