



ISSN (E): 2277- 7695
ISSN (P): 2349-8242
NAAS Rating: 5.03
TPI 2018; 7(6): 522-531
© 2018 TPI
www.thepharmajournal.com
Received: 18-04-2018
Accepted: 26-05-2018

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Role of IPR for commercialization of pharma products

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Abstract

Intellectual Property (IP) is defined as any product of intellect that the law protects from unauthorized use by others. These include patents, copyrights, trademarks and trade secrets. It has been listed that globally only 0.3% research patents have been commercialized till now. Management of intellectual property product is a major challenge and in this paper we attempt to give an overview of the process involved.

This paper briefly reviews the intellectual property issues and evaluates main components/ perspectives for implementation of policies. In this era of globalization its vital to understand intellectual property rights and existing barriers. The organizations can enhance their growth by using the tools like tech transfer and compulsory licensing procedures to take their business to a next level. Besides patents, industrial design, trade secrets, geographical indications, trademark and copyrights are the essential components of IP. It also helps in trading and collaborating the business with other countries of the world.

Keywords: Patents, Licensing Technology, Technology Transfer, Market Scenario

Introduction

These lawful IP rights present selective exclusive rights to inventor or his assignee to completely use his innovation/creation for a given timeframe. IP plays a key part in the advanced economy. The intellectual labor linked with innovation ought to be given due significance so that public good emanates from it. There has been a quantum hop in innovative work (R&D) costs with a related bounce in speculations required for putting another innovation in the market place. The stakes of the developers of innovation have turned out to be high, and thus, the need to shield the knowledge from unlawful utilize has turned out to be practical, in any event for a period, that would guarantee recuperation of the R&D and other related expenses and sufficient benefits for continuous investments in R&D. IPR is a strong tool, to safeguard investments, time, money, exertion contributed by the innovator of an IP, since it allows the inventor the exclusive right for a specific timeframe for utilization of his innovation. Thus the IPR helps in economic advancement of the nation by advancing strong competition and empowering industrial development and economic growth^[1].

Brief History

The laws and managerial techniques relating with IPR have their foundations in Europe. The pattern of granting patents began in the fourteenth century. In contrast with other European nations, the England was advanced technically and attracts artisans from other places. The primary known copyrights appeared in Italy. Venice can be viewed as the cradle of IP framework as most lawful thinking was done here of that area; laws and frameworks were created here for the first time and different nations followed in due course. Patent act in India is over 150 years of age. The inaugural one is the 1856 Act, which depended on the British patent framework and it has given the patent term of 14 years took after by various acts and amendments^[1].

Types of Intellectual Property Rights

There are six types of IPR viz:



Fig 1: Depiction of types of Intellectual Property Rights

1. Copyright

Copyright (or author's right) is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture, and films, to computer programs, databases, advertisements, maps, and technical drawings [2].

What can be protected using copyright?

Exhaustive lists of works covered by copyright are usually not to be found in legislation. Nonetheless, broadly speaking, works commonly protected by copyright throughout the world include:

- literary works such as novels, poems, plays, reference works, newspaper articles;
- computer programs, databases;
- films, musical compositions, and choreography;
- artistic works such as paintings, drawings, photographs, and sculpture;
- architecture; and
- Advertisements, maps, and technical drawings.

Copyright protection extends only to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such. Copyright may or may not be available for a number of objects such as titles, slogans, or logos, depending on whether they contain sufficient authorship [3].

Copyright Owner's Rights

The principal end of copyright law is to protect the time, effort, and creativity of the work's creator. As such, the Copyright Act grants the copyright owner certain exclusive rights, including the right to:

- Reproduce the work
- Prepare "derivative works" (other works based on the original work)
- Distribute copies of the work by sale, lease, or other conveyance of ownership
- The right to perform the work publicly
- Exhibit the work publicly

The copyright owner also receives the right to authorize other

people to do any of the rights mentioned above. The copyright owner owns the option and the ability to change his or her exclusive rights or any subsection of those rights to others as easily [3].

2. Patents

What is a patent?

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 [3].

What kind of protection does a patent offer?

In principle, the patent owner has the exclusive right to prevent or stop others from commercially exploiting the patented invention. In other words, patent protection means that the invention cannot be commercially made, used, distributed, imported or sold by others without the patent owner's consent [3].

How long does a patent last?

The protection is granted for a limited period, generally 20 years from the filing date of the application [3].

Patent Categories

There are three different forms of patents: utility patents, invention patents and plant patents.

