

Intellectual Property Rights and Challenges Associated in Drugs and Pharmaceuticals

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Abstract: This review article aims to present in-depth study of intellectual property rights and challenges associated in drugs and pharmaceuticals. Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. This intellectual property right comprises copyright-related rights as well as patent, trademark, trade dress, and commercial crate rights. A pharmaceutical product's quality, safety, and effectiveness depend on its intellectual property rights. To ensure the certification and recognition of items within a vast market, it functions as an established authority and certification entity. Intellectual property rights are the legal entitlements provided to creators for their creative endeavors, affording them exclusive usage privileges for a defined period. The concept of "intellectual property" encompasses human innovations across art, literature, science, and industry. Its significance lies in safeguarding inventors' creations and maintaining the quality and integrity of their contributions. Further this paper also explain the management of Intellectual property in pharmaceutical industries which is necessary for pharmaceutical companies to locate, organise, market, and safeguard their ideas. It is also a vital instrument for preserving investment, time, and effort as well as for fostering healthy competition, which supports economic growth and industrial advancement. This paper also explains challenges related to IPR which is an effort to highlight the difficulties and problems that India has in providing intellectual property rights to businesses that fall under Indian law.

Keywords: IPR, copyright, patent, trademark

1. Introduction

Intellectual property rights (IPRs) are the legal claims to intangible property that belong to a person or business and are safeguarded against unauthorized use. Thus, rights pertaining to intellectual property ownership are known as IPR. These legal protections permit the owners of trademarks, patents, or works protected by copyright to profit from their inventions in order to safeguard intellectual property (works of human intellect).

By giving creators of inventions, works of art, music, and other creative works exclusive rights over their creations, IPR serves to reward the intellect of humans.

2. Meaning and nature of the intellectual property

Intellectual property (IP) is an intangible asset created by human intellect. It refers to mental constructions or intellectual outputs such as commercially used symbols, names, and images as well as inventions, designs, scholarly and creative works.

"Intellectual property" is defined under the "Convention Establishing the World Intellectual Property Organisation." refers to the following rights:

- 1) Literary, artistic, and scientific works,
- 2) Performances of performing artists, phonograms, and broadcasts,
- 3) Inventions in all fields of human endeavour,
- 4) Scientific discoveries,
- 5) Industrial designs,
- 6) Trademarks, service marks, commercial names and designations,
- 7) Protection against unethical company conduct, and

- 8) All additional legal rights related to innovative ideas in the industrial, scientific, literary and artistic fields.

3. What IPR means

"Intellectual property rights" (IPR) are a group of formalised rights given to a person who creates or owns intellectual property. These are the manageable rights that a person has over his or her thoughts. By rewarding the creators' mental effort and allowing them to keep their property rights over their works, they aim to protect the interests of the creators. Therefore, the innovators and creators are allowed to make money off of their creations. IP rights are the legal rights that govern how intellectual property is used.

Need for legal protection of intellectual property

The following list outlines the various justifications for protecting intellectual property by enacting appropriate Intellectual Property (IP) laws:

- 1) To motivate inventors and creators and give them the opportunity to profit financially from their work in order to encourage developments and innovations that progress the social, economic, scientific, and cultural development of society.
- 2) To grant legal protection of intellectual property.
- 3) To prevent others from benefiting from someone else's innovative ideas.
- 4) To encourage impartial trading.
- 5) To encourage the proliferation of creativity.
- 6) Giving credit for the creators' efforts.
- 7) Preventing the infringement of the creators' proprietary rights in their works by unauthorized use.
- 8) To promote the utilisation of information, skills, time, money, and other resources to aid in innovative actions that benefit society

4. Types of intellectual property rights

India has regulation governing different aspects of IP, as listed under:

- Trade Marks
- Patents
- Copyrights and Related Rights
- Industrial Designs
- Geographical Indications
- Layout Designs Of Integrated Circuits
- Plant Varieties
- Information Technology and Cyber crimes
- Data protection

The protection of IP is generally covered by the following laws:

The Trade Marks Act, 1999

The Trade Marks Act defines a "trade mark" as "a mark that can be shown graphically and can tell one person's goods or services apart from those of others. It can be the shape of the goods, the way they are packaged, or a combination of colors. In simple terms, a trademark offers protection for images that identify and relate to a good or service, such as words, colors, shapes, and symbols.

