Review Article

An impressive and effective overview on Intellectual Property Rights and their vibrant applicability in Pharmaceutical Sector

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Received: 25 October 2016 Revised: 20 November 2016 Accepted: 23 November 2016

Abstract

Intellectual property refers to the formation of the intellect for which a monopoly is granted to the owners. Intellectual property rights (IPRs) are the protections granted to the creators of IP, and involve trademarks, copyright, patents, industrial design rights, or sometimes trade secrets. Artistic works including music and literature, as well as discoveries, inventions, words, phrases, symbols, and designs can all be protected as intellectual property. In order to regularize IPRs, GATT (General agreement on trade and tariff) was signed. WTO was established on 1st January 1995 after the discussion of 8th GATT round at Uruguay. DOHA Declaration was adopted by WTO Ministerial Conference at DOHA on 14th November, 2001. Hatch–Waxman Act (Drug Price Competition and Patent Term Restoration Act) came in 1984 that deals with the approval of generic drugs and their listing in the orange book in patent offices. The present review deals with the types of IPR, the related treaties and agreements and the recent scenario of IPR across the world.

Keywords: Intellectual property, patent, trademark, copyright, industrial design rights, trade secrets

Introduction

IPRs are the set of legal rights that are granted to a person for creations of the mind or intellect; having both artistic and commercial value. The term 'Intellectual property' refers to the outputs of creative endeavor in literary, artistic, scientific and industrial field (Saha and Bhattacharya, 2011).

The major objectives to provide IPR are:

Financial incentives: These exclusive rights allow owner of intellectual property to have monopoly benefits over a limited period of time. IPRs help to pay associated research and development cost as well as pays the financial benefits to the right holders**.**

Scientific and technological development: IPRs help to encourage the new innovation and creativity in the mind of people thus they are responsible for scientific and technological developments.

Economic growth: The legal monopolies granted by the IP laws are credited with significant contributions towards economic growth because IPRs are provided for innovations that also have the commercial value. A joint research project of United Nations universities measuring the impact of IP on six Asian countries found a positive correlation between the strengthening of IP system and subsequent economic growth.

Types of IPR

1. Patent

A patent is an exclusive right granted by the government to the inventors to make use of their inventions for a limited period of time. Once the owner of an invention has been granted a patent, he can have the legal authority to exclude others from making, using or selling the claimed invention in that country without his consent. In return for such ownership rights, the applicant must make the public aware of complete details of patented inventions like background information related to the invention, a detailed description of the invention and nature of the technical problems solved by the invention. The patent protection in a given country

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does not extend to the other countries; the inventors must file an application in each country where they want their patent to be effective (Ghai, 2010).

The types of patent include:

a) Utility patent:

It may be granted to any one who invents any new and useful process, machine or article.

b) Design patent

A design consists of the visual ornamental characteristics embodied in or applied to a product. Thus it represents the appearance, configuration, shape or surface ornamentation of an article. Patent can be granted for the design but design patent protects only the appearance of the article and not the structural or utilitarian features.

c) Plant Patent:

It is granted by the government to the person, who has invented a new plant other than a tuber propagated plant. Algae and fungi can be patented but bacteria are not patented under plant patent.

The vital conditions for an invention to be patentable are:

a. Novelty:

An invention is novel if it has not been disclosed in the public through any type of publication, seminar any where in the world before filing of the patent application.

b. Utility:

An invention must be useful for being patented. No patent can be granted for an invention devoid of utility.

c. Inventiveness:

The application that is filed for patent should have some inventive step. Inventiveness has no concern with simplicity or complexity of invention. In other words even a very simple invention can qualify for a patent, if it fulfills all these characteristics of novelty, utility and inventiveness. Invention is supposed to contain inventiveness if it actually works and it is not only theoretical.

Patent application can be filed at four offices in India:

Mumbai: Maharashtra, Gujarat, Madhya Pradesh, Goa, Daman, Div, Dadra Nagar Haveli.

Chennai: Andhra Pradesh, Kerala, Karnataka, Tamilnadu, Pondicherry, Lakshadweep.

Delhi: Delhi, Punjab, Uttar Pradesh, Uttarakhand, Haryana, J&K, Rajasthan, Himachal Pradesh, Chandigarh.

