

INTELLECTUAL PROPERTY RIGHTS AND ITS CONSEQUENCES FOR THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

The term "intellectual property rights" (IPR) refers to the legal privileges granted to the inventor or creator to safeguard their work for a predetermined amount of time. These legal rights allow the inventor or creator, or his assignee, the sole right to fully exploit their idea or creativity for a specific amount of time. It is widely acknowledged that IP is essential to the modern economy. Research and development (R&D) expenses have increased dramatically, and this has led to an increase in the investments needed to introduce new technologies to the market. A legal notion known as intellectual property relates to works of creative genius for which exclusive rights are acknowledged. Copyright, trademarks, patents, industrial design rights, trade dress, and, in some jurisdictions, trade secrets are examples of common

intellectual property rights. Despite the fact that the medical and scientific community around the world has a very strong opposing opinion regarding the safety and efficacy of Ayurvedic medicines, Ayurveda is receiving its just due recognition as a logical system of medicine. The Indian patent law has provisions that make it difficult to patent Ayurvedic medications. It is urgently necessary to alter the patenting rules with practical promotional strategies if the authors must invite researchers from basic science to ensure the quality, safety, and efficacy of Ayurveda medications. Many people and organizations are exploring the potential for business benefits of using traditional Ayurveda knowledge due to provisions of intellectual property rights under the International Intellectual Property Organization and patents.

KEYWORDS:- Intellectual property, Research, patent copyright, Ayurveda, Quality, Safety etc.

INTRODUCTION

Any original work of the human mind, including those in the arts, sciences, literature, technology, or other fields, is considered to be the subject of intellectual property (IP). The term "intellectual property rights" (IPR) refers to the legal privileges granted to the inventor or creator to safeguard their work for a predetermined amount of time. These legal rights allow the inventor or creator, or his assignee, the sole right to fully exploit their idea or creativity for a specific amount of time. It is widely acknowledged that IP is essential to the modern economy. Additionally, it has been unequivocally proven that the intellectual labour connected to the innovation deserves to be given the respect it deserves in order for it to serve the greater good. Research and development (R&D) expenses have increased dramatically, and this has led to an increase in the investments needed to introduce new technologies to the market. The stakes for technology developers have increased significantly, making it necessary to secure knowledge from un-authorized use, at least temporarily, in order to ensure recovery of R&D and other related expenditures as well as sufficient earnings for further R&D investments. IPR is a powerful weapon for protecting the inventor's or artist's time, money, and effort since it gives the inventor or creator an exclusive right to utilize his invention or creation for a specific amount of time. IPR so promotes healthy competition, fosters industrial progress, and supports economic growth, all of which contribute to a nation's economic development. With a focus on pharmaceuticals in particular, the current paper provides a succinct summary of IPR.

Intellectual property Right (IPR)

There are two type of properties

Physical property - house, plots etc.

Intellectual property – It is a term referring to creation of the intellect for which a monopoly is assigned to designated owners by law. Intellectual property is an idea, a design, an invention, a manuscript etc. which can ultimately give rise to a useful product and application. Intellectual property Right – IPR are protection rights which are granted to the creators of the Intellectual property and includes patent, copyrights, industrial design rights, trademarks, plant variety rights, trade design and in some jurisdiction trade secrets. or rights of an inventor to derive economic benefits from his intellectual property.

Objectives of the IPR

- To enhance the performance level of the institutions etc.
- To give recognition and financial benefits to the efforts for the creativity.
- To create the competition among the researchers and institution for the quality of the research.
- To have return on investment in research.
- To fasten the technology transfer through licensing and other means.
- Society benefits in the long term because Intellectual property protection encourage creation and inventions enter the public domain, the public can realize the benefits at low cost.
- To growth of society.
- Economical incentive.

Need of IPR

- Hard-Work
- Time duration
- Cost
- Mind work
- Research Development

Types of IPR

Industrial - Patent, Trade Mark, Industrial Design, Geographical Indication etc.

Copyright – Books Publication, Novel, Drawing, Article Design etc.

Note – IPR is mention in Universal Declaration of Human Rights, 1948

WIPO (World Intellectual Property Organization)

Every nation has framed their intellectual property law. But on international level it is governed by World Intellectual Property Organization. This organization is one of the 17 specialized agencies of the UN and was created in 1967 to *“Encourage creative activity, to promote the protection of intellectual property through the World”*

Headquarter – Geneva, Switzerland

CEO – Francis Gurry (1 Oct. 2008 – till now)

Established – 14 July 1967

Parent organization – United Nations Economic and Social Council

Member - 191

India has become the member of this organization in 1975.