The two main requirements for registering a trademark are that it should contain a mark that can differentiating one's product or system from the particular participant and it can be represented graphically.

A trademark registration is essential because it provides protection for the brand name, logo, sound, shape, and other elements while also distinctively identifying the products or services to the brand and giving the mark its individuality. Additionally, the initial trade mark registration is credible for a maximum 10 years, which be always renew for additional periods of ten years.

The Patents Act, 1970

A Patent is an IPR that preserve any brand-new innovation. It safeguards the exclusive inventor's rights and restricts unauthorized use and appropriation of the registered patent by other individuals.

A patent is issued for a period of twenty years beginning on the date the application is submitted. It is crucial to remember that an invention must be innovative and original in order for a patent to be granted, meaning it cannot have previously been made available to the public in India or anywhere else in the globe. It is equipped for modern application, which alludes to the capacity of the creation to be utilized in an industry; and is an invention that calls for a series of creative steps to be taken.

The Patents Act grants the following rights to each inventor whose patent has been registered:

- The ability to stop other people from making, importing, sale, or otherwise using a patented product without permission; and
- The right to stop others from using, sale, benefaction, etc. a product derived from a procedure for which a

patent is obtained without the prior approval of the original inventor.

The Copyrights Act, 1957

An "exclusive right" to do or authorize to do certain things with regard to a work that is protected by a copyright is known as a copyright. For instance, when it comes to performing, translating, adapting, and other uses of a artistic, theatrical, or musical work, the holder (or any person the owner has given permission to) is allowed to do so.

For "original literary, dramatic, musical, and artistic works; cinematograph films; and sound recordings," copyright protection may be obtained.

The original author of the work must be the first owner of the work, according to Section 17 of the Copyright Act. Additionally, the owner has the authority to grant written permission to third parties to use the copyright of their creation.

Literary, dramatic, and artistic works that have been published are secured by copy right for a span of 60 (sixty) years , in addition to the author's lifetime.

The Design Act, 2000

The Designs Act defines a design as only those characteristics of a shape, structure, pattern, ornament, or composition of lines or colours, relevant to any article, whether or not in two-dimensional or three-dimensional form, or in both forms, by any industrial process or means, whether manual, mechanical, or chemical, separate or combined, which in the finished article appeal to and are judged primarily by the eye.

A request to register an industrial design must be made to the Controller-general of Patents, Design, and Trademark. However, a design will only be taken into consideration to register if:

- 1) It is new and an initial innovation, which means that no one has ever produced or copied it.
- 2) It hasn't been made public anywhere in India or outside of its legal jurisdiction.
- 3) It is easily distinguishable from other common designs.

Additionally, when a design is registered, the registered owner receives protection for a first period of ten years, which can be extended for an additional five years by filing an extension application.

The Geographical Indications of Goods

An indication that identifies agricultural, natural, manufactured items as coming from the nation's territory, or from a certain area or town inside, when a certain quality, reputation, or other aspect of such commodities is primarily attributed to their geographic origin is known as a geographical indication and if the products are produce, one of the project that involves either the manufacture, processing, or composition of the products in question occurs in the territory, region, or location.

The GI Act only applies to products that are natural,

manufactured, or related to agriculture, food, crafts, or other industries.

A geographical indication that has been registered is given protection for ten years, with the option to renew and extend this preservation for additional term of ten years from the date of original registration expires.

5. Managing Intellectual Property in the Pharmaceutical Sector

Pharmaceuticals and drugs guide all other fields of technology, efficiently suitable how globalization is described and require a reliable IP system.

No company would want to take the chance that its intellectual property would become public property without receiving adequate compensation, given that the risks associated with the development stage, as well as the cost of introducing a new drug to the market.