1. **Utility Patents:** The most vulgar type of patent, these are given to new machines, chemicals, and procedures.
2. **Design Patents:** They are granted to protect the unique visual aspect or pattern of manufactured objects, such as the surface ornamentation or overall design of the object.
3. **Plant Patents:** Granted for the invention and asexual reproduction of new and distinct plant varieties, including hybrids.

Det-Agreement Patents: Granted for the invention and asexual reproduction of new and distinct plant varieties, including crossbreeds, even if it is dissimilar from the other inventions means it must not have been sold and used publicly or must not be patented by another inventor within a twelve month of the date patent application was lodged.

- The sum which is obtained naturally, yet if they newly discovered, cannot be patented
- Abstract principles, fundamental truths, calculation methods, and mathematical formulas are also not patentable.
- A patent cannot be obtained for an estimate or proposition.
- For unsafe drug and a conception with no legal purpose cannot get a patent [3].

3. Trademarks

What is a trademark?

A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights [4]

What rights does trademark registration provide?

In principle, a trademark registration will confer an exclusive right to the use of the registered trademark. This implies that the trademark can be exclusively used by its owner, or licensed to another party for use in return for payment.

Registration provides legal certainty and reinforces the position of the right holder, for example, in case of litigation^[4].

How long does trademark protection last?

The term of trademark registration can vary, but is usually ten years. It can be renewed indefinitely on payment of additional fees. Trademark rights are private rights and protection is enforced through court orders^[4].

What kinds of trademark can be registered?

A word or a combination of words, letters, and numerals can perfectly constitute a trademark. But trademarks may also consist of drawings, symbols, three-dimensional features such as the shape and packaging of goods, non-visible signs such as sounds or fragrances, or color shades used as distinguishing features – the possibilities are almost limitless^[4].

4. Industrial Designs

What is an industrial design?

In a legal sense, an industrial design constitutes the ornamental or aesthetic aspect of an article.

Industrial Design protection is provided for a shape, configuration, surface form, color, or line (or a combination of these), which, when applied to a functional article, produces or increases aesthetics, and improves the visual appearance of the design, be it a two-dimensional or a three-dimensional article

Industrial Design protection is a type of intellectual property right that gives the exclusive right to make, sell, and use articles that embody the protected design, to selected people only. Security rights are provided for a period of 10 years. They can then be renewed *once* for an additional period of 5 years

The pre-requisites for a design to qualify for protection are as follows:

1. It should be Unique and original
2. It should be applied to a functional article
3. It should be visible on a finished article
4. It should be non-obvious
5. There should be no prior publication or disclosure of the design^[4].

What kind of protection does an industrial design right offer?

In principle, the owner of a registered industrial design or of a design patent has the right to prevent third parties from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes^[4].

What cannot be registered as an industrial design?

There are certain things that do not fall under industrial designs, such as:

- A method of construction;
- An estimate (which is usually protected under patent);
- The actual materials utilized in drawing something (for example, the material a protective mask is made of)
- The function of something (again that is usually covered by patents)^[4].

5. Geographical Indications

What is a geographical indication?

A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. In order to function as a GI, a sign must identify a product as originating in a given place. In addition, the qualities, characteristics or reputation of the product should be essentially due to the place of origin^[3].

What rights does a geographical indication provide?

A geographical indication right enables those who have the right to use the indication to prevent its use by a third party whose product does not conform to the applicable standards. For example, in the jurisdictions in which the Darjeeling geographical indication is protected, producers of Darjeeling tea can exclude use of the term “Darjeeling” for tea not grown in their tea gardens or not produced according to the standards set out in the code of practice for the geographical indication. However, a protected geographical indication does not enable the holder to prevent someone from making a product using the same techniques as those set out in the standards for that indication. Protection for a geographical indication is usually obtained by acquiring a right over the sign that constitutes the indication^[3].

6. Trade Secret

Any confidential business information which provides an enterprise a competitive edge may be considered a trade secret. Trade secrets encompass manufacturing or industrial secrets and commercial secrets. The unauthorized use of such information by persons other than the holder is regarded as an unfair practice and a violation of the trade secret. Depending on the legal system, the protection of trade secrets forms part of the general concept of protection against unfair competition or is based on specific provisions or case law on the protection of confidential information.

The subject matter of trade secrets is usually defined in broad terms and includes sales methods, distribution methods, consumer profiles, and advertising strategies, lists of suppliers and clients, and manufacturing processes^[2].