Important Convention of WIPO

Paris convention in 1883 – The protection of industrial property/Importance in invention, patents and industrial design.

Berne Convention in 1886 – For the protection of literary and artistic work.

Application of IPR

- Industrial design
- Scientific discovery
- Protection against unfair competition
- Invention in all field of human endeavor
- Performance of artists, phonograms and broadcast
- Trademark, service marks and commercial names and designation
- All other rights from intellectual activity in the industrial, scientific, literary or artistic field.

Legislation covering the IPR in India

- **Patents** – The Patent Act – 1970, amended in 1999 and 2002
- **Design** –The Design Act -1911.
- **TradeMarks** – New Trade Mark Act – 1999 has been enacted superseding the earlier, Trade and Merchandise Marks Act – 1958.
- **Copyright** – The Copyright Act – 1957, The Copyright Rules – 1958, as amended in Act in 1983, 1984, 1992, 1994, 1999, 2012.
- **The Sui-Generis** – It was approved by both houses of the parliament on 23 Dec 1999 and named as the Geographical Indication of Goods (Registration and Protection) Bill- 1999.

TRIPS (Trade related aspects of intellectual property rights)

The agreements on TRIPS is an international agreement administered by World Trade Organized that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO members. TRIPS was negotiated at the end of Uruguay round of the “**General Agreement on Tariffs and Trade (GATT) in 1994**”. The TRIPS agreement introduces intellectual property law into the international trading

system for the first time and remains the most comprehensive international agreement on intellectual property date.

❖ **Trade secret** – When an individual organization owning and intellectual property does not disclose the property of anyone and keep it as a closely guarded secrets, it is called as Trade Secret. Trade Secret may relate to formulation, processes of materials etc. For example, best guarded secrets of the modern time concern the formulation of Coca cola. In the area of biotechnology materials kept as trade secret include cell lines, micro-organisms strains production processes.

Advantages

- They are for unlimited time duration.
- It is not necessary to satisfy the reather stringent requirement for protection under patents
- The cost of filing, contesting and enforcing patent is saved.
- The risk of someone improving upon the product, process is minimized.

Disadvantage

- Maintaining a trade secret itself a costly affair.
- It offers not protection from independent innovation invention.
- Non-disclosure of the invention, innovation does not give others a chance to improve upon the original invention.
- It cannot be applied to many inventions example equipment designs, plant varieties, books etc.

1. **Patents** – A patent is a Right which granted by the Govt. to an inventor to exclude others from imitating, manufacturing, using or selling the invention in question for commercial use during the specific period.

A patent is set to exclusive ownership rights granted by a sovereign state to the inventor or assignee for a limited period of time in exchange for detailed public disclosure of an invention patents are a form in intellectual property.

❖ Different aspects related with patent

Exclusively of rights implies that no one can else make, use, manufacture or market the invention without of consent of the patent holder. However, use or exploitation of a patent

may be affected by other law of the country which has awarded the patent. These laws may relate to health, safety, food security etc.

A patent in the law is a property right and hence it can be gifted, inherited, assigned, sold and licensed. As the right is conferred by the state, it can be revoke by the state under very special circumstances for the benefit of public even if the patent has been sold or licensed or manufactured or marketed in mean time.

- *A patent can be obtained only if the invention is novel and is not known to the public through publication or prior use anywhere in the world. It should not be a part of the existing global state of art (information in magazines, journals, newspaper, books, published patent etc.)*
- *Novelty on an invention can be ceased if disclosed by oral description in a seminar/conference or by publication anywhere in the world before filing of the form for the patent.*
- *Patent search is essential and critical for ascertaining novelty as most of the information reported in the patent document does not usually get published anywhere else or it is published in technical literature after a fairly long gap.*

❖ **Patents are grant for**

- An invention including a product.
- Innovation or improvement in an invention.
- Process or product of an invention.
- A concept.

❖ **Property which can't be patent**

- A scientific principle or an abstract theory.
- A discovery of a new property or new use of a known substance.
- A method of agriculture or horticulture.
- Inventions relating to atomic energy are not patentable.

❖ **Patents requirement**

- **Novelty** – The invention must be new and should not be already known to the public.
- **Inventiveness** – The invention should not be obvious to a person skilled in the art and should represent an innovation.