The creation, acquisition, protection, and management of intellectual property are business activities in the same way that resource and financial raising are. We shall surely experience a revolution in knowledge, it will call for IP to be given special consideration and status throughout the entire decision-making process.

The progress of a company will largely depend on its R&D efforts because scientific knowledge rather than manufacturing expertise drives competition in the global pharmaceutical industry. As a result, Research and Development spending in the pharmaceutical business accounts for a large portion of overall sales; some estimates put it as high as 15%. Innovative risk management techniques while attempting to a competitive advantage against a rival organisations is one of the major problems in this sector. The creation of possible drugs that can't pass the stringent safety requirements must be stopped, occasionally, following several years of investing, and this comes at a high cost to pharmaceutical research and development.

It takes roughly 8 to 10 years from the day the molecule was originally synthesised for those medications to overcome development hurdles. As product patents increasingly replace other forms of IP protection, pharmaceutical businesses must shift their focus from creating new methods for manufacturing existing drugs to creating unique drug molecules and chemical entities.

It is acknowledged that in the previous ten years, the number of documents has nearly quadrupled in size and must be reported to regulatory authorities. In addition, it now takes regulatory agencies a lot longer to authorize a novel drug. As a consequence, the duration of copyright protection is shortened, requiring greater work to generate sufficient profits. When it comes to medicines created using biotechnology, particularly those that use gene technology, the scenario might be worse. The developed world is likely to start organizing for extended medication protections very soon. In order to achieve their objectives, many governments might also start to exercise price control more and more. This would highlight the requirement for reduced

costs associated with medication research, manufacture, and marketing. It would also necessitate budgeting for lower profit margins in order to spread out expenditures over a longer period of time. It follows that it is apparent that the pharmaceutical sector must deal with several competing demands.

Nature of Pharmaceutical Industry

The situation of the pharmaceutical industry today implies that intellectual property rights are being unfairly referred to and misuse at the cost of competitiveness and customer wellbeing. The drug industry's lack of risk-taking and modification highlights the unfairness that is occurring at the expense of the general welfare.

Antitrust law can assist in stabilising the equilibrium between rewarding innovations and maintaining competition in a number of situations, included employing publicizing to create hurdles for generic market beginner, patenting insignificant parts of an existing medicine to get new patents, and patenting smaller components of an old drug.

Some Special Aspects of Drug Patent Specification

Writing patent specifications needs a strong combination of scientific, technical, and legal knowledge and is a highly professional skill that is developed through time. Any patent specification's claims serve as the foundation for the patent beyond which legal proprietary is declared. A known material cannot be patentable when a new property is discovered in it.

The discovery of a substance's novel property may not mean that the substance is novel. If it is combined with some other known compounds and produces a unique result, it could be feasible to patent the combination. The reason is that no one has ever utilised that mixture to create a medicine, pesticide, or fertiliser before. Although the exact structure of the new molecule is unknown, it is entirely possible that an inventor has created it. The substance's description, along with its characteristics and manufacturing procedure, will be essential in this situation.

6. Challenges related to IPR

The phrase "intellectual property rights" refers to the transfer of property rights through the use of patents, copyrights, and logos. But there are some problems with intellectual property rights that the Indian government must deal with. The primary goals of intellectual property are to promote study innovation and provide security. Over the past 20 years, India has made significant success in developing a solid intellectual property rights strategy. For example, in 1995, India ratified the trade related aspects of intellectual rights deal.

The process of obtaining intellectual property rights in India comes with numerous problems.

As a result, obtaining IP rights in India is a contentious issue, but individuals are hopeful that India will resolve these problems. India must deal with a variety of problems and obstacles in order to increase business earnings. The following problems include:

1) From Process to Product Patents

The requirement that all signatory nations change the patent system from Process Patent to Product Patent is one of the trade related aspects of intellectual rights agreement mandatory clauses. A process patent regime safeguards only processes, whereas a product patent regime shields products. This is the key distinction between the two. Obtaining IP rights for food and medicinal goods raises a controversial problem.