Procedure of Patent Filing across the World

Patent filing is the utmost requirement for the protection of the new idea that has procured in the mind. For that, a set of fully finished forms has to be submitted to the patent office with the required information. The forms can be on online on the given link

<http://ipindiaonline.gov.in/epatentfiling/goForLogin/doLogin> if the patentee has the three certificates. The patent can be filed offline also but the offline applications are charged 10% extra than the online applications^[6].

The most important part is preparing in patent application is patent specification. Highly skilled persons are needed who have the technical knowledge as well as patent law expertise, to write up the patent specification part of the patent application. The person filing the patent the patent should be thorough with the Indian Patent Law so as to avoid mistakes^[6].

Indian patent offices are located at Delhi, Kolkata, Mumbai and Chennai. The patent application has to be filed in the appropriate office based on your/your company's location. The table below provides the addresses of the patent offices in India and their respective territorial jurisdiction^[6].

Table 1: Location of Patent Offices in India

Office	Address	Territorial Jurisdiction
Mumbai	Intellectual Property Office, Boudhik Sampada Bhawan, Near Antop Hill Post Office, S.M.Road, Antop Hill, Mumbai – 400 037. Phone: 24137701, 24141026, 24150381, 24148165, 24171457 FAX : 24130387 EMAIL: mumbai-patent@nic.in	The States of Maharashtra, Gujarat, MadhyaPradesh, Goa and Chhattisgarh and the Union Territories of Daman and Diu & Dadra and Nagar Haveli
Chennai	Intellectual Property Office, Intellectual Property Office Building, G.S.T. Road, Guindy, Chennai-600032, Phone: 044-22502081-84 FAX: 044-22502066, Email: chennai-patent@nic.in	The States of Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and the Union Territories of Pondicherry and Lakshadweep
New Delhi	Intellectual Property Office, Intellectual Property Office Building, Plot No. 32, Sector 14, Dwarka, New Delhi-110075, Phone : 011-28034304, 28034305 28034306 FAX:011- 28034301,02 Email: delhi-patent@nic.in	The States of Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal, Delhi and the Union Territory of Chandigarh.
Kolkata	Intellectual Property Office, Intellectual Property Office Building, CP-2 Sector V, Salt Lake City, Kolkata-700091, Phone : 23671945, 1946, 1987, FAX-033-2367-1988, Email:- kolkata-patent@nic.in	The rest of India.

Forms for Filing the Patent Application

1. Form 1 – Application for Grant of Patent

This form is an application for grant of patent in India. Information, such as, name and address of the inventor(s), name and address of the applicant(s), information corresponding to prior patent applications relating to the current invention, which any authorized entity has filed, and some declarations, among other information ^[5].

2. Form 2 – Provisional/Complete Specification

It is used to furnish your patent specification. The patent specification can be provisional or a complete patent specification depending of the type of patent application (provisional or complete) being filed ^[5].

If the filing of patent is being done offline then, 2 copies of the patent specification has to be sent to the patent office. Additionally, count the number of sheets and claims (extra fee for more than 30 sheets and more than 10 claims) and calculate the appropriate fee ^[5].

3. Form 3 – Statement and Undertaking Under Section 8

It is used to furnish information/actions relating to patent applications filed in other countries for the current invention. Form 3 is used to undertake that the patentee will be keeping

the patent office informed in writing the details regarding corresponding applications for patents filed outside India ^[5].

4. Form 5 – Declaration as to Inventorship

It is used to declare the inventors of the subject matter sought to be protected using the current patent application ^[5].

5. Form 9 – Request for Publication

If this form is not filed, then the patent specification will be published by the patent office after 18 months from the priority date (filing of the first patent application for the current subject matter). By filing this form, patentee can have patent specification published within 1 month from filing this form. The patent rights start from the date of publication of the patent application (enforceable after grant of patent) ^[5].

6. Form 18 – Request for Examination of Application for Patent

This form can be filed within 48 months from the priority date. The patent office will not consider the patent application for examination unless this form is filed. A startup can also request for expedited examination of their patent application. The fee for this is INR 8000 ^[5].

Table 2: List of forms that ave to be submitted along with the fee they are charged. The above mentioned fee is for E- Filing only

Form	Title	Patent office Fee (INR) 1\$ = ~ 60 INR E-Filing only			Comment
		Applicant-Natural person/ Startup	Applicant – other than natural person		
			Small Entity	Others except small entity	
1	Application for Grant of Patent	1600	4000	8000	Mandatory
2	Provisional/Complete Specification	No fee*	No fee*	No fee*	Mandatory
3	Statement and Undertaking Under Section 8	No fee	No fee	No fee	Mandatory
5	Declaration as to Inventorship	No fee	No fee	No fee	Mandatory
9	Request for Publication	2500	6250	12500	Optional
18	Request for Examination of Application for Patent	4000	10000	20000	Mandatory

Note: After the selection of the Patent Office in which filing has to be done, Forms 1, 2, 3 and 5 have to be submitted. Thereafter submission of these forms, patent application number will be provided by the patent office. Form 9 and 18 can be filed along with the initial application or after the complete filing of application ^[5].