- **Industrial application and usefulness** – The subject matter of the patent must have on industrial application, either immediate or in the future that is useful to the society or nation.
- **Patentability** – The subject of a patent must be patentable under the existing law and its current interpretation. For example - The Indian Patent Act- 1970 did not allow the product patent in pharmaceutical food and Agro-Chemicals. But this act has now been amended as Indian Patent Act -1999 and the new act allows product patents except for some specific medicine drugs.
- **Disclosure** – The inventor is required to describe his invention in sufficient detail so that a person of normal skill is able to reproduce it.

❖ **Procedure for obtaining patent**

A. Application for patent

- Application should be in prescribe form and filed in the patent office.
- The application shall state that the application is in possession of the invention and give the name of the owner claiming to be the true and the first inventor.
- If the person so claiming is not the application, the application shall contain a declaration that the applicant believe the person so named to be true and first owner.

B. Whom to apply – There are four patent office in India which are located in Mumbai, Calcutta, Delhi and Chennai etc. The application must be an Indian national or a national of conventional country. Foreign applicants who do not have a place of business in India are required to file their patent application through an Indian patent agent.

C. Provisional and Complete specification – Where the application is accompanied by specification, a complete specification should be filled within 12 months from the date of filing the application. If this is not done application shall be deemed to be abandoned. The methods by which invention was carried out should be fully described. Application should end with a claim defining the scope of invention for which the protection is claimed.

D. Documents and Fee – A set of the forms has to be submitted to the patent. The form can be submitted online using www.ipindiaonline.gov.in/on-line, if the applicant has class 3 digital certificate.

Note – A fee of Rs. 100/sheet (Natural person) and Rs 400/sheet (other than natural person) is applicable for each sheet exceeding 30 sheets in a patent specification. Further a fee of Rs. 200/claim (Natural person) and Rs 800/claim (other than natural person) is applicable for each claim exceeding 10 claim in the patent specification.

E. Renewal fee

1. For 2-6 years Rs. 500 for individual and Rs. 2000 for legal entity.
2. From 7-10 years Rs. 1500 for individual and Rs. 6000 for legal entity respectively.
3. From 16-20 years Rs. 5000 for individual and Rs. 20,000 for legal entity respectively.

F. Publication of application - A patent application shall be published in the official journal of the patent office on expiry of 18 months from the date of filing of the application. Every application shall be published on expiry of the period prescribed. Except –

- Where secrecy directions is imposed under section 35.
- Has been abandoned under section 9.
- Has been withdrawn 3 months prior to the period specified.

G. Examination of application - Within a period of 48 months from the date of filing of application, the applicant or any other interested person may request the register to examine the application. If no such request is made than the application will be deemed to have been withdrawn and thereafter can't be reviewed. The examiner makes a search in the patentoffice for specification of prior application and patent to see whether the same invention has already been published or claimed or is the subject matter of existing or expire patents. A report is accordingly made to the controller within 14th from the date of reference. The patent office after the examination of the application will communicate to the applicant the objection, if any to the grant of a patent.

H. Granting of patent - When applicant satisfactorily removes the objections, the controller will accept the complete specification and advertise it in the official gazette. The patent shall be granted as soon as possible with the seal of the patent office and the date on which the patent is granted shall be entered in the register.

It will be grant according to section 43 and provide a stamp with sealed. This process is called “sealing of patent”.

Limitation of Time – A patent is valid for specific time period i.e. 15-20 years.

Limitation of Space - A patent is valid only in the country of its award and not in other country.

❖ Objectives of granting PATENT

- To encourage scientific research, new technology and industrial progress.
- Accelerate the technological and industrial development of the country.
- To induce an inventor to disclose the discoveries instead of keeping them as a trade secret.
- To offer a reward for expenses of developing invention to the stage at which they are commercially practicable.
- To provide inducement to invest capital in new lines of production.

2. Copyright

It provides the protection for specified period or only from re-production of the copyright material. Example – Biotechnological copyrights protection is available for DNA sequence.

A copyright gives the creator of an original work exclusive right to it, usually for a minimum period of 50 years after death of the author. Copyright may apply to a wide range of creative, intellectual or artistic forms or works. Copyright doesn't cover and information themselves only the form or manner in which they are expressed. Subject matter in the copyrights which may be original work of authorship.