Kolkata: Rest of India.

Patenting Process

For obtaining a patent, the inventor has to file an application in the patent office. There are two types of patent applications:

a) Provisional Patent application

Provisional application allows filing patent without disclosure of invention. It only provides a means to establish an early effective filing date, so that no body can file same application for respective invention meanwhile. Provisional application should have details like name of concerned inventors, residential address, title of invention, correspondence address, name and registration number of patent agent (if application is filed through agent). If provisional application for patent is filed, its complete specification must be given within 12 months otherwise it will be considered cancelled (Shukla, 2004).

b) Non provisional application/complete specification

Within 12 months from filing of provisional application, the complete specification must be filed by the applicant. It includes details of the invention along with its procedure and use. The complete specification must include:

Tile of invention, field to which invention belongs, background of invention, complete description of invention along with experimental results, tables, diagrams, figures, graphs related to invention, abstract of invention, name address and nationality of applicant, date and sign of inventor. If the applicant wants he can directly file the complete specification without filing provisional patent application(Shukla, 2004).

When the application is filed, the patent examining committee examines the application and if it finds that application does not fulfill the criteria of novelty, utility and inventiveness; they may either refuse to proceed with the application or inform the applicant for amendment in written. For examination of patent, special examination fees is to be paid by applicant. The applicant has to deal with and answer the objections in written within 15 months to the examining committee. This period of 15 month can be extended up to total 18 months by writing special extension application to controller of patents. If satisfied, the patent office sends a notice of acceptance to the applicant and patent claims are published in the official gazette for opening it to public (Ghai, 2010; Shukla 2004).

Anytime within 4 months from the date of publication of patent in official gazette, a person can oppose by writing application to the controller. The opposition can be made on following ground namely:

a) If the invention claimed in application is published in any document.

b) If invention or any part of invention is illegally obtained from a source that is already patented.

c) If the invention claim was publicly announced in some

conference or seminar.

If opposition is made, the controller informs the applicant as well as the opponent to come for a hearing about the case. After hearing, controller decides whether patent should be granted and registered or not. If there is no opposition or if a claim of opposition is not valid, patent is granted to the applicant and patent is registered in the patent register. The patent term is valid for 20 years.

If a person gets patent for a product, he has rights to prevent others from making, using, selling, offering for sale or importing the patented product. If patent is granted to a person for a process, he gets the right to prevent others from using the process, selling the product using the process, importing the product using the process, offering for sale the product using the process. If a person is interested in making the patented product, he has to pay the royalties to the patentee that is set by the patenting authority (Shukla 2004).

In Indian patent office, a traditional knowledge digital library is being compiled to make a document of several centuries old healing remedies, formulas, compounds and medical treatments. Its purpose is to prevent the patenting of ancient indigenous practices and techniques. This digital library will be accessible in five languages- English, French, German, Japanese and Spanish. The Indian government asserts that this library will serve to prevent patenting of ancient medicines as well as it will serve as a collection of traditional remedies that researcher can study. India has also planned to grant web access of digital library to foreign patent offices by which these offices can determine whether or not proposed remedies can be assigned a patent (Angell, 2000).

Patent Agents

The controller of patent shall maintain a register of patent agents containing names and address of the patent agents. A person may become patent agent in India if he is a citizen of India, has completed the age of 21 years, is an advocate or completed his bachelor degree in law from Indian university and has passed the qualifying examination of patent agents. No person can practice as a patent agent unless he has registered himself in the patent office and his name is entered in register of patent agent.

Under the Patent act following are not patentable:

- ✓An invention that claims anything contrary to well established natural laws.
- ✓The mere discovery of a scientific principle.
- ✓An invention, the use of which is injurious to public health.
- ✓A substance obtained by mere admixture of several components.
- ✓A method horticulture and agriculture.
- ✓A mere rearrangement of known devices.
- ✓Invention related to atomic energy.