Types of Patent Application

1. Provisional Application

This temporary application is filed when the invention is not fully ready and is still under experimentation.

Advantages of filing a provisional application

- 12 months time is being granted to the applicant for completing the experimentation process and knows its market value.
- The applicant gets the priority over the other applicants working on the same topic.
- After filing provisional application, “patent pending” term can be written over the product label.
- Preparation of patent filing becomes cheap.
- With this, the applicant can file international application and can claim for priority in the time period of 12 months.

Note: Complete specification has to be given within 12 months after submitting the provisional application for the grant of patent. The provisional application should be drafted in such a way that the priority rights are protected and detailed enough to provide sufficient information [6].

2. Convention Application

This application claims for the priority date in which the patent has been filed in the patent office. This gives the priority rights over the claim date for filing and gives priority to the applicant over the other applicants who are filing patent for the similar application. Applicant should file an application to get the convention status of the application in the Indian Patent Office within 12 months from the date of filing in the convention country of similar application [6].

3. Non-Provisional Application Or Ordinary Application

This is the application which doesn't claim for priority right in a convention country or any other reference to other patent application being processed in the patent office. This application includes complete bifurcation of specifications and the claims [6].

4. PCT International Application

It is an international application which once filed can give the priority rights in 142 countries because it is governed by PCT (Patent Cooperation Treaty).

Advantages of filing a PCT application

- This application allows the protection for invention in 142 countries around the world as it comes under PCT.
- The date of filing the patent is given the priority in each country that comes under PCT.
- It provides more viability and time to the applicant as it takes 30 – 31 days to recognize the application in different countries from the international date of filing.
- It provides the information about the patent's novelty and innovativeness through the International Patent Search Report.
- The opinion on the patentability of the invention can be asked through this application as it provides the International Preliminary Examination Report.
- This application provides a chance to amend the application before the application goes for national phase patent process [6].

5. Patent Of Addition

This is the application which provides the feature for addition in the existing patent application. It is filed when the applicant finds a modification in the invention and wants to add this modification in the patent application. If a new step that has to be added is indicative of a substantial inventive step, then this application cannot be filed. No extra fee has to be submitted for filing patent of addition if the patent has its exclusivity [6].

6. Divisional Application

As the name suggests, it is a divided application off the parent patent application. This means that when more than one invention is claimed in the same application, then the applicant voluntarily or to meet the official requirements breaks his application into two or more parts depending on the number of the inventive steps described in the parent patent application. It is called as Divisional Application. The date of claiming the parts parent application will be the same [6].

Patent Related Terminologies

1. GATT

It stands for General Agreement on Tariffs and Trade (GATT). It became forceful on January 1, 1948. This agreement was formed to regulate the international trade. It was signed by many countries. At its decline phase, it involved 123 countries as members. The goals of GATT were:

1. Forming a reliable system of international trade
2. Equal and fair treatment of participants
3. Stimulating economic activity through guaranteed policy bindings
4. Liberalization in trade and its development [7].

2. WTO

This stands for World Trade Organization (WTO). It is an international organization which administers the rules of trade globally for liberalization and expansion of international trade by developing agreements, frameworks and dispute resolution processes. It came into force on January 1, 1995. Its major principles are similar as that of Uruguay Round and GATT. The headquarters of WTO is located in Geneva, Switzerland. The role of WTO is as follows:

1. It regulates trade negotiations
2. It enforces the negotiated multilateral trade rules [7].

3. WIPO

WIPO implies World Intellectual Property Organization (WIPO). It was established in 1974 in United States. It has 148 countries as a member and administers 26 treaties in the field of intellectual property rights. It was established under a convention on July 14, 1967. The headquarters of WIPO is located in Geneva, Switzerland. The main objectives of WIPO are:

1. Intellectual property protection globally with cooperation amongst the participating states.
2. Ensuring administrative cooperation among the intellectual property unions created by the Paris and Berne Conventions and sub-treaties concluded by the members of the Paris Union [7].