India has chosen a mixed growth model, balancing capitalism and socialism, in contrast to developed nations where the capitalist economic model is successful. This strategy was chosen to protect the interests of common people who are unable to afford fundamental necessities like food and medication. When it comes to awarding trademarks in the medicinal and agricultural industries, developed nations accuse developing nations like Brazil and India of being protectionist.

2) Compulsory licensing

The Indian government has the option of requiring licencing has the power to order the owner firm or other businesses to make certain medicines in large quantities in times of need, regardless of who holds the patent. Multinationals want to repeal this clause because they claim India is taking a selfish stance. To protect the interests of the general public, the Indian government is unwilling to repeal this clause.

3) Provision of Drug Price Control Order

Companies are prohibited from setting an inflated price for the medicines they manufacture under this clause. Regarding assets, the cost must be reasonable, and if someone misbehaves, the government has the right to step in and take enforcement action.

4) Food Security and IPR

The majority of India's internal support programs take the form of "minimum support prices" for important agricultural products and "input" payments that are given to farmers in the form of energy, manure, seeds, and other items. However, these benefits will need to be scaled back or removed in order to fully execute trade related aspects of intellectual rights agreement. In order to combine ensuring food security with granting IP rights in India, the Indian government is currently having difficulty.

5) IPRs, Community property rights, & Indigenous knowledge

To demonstrate the effectiveness of the broad traditional understanding, pharmaceutical firms can easily create a new formulation using traditional knowledge to provide them with ready-made leads. The Indian government is required to safeguard the extensive repository of traditional knowledge by prohibiting foreign corporations from obtaining copyrights on traditional culture. The government established the TKDL (customary Knowledge Digital Library) as a preventive measure against attempts to copyright customary Indian wisdom. Developed nations and multinationals are also opposed to this actions.

References

- [1] Baker, B.K., 'A Critical Analysis of India's Probable Data Exclusivity/ Data Compensation Provisions', Health Gap, available at www.healthgap.org, 2004.
- [2] Clift, C., 'Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals', in A. Krattiger, R.T. Mahoney and L. Nelsen (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, available at <http://www.ipHandbook.org>, MIHR/PIPRA, Oxford, UK/Davis, US, 2007.
- [3] Grabowski, H., 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries', Duke University, July 2002.
- [4] Grabowski, H., 'Data Exclusivity for New Biological Entities', Working Paper, Duke University of Economics, June 2007.
- [5] Kuanpoth, J., 'Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts of Technological Capability: A Case Study of the Pharmaceutical Industry in Thailand', ICTSD Program on IPRs and Sustainable Development, ICTSD, Geneva, November 2006.
- [6] Lokuge, B., T.A. Faunce and R. Dennis, 'A Backdoor to Higher Prices? Intellectual Property and the Australian US Free Trade Agreement', The Australia Institute, 2003.
- [7] Pugatch, M.P., 'Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access', ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, Italy, October 12-16, 2004.
- [8] Controller General of Patents, Designs and trademarks. History of Indian Patent System. [Last accessed on 2018 Jun 27]. Available from: <http://www.ipindia.nic.in/history-of-indian-patent-system.htm>.
- [9] Nair GG. Impact of TRIPS on Indian pharmaceutical industry. *J Intellect Prop Rights*. 2008;13:432-41. [Google scholar]
- [10] World Trade Organization. WTO What Is the WTO? – Who We Are. [Last accessed on 2018 Jun 27]. Available from: https://www.wto.org/english/tratop_e/trips_e/intell_e.htm
- [11] World Intellectual Property Organization. (n.d.). Pharmaceuticals and IP <https://www.wipo.int/patents/en/pharmaceuticals.html>
- [12] World Health Organization. (2017). Intellectual property rights and access to essential medicines. <https://www.who.int/medicines/areas/policy/ip_rights/en/>
- [13] Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004. Law relating to intellectual property.
- [14] World Intellectual Property Organization (WIPO) - www.wipo.int
- [15] World Trade Organization (WTO) - www.wto.org