Under Ministry of Human Resource Development

Administration of the act

Copyright office – Registration

Copyright Board - Decide the disputes

Copyright Society - Copyright grant

Protection under copyright

- Choreography - Gestures and Facial Expressions, Dance Moments.
- Literary Works – Books, Speech, Advertising, Copy, Games, Computer Programs
- Musical Composition - Musical score, CD, DVD, Cassettes, Tape, Mp3 files etc.
- Dramatic Activities -Play movies, TV shows, News etc.

- Graphics and Sculptural activities – Photographs, Prints, Maps, Cartoons, Fabrics, Games, Posters etc.
- Additional activities – Audio Visual Works, Sound Recording , Architectural Works etc.

Exceptions to copyrights

- Name of products, business, organizations or group
- Pseudonyms of individuals
- Titles of works
- Listing of ingredients in recipes, labels and formulas.

3. Trademark

Trademark is a recognizable sign, design or expression which distinguishes products or services of a particular trader from the similar products or services of the other products. In short Trademark is a logo or sign of particular brand. Indian Trademark law protects *Domain names* as demonstrated in landmark case of : Tata sons Ltd. V. Manu Kosuri & ors.

Important facts

- Trademark is defined in sec. 2(zb) of **Trade mark Act - 1999**
- Trademark may be a name, symbol, sign or shape of goods.
- It is mentioned industrial property.
- **Duration** – Trademark registered is valid for a period of 10 years.
- **It can be further renewed for a term of 10 yrs.**
- The failure in the renewing of the trademark within the stipulated period of time, a grace period of maximum 1 year granted for restoration of the trademark.

Requirement of trade mark registration

- A. Graphically presented (offline or online)
- B. Capable to distinguishing goods or services from others.

Not – if any trade mark application is not completed within 12 months from the date of filing of the application, it is deemed to be abandoned.

4. Geographical indication

Geographical indication is a sign that identifies a product as originating in a given place. It states that a particular product belongs to a particular place. Since the qualities depend on the geographical place of production, there is a clear link between the product and its original

place of production. Geographical indication is primarily granted to agriculture, natural, manufactured, handicraft originating from a definite geographically territory.

Example – Darjeeling tea

Intellectual property rights provide the protection to copyright, patent, trademark etc. geographical indication tag provides similar rights and protection to the holders.

Article 1(2) and 10 of the Paris convention for the protection of industrial property, geographical indications are covered as an element of IPRs.

Provisions of geographical indication

G.I. related provisions are under cover the Articles 22 to 24 of the TRIPS agreement.

Article 22(1) of the TRIPS agreement “*indication which identify a good as originating in the territory of a member or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attribute to its geographic origin*”. In India Geographical Indication are protected and governed by the “*Geographical Indication of Goods (Registration and Protection) Act 1999*”. It come into force with effect from 15th September 2003. Geographic Indication registry office is establish at Chennai.

Benefits of the registration of G.I.

- It provides legal protection to Geographical Indication in India.
- It prevents unauthorized use of a registered Geographical Indication by others.
- It provides legal protection to Indian Geographical Indication which in turn boost exports.
- It promotes economic prosperity of producers of goods produced in a Geographical territory.

Protection under G.I.

- Agricultural product (Basmati rice)
- Natural product
- Handicraft or any industry (Kashmiri pashmina)
- Foot stuffs

Who can apply

- Any association of the persons

- Producers
- Organisation
- Authority which established under the law

Who can't apply (U/S 9)

- Which would likely to deceive or cause confusion
- Which would be contrary to any law for the time being in force or
- Which comprises or contains scandalous or obscene matter or
- Which comprise or contains any matter likely to hurt the religious susceptibilities of any class or section of the citizen of India or
- Which would otherwise be disentitled to protection in a court or Generic name
- Falsely represent to the person that the goods originate in another territory, region or locality as the case may be.

Duration

- G.I. shall be for a period of 10 years.
- It can be renewed for a period of another 10 years on an application made in the prescribed manner and within the prescribed period and subject to the payment of the prescribed fee.

- **Industrial design** - An industrial design rights protects the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or combination of pattern and color in three dimensional form containing aesthetic value. An industrial design can be a two or three dimensional pattern used to produce a product.
- **Trade dress** - Trade dress is a legal term of art that generally refers to characteristics of the visual appearance of a product of its packaging or even the design of a building that signify the source of the product to the consumers.
- **Plant varieties** - Plant breeder's rights or plant variety rights are rights to commercially use a new variety. The variety must amongst others to be novel and distinct and for registration, the evaluation of propagating material of the variety is examined.

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