4. International Bureau

It is the administration body of the WIPO which act as a secretariat. International patent application can be directly filed with IB as receiving office for WIPO instead of filing to

the national or regional patent office ^[7].

5. Paris Convention

This convention was developed to promote the international trade by protecting the industrial property amongst the other member state. This convention was signed in Paris, France on March 20, 1883. The convention has been revised several times and the last amendment was done in 1979. This convention has 176 countries as its members and is one of them. India became a member of this convention on December 7, 1998. This convention helps the members to enjoy the equal treatment for his invention in the other countries also, apart from their country, coming under convention ^[7].

The Paris Convention aims at:

1. National Treatment
2. Right of Priority
3. Independence of patents
4. Parallel importation
5. Protection against false indications and unfair competition.

This convention ensures that each member country has a right to advocate for the grant of compulsory licenses to prevent the abuses resulting from the exclusive rights offered by a patent ^[7].

6. PCT

It stands for Patent Co-operation Treaty. It is administered by WIPO. It became operational in 1978 but was adopted in 1970. PCT has 150 Member states which includes India also. It serves as an international treaty which facilitates the blocking of priority date with simultaneously designating the country where the invention is intended to be protected. It also acts as information centre globally for the general public. The patent application can be filed at the national office of the respecting member state or International Bureau of the WIPO ^[8].

PCT procedure includes filing followed by international search, publication, supplementary international search (optional), international preliminary examination (optional). The last phase is national phase in which patent is granted to the applicant ^[8].

The patent protection for an invention in more number of countries is possible by filing an international patent application through the Patent Cooperation Treaty (PCT). Such an application might be filed by any individual who is a national or inhabitant of a PCT Contracting State. On the international filing date all contracting states are automatically designated on the filing of PCT application. The granting of patent is done in national phase and is under the control of national or regional patent office ^[8].

The international search is done by the competent International Search Authorities (ISA) of international application within PCT and international search report is published with results having list of citations of published documents that would affect the patentability of the invention in international application. The search report and written opinion is communicated to applicant who upon evaluation may decide whether to withdraw or amend the claims in application ^[9].

The international application is then published to International Bureau along with international search report. The application can also request Supplementary International Search Authority (SISA) for additional search of relevant

documentation prior the expiration of 19 months of priority date ^[9].

The applicant upon decision can continue to obtain national or regional patents with the international application until the end of thirtieth month from the priority date to begin the national procedure phase before each appointed office by providing the translation of application into official language of that office with payment of fees and obtaining services of local patent agents ^[9].

The PCT brings the world within reach, put off major costs linked with international patent protection, used as a tool for strong patenting decisions, used for international patent protection worldwide and is utilized by corporations, research institutions and universities ^[9].

Role of Patent Cooperation Treaty

Through PCT, an innovator of a member country contracting state of PCT can at the same time get priority for his/her invention in all or any of the member countries, without filing a different application in the countries of interest, by assigning them in the PCT application ^[10].

An independent patent application is needed to be filed in each country of interest in order to safeguard invention in other nations within a specific time to get priority in these nations. This would involve big investment, within a brief span, to meet expenses towards filing fees, translation, attorney charges, etc ^[10].

The Inventors of contracting states of PCT can obtain priority for their inventions simultaneously without filing separate application in countries of interest therefore initial investments towards filing fees, translation etc. could be saved ^[10]

The time accessible under Paris Convention for securing priority in other nations is 12 months beginning from the initial filing date. Under PCT, the time accessible could be 20 months minimum and 31 months maximum. To become sure about the patentability of the invention the inventor can go for preliminary examination prior to filing in other countries ^[10]

7. ISA

It stands for International Search Authority (ISA). It evaluates the patent application for the patentability and gives the option for international search and written opinion. The queries are then answered if any. Applicants have the right to choose the ISA/ International Preliminary Examination Authority (IPEA). The various ISA's are as follows ^[11]:

1. Indian Patent Office
2. Australian Patent Office
3. European Patent Office
4. State Intellectual Property Office of the People's Republic of China
5. Swedish Patent and Registration Office
6. United States Patent and Trademark Office ^[11]

The fee structure for Indian patent office as the ISA, search fees is INR 10,000 (\$154) for large entity whereas INR 2500 (\$38) for a natural person, whereas if the designated office is any International Patent office then the fees ranges from 330 \$ for State Intellectual Property Office of the People's Republic of China to 2097 \$ for European Patent Office. For the supplementary searches, only Austrian, Swedish and European patent office are available for an Indian applicant and the fees ranges from CHF 928 to CHF 2046, along with CHF 200 as handling fees which is same for all the International Search authorities. European Patent office and

Austrian Patent office provides 70% discount for the natural persons ^[11].

8. Budapest Treaty

It was signed on April 28, 1977 and amended on September 26, 1980. This treaty states that when a biological product involves the use of strain of micro-organism, the specification describing the invention cannot efficiently enable third parties to carry out the invention in the absence of biological material. Hence, deposition of biological material is imperative for such type of inventions. For this purpose, this treaty was signed. It has institutes in its member states which mandate the deposition of the microbial strain in the International Depository Authority (IDA). It asks the description of the microbial strain in the patent application also ^[11].

Licensing and Technology Transfer

I. Licensing

A license is a legal agreement by which the owner of an invention (licensor) grants rights to the licensee to make, use, and/or sells the invention within the framework of license agreement. To manufacture and market a patented product, a firm needs a license which is issued by a licensing authority ^[12].

- **Licensing an invention**

Licensing can be defined as the buying or renting the intellectual property i.e. invention so that it produce a market on commercial basis. The inventor who rents his invention receives a fee for his invention. If the payment is done as onetime payment, then it is called as lump sum payment. The percentage of the revenue generated would be given as royalty to the inventor. The parameters which are to be included in licensing is as follows:

1. Exclusivity of the license
2. Lump sum upfront payment
3. Rate and mode of payment royalty
4. Territory for the licensing agreement
5. Liability issues ^[12]

- **Issues to be considered while collaborating with a company**

To protect the exploitation of the patent, the inventor must sign the Non-Disclosure Agreement (NDA) with the company that is properly drafted by a highly qualified person ^[12].

- **Material Transfer Agreement**

The research materials which are perceptible of being felt, created by researches, must be protected by a specific legal document. These documents are called as Material Transfer Agreement. Through this agreement, the collaborator or firm which has taken the invention from the researcher has the right to test and evaluate that research material without exploiting the invention ^[12].

- **Confidential Disclosure Agreement**

This is a legal document signed between transferor of the information (inventor/ researcher) to the other party (firm to which the invention has been given on the rent or on legal terms or the corporate representative of the invention), to protect the proprietary information of the product. Within this agreement, both the parties are not allowed to speak even on the casual conversation about the research based product ^[12].

- **Commercial Evaluation License**

This type of license grants a non-exclusive right to the licensee to make and use the invention as a tool in the Research & Development (R&D) activities. This license does not give the right to sell or commercialize the invention ^[12].

- **Advantages of Licensing a technology**

1. Ensures the commercialization of the invention
2. Helps bringing the product into the market for use by public
3. Generates revenue to the inventor and the firm
4. Prestige of the inventor is increased as the license carries the name of the inventor as well as the organization ^[12].

- **Compulsory Licensing**

It is the licensing system when a government allows a company to produce a patented commodity or use a patented process without the consent of the patent owner. The term compulsory license has been defined in the Indian Patent Act. As per the Act, a compulsory license can be obtained after 3 years from the date of grant of patent. Compulsory license is given on the following grounds:

- a. Needs of the public were not fulfilled or satisfied for the product.
- b. Cost of the patent was above the expected limit of the public.

This license can be categorized based on the condition requirement for its application. Under Indian Patent Act, 1970 (amended in 2005), the categories of compulsory license are as follows:

- a. Section 84 for patent misuse
- b. Section 92 for compulsory licensing in public interest
- c. Section 92 (A) for exports of pharmaceutical products
- d. Section 91 for related patent compulsory licensing ^[12]

II. Technology Transfer

It is the formal terminology used for the transfer of intellectual property or other rights of any product to the other firm for use and commercialization of new invention. Technology transfer is done after the invention has been protected under the patents or copyright category. It's a process that highlights the practical and commercial aspects of the researches, inventions and discoveries so as to benefit the public on large scale and increase further innovation. Technology Transfer/management also comprises evaluation and management of invention portfolios, patent prosecution, demonstration of knowhow, negotiating licensing agreements and periodic review of cooperative research agreements already in place. Technologies can be categorized in three ways as emerging technology, developing technology and established technology ^[12].

1. **Emerging Technology:** This type of technology has been field- tested but does not have a history or proof of its safe use.
2. **Developing Technology:** This type of technology is under innovative stage. Samples under this technology are being under pilot scale study in the laboratory to get the documented results.
3. **Established Technology:** It is that type of technology that has its valuable data related to cost and its performance already available moreover is fully documented ^[12].

Steps considered while transferring the technology

1. Evaluation/assessment of the invention.
2. Protection of intellectual property relating to the technology.
3. Finding the most suitable partner for licensing
4. Licensing to that entity.
5. Demonstration of the working of technology
6. Assist in Pilot level and later large scale manufacturing [12].

Purpose of technology transfer

There are three basic functions of the technology transfer process i.e. coordination, nurturing and linkage.

1. **Coordination:** It should be developed between the researchers, developers and the manufacturers. This constitutes an important element in the technology transfer process. This process enables the exchange of information of internal and external resources amongst the participating parties.
2. **Nurture:** The new technology will be nurtured by proper guidance, counselling and resources available. This will help to commercialize the new technology in a better way.
3. **Linkage:** For linking the various components of technology it is required to catalogue resources related to business enterprises and connecting would-be entrepreneurs/researchers and other technology developers to outside entities which can help in the manufacturing and marketing of products [12].

Freedom to Operate (FTO)

It is a search done before commercialization through which we check whether the technology being licensed, is not infringing the IP technology of the other party. A Freedom to operate is typically a professional and extensive search in the field of intellectual property (not restricted to patents only) [12].

A freedom to operate opinion related to patents usually includes the findings on patent searches in relevant jurisdictions and their expiration dates [12].

IP & Business: Intellectual Property, Innovation and New Product Development

Invention or innovation

The leading determinants of business success are technological innovation. IP system tools minimize risk and facilities involved in taking the innovative technology to market place also enhancing competitiveness of technology-based ventures [13].

Innovation is concerned with the commercialization of the new ideas whereas invention is not associated directly with commercialization. Invention leads to generation of new ideas with the aim of solving specific technical problem and innovation is interaction and feedback process during different stages of product development. Patents are used for the protection of technological innovations [13].

Stage of Idea

If the enterprise have an innovative idea, it is important that the information surrounding the creation of idea is safeguarded as trade secret. This is because not all commercially viable ideas will patented but at inception stage can be treated as trade secrets. The idea that may result in patentable invention, the choice of protection via trade secret

or patent is a business strategic decision and taken at later stage when all patentability requirements are met [14].

Stage of R&D

For the success of project extensive research and consultation must be done. Greater than 800,000 patents granted every year around the world, offer an abundance information, like information on the state-of-the-art, helps to avoid wasting resources like money and time during R&D process. Patent documents may hold information that can prompt further improvements in the product or abbreviate the time taken to get the product to showcase [14].

Global Patent Trends from WIPO

The innovation is trending inclined upward around the globe, with increments in each of the three kinds of licensed innovation applications – patents (7.8% expansion), trademarks (15.3% expansion) and industrial designs (2.3% expansion). China played a noteworthy part in driving this growth, turning into the main national patent office to get more than 1 million applications in a solitary year. Other best patent workplaces incorporate the U.S., Japan, South Korea and Europe [15].

Table 3: The activities and trends that shaped the Global IP system of 2015

Year	Patent application filed (in numbers)
2010	1,997,000
2011	2,158,100
2012	2,356,700
2013	2,564,900
2014	2,680,900
2015	2,888,800

In 2015, there is 2.3% global increase in industrial design application, 7.8% global increase in patent applications and 15.3% global increase in trademark applications over 2014. In China, 84% of additional 207,900 patent applications filed in 2015 in comparison to 2014. The 65% of 872,800 design applications and 45% of 5.98 million trademark applications filed around the world came from China. Closely 1.2 million patent right applications were granted in 2015. The 48% were from computer technology, electrical machinery, digital communication, measurement, medical technology, transport, semiconductors, civil engineering, pharmaceuticals and audio-visual technology [16].

About 83% of the 2.9 million patent applications came from the patent offices of China 38%, USA 20%, Japan 11%, South Korea 7% and Europe 6%. Over 1 million applications were received from China patent office in a single year. In 2015, around 1.2 million previously filed applications granted the patent rights. The 86% of proposals were received from China 30%, USA 25%, Japan 16%, South Korea 9% and Europe 6%. China became the largest patent issuing office surpassing the US in the world with 359,316 granted patents in 2015. [16]

Patents

China's State Intellectual Property Office (SIPO) got the most astounding number of patent applications in 2016, a record aggregate of 1.3 million. It was trailed by the United States Patent and Trademark Office (USPTO) (605,571), the Japan Patent Office (JPO) (318,381), the Korean Intellectual Property Office (KIPO) (208,830) and the European Patent Office (EPO) (159,358). [17]

The best five offices represented 84% of the world aggregate. Among the main five offices, China (+21.5%) and the U.S. (+2.7%) saw filings growth, while the EPO (-0.4%), Japan (-0.1%) and the Republic of Korea (-2.3%) got less applications in 2016 than in 2015(2). Asia's applications share worldwide has expanded from 49.7% in 2006 to 64.6% in 2016, essentially determined by strong growth in filings in China^[17].

In abroad filing, residents of U.S. filed in excess of four fold the number of patent applications abroad (215,918) as Chinese inhabitants (51,522). The U.S. was trailed by Japan (191,819), Germany (75,378) and the Republic of Korea (69,945). Among large middle-income countries Brazil, India, Malaysia, Mexico and South Africa offer greater proportion of applications abroad – extending from 27.3% for Brazil to 47.5% for India. Of the 11.8 million patents over the world in 2016, 2.8 million were in constrain in the U.S., 2 million in Japan and 1.8 million in China^[17].

The WIPO collects data on the rate of women's cooperation in patent applications at national/regional offices, utilizing a name-acknowledgment innovation created by WIPO. It showed relatively high rates in the Russian Federation (38.7% of resident patent applications containing no less than one woman), Mexico (36.4%), the U.S. (27.5%), Spain (24.6%) and Brazil (24.5%)^[17]

Trademarks

An expected 7 million trademark applications covering 9.77 million classes were documented worldwide in 2016, 16.4% a bigger number of utilizations than in 2015.^[17]

The China office had the greatest volume of filing activity of around 3.7 million, trailed by the U.S. (545,587), Japan (451,320), the European Union Intellectual Property Office (EUIPO) (369,970) and India (313,623). Among top five offices, China (+30.8%), Japan (+30.8%) and India (+8.3%) revealed strong yearly growth. Russian Federation (+14.8%), U.K. (+19.1%) and Viet Nam (+21.1%) were also included among top 20 offices^[17].

Trademarks related with advertisement and business management represented 10.5% of all worldwide trademark filing activity in 2016, trailed by PCs, programming and instruments (6.9%), education and entertainment (5.8%) and apparel (5.7%)^[17].

There were an expected 39.1 million dynamic trademark enrolments around the world, of which 12.4 million were dynamic in China alone, trailed by the 2.1 million in the U.S., 1.9 million in Japan, 1.3 million in India and 1.1 million in Mexico^[17].

Industrial Designs

Worldwide industrial design filing in 2016 grown by 10.4% to an expected 963,100 applications containing 1.2 million designs. Design counts grown worldwide by 8.3%, driven fundamentally by solid growth in China^[17].

The office of China got applications containing 650,344 designs in 2016, comparing to 52% of the world aggregate. It was trailed by the EUIPO (104,522), the KIPO (69,120), Germany (56,188) and Turkey (46,305). Among the top 20 offices, the quickest growth in design counts included Islamic Republic of Iran (+34.8%), trailed by Ukraine (+17.4%), China (+14.3%) and the U.S. (+12.1%). The aggregate number of industrial designs grown by 6% and achieved 3.6 million worldwide^[17].

According to RWS in via, an international patent filing

service done survey of global patent partners in June 2017 and the key finding was overall patent filing became more international patent filing with larger than 41% of respondents filed patent application in foreign offices in 2016 with 34% filing in 2015 under Patent Cooperation Treaty (PCT)^[18].

As far as significance of jurisdiction, the United States' framework still positioned number one among the study's respondents. Surprisingly, the U.S. Chamber of Commerce innovation index ranked the current U.S. system of patent rights as 10thwith Hungary. Despite the fact that the U.S. still keeps up a lead over Europe as concerned with the patent filing entities, the European Patent Office is utilized more frequently as search authority than the U.S. Patent and Trademark Office; 77.4 percent of respondents utilized the EPO instead of 61.3 percent utilizing the USPTO^[18]

Conclusion

There are different forms of IP which require different handling, planning and strategies in different fields like law, science, economics etc. Each industry type should have their own laws and policies which must deliberately fulfil their requirements. Pharmaceutical industry currently has an evolving IP strategy. Market needs, Market response and the cost to convert technology in a commercialized state have an impact on IP. Trade and commerce are the important tools which determines the success rate of IP policies.

IP plays an important role in providing access to providers of beginning stage capital, by providing lifeline to invention and reach to market place. IP possession have an imperative part in influencing the decision of external partners to think whether to put resources into a firm and provides the holder more choices. The organizations can gain more benefit through IP awareness.

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