In patent amendment act 2005, special exceptions to patentability of some pharmaceuticals have been added:

- ✓Healing techniques in ayurveda, siddha and unani systems cannot be patented.
- ✓Surgical processes are not patentable.
- ✓Method of treatment of malignant tumors is now not patentable.
- ✓Process of removal of dental plaque and caries is not patentable.
- ✓Mere discovery of new areas of some drug is not patentable.
- ✓If any invention which is found to be injurious to public health is not patentable, e.g. method of adulteration of food.
- ✓Invention related to method of production of enzymes, antibiotics, hormones, interferons and vaccines are patentable.

International patenting

A patent is valid only in the country where it is filed. Thus if an invention is patented in India it can be freely copied in USA without the need of any permission. But at present the provision of PCT route is made. PCT refers to Patent Cooperation Treaty. It is an agreement initiated in the year 1970 and signed by hundred countries. It was administered by WIPO (World Intellectual Property Organization) having headquarters at Geneva. According to PCT, there will be a separate international application so that applicant can file a single application for filing the patent in more than that is a member country of PCT. Now 140 countries are its member and India is one of its members since December 1998. The aim of international patenting through PCT route is to promote easy exchange of technical information between different countries by providing a common platform for publication of patent application from different countries (Ghai, 2010).

The procedure for international patenting involves international and national phase. Applicant has to pay predecided fees for filing in several countries using single application. Application is filed in the patent offices (Mumbai, Chennai, Kolkata, Delhi), which then passes through two distinct phases(Angell, 2000):

a) International phase:

Application is verified to see whether any patent of the similar invention has been granted anywhere internationally, if not this patent is published in international patent gazette. If there are no objections from

anybody the application has passed the international phase.

b) National phase:

Within 30 months of filing the application the applicant has to give his choice regarding the countries in which applicant wants his patent to be valid. He must pay the fees for filing of patent in the countries in which he has applied. Now patent is granted that will be valid in those countries in which applicant has made choice and paid fees.

2. Copyright

Copyright is a set of exclusive rights granted to the creators and producers of creative expressions like literary, musical and cinematographic works, thus it is a monopoly right for the work of art, literature, music picture and sculpture. It provides protection of the art, music from copying by others. It imparts commercial value to the work and ensures rewards in form of recognition. If someone uses copyright with permission of the owner, royalty has to be paid, thus it also provides financial benefits. It is valid for entire lifetime of the copyright holder plus fifty years after his death. The registration for copyright can be done by writing an application to the registrar of copyright, New Delhi along with the prescribed fees (Rs 50/-). Once granted, copyright is claimed by the use of the symbol © year and name of the claimant. A major limitation on copyright is that copyright protects only the original expression of ideas, and not the underlying ideas themselves (Angell. 2000; Lexchin, 2005).

India being a member of WTO (World Trade Organization) enacted Indian copyright Act, 1957. This Act has following provisions:

- Copyright can be granted for the painting, sculpture, drawing including diagram, map, chart, engraving or photograph, music, song, dance, publications and cinematographic films.
- A copyright office shall be established by central government and it shall appoint a registrar and one or more Deputy Registrar of copyrights.
- Central government shall constitute a copyright board having a chairman and 2-14 committee members.
- There shall be a registrar of copyright which will contain names or titles of work, name address of authors, publishers and owners of the copyright. This register will be kept in copyright office.
- Any person may apply to the copyright board for a license to produce and publish a translation of copyright in any language.
- The license will not be granted to the applicant unless:

  A translation of work in the language mentioned in the application has not been published by the owner of copyright.

  The applicant has proved to the copyright board that he had requested the owner to permit him for publication, but owner had denied.

  Copyright board is satisfied that the applicant is able to produce and publish a correct translation of the copyright work.

  Copyright board has assured that applicant can pay the royalties to the owner for the whole time till license is valid.

Any persons who infringes the copyright shall be punishable with an imprisonment of one year and fine of Rs 5000/- or both. Copyright is considered to be infringed:

- When any person without obtaining a license from the copyright board uses the copyright for commercial purpose.
- When any person without license by means of trade, exhibits the copyright work in public.
- When a person imports/exports the copies of original copyright without license.
- If a person fairly uses the copyright for research work.
- If a person fairly deals with copyright dramatic/musical/artistic work for the purpose of reporting current events in a news paper, magazine, or similar periodical
- If a person takes some example or takes same quotations from copyright literary/dramatic work in public(Lexchin, 2005).

3. Trademark

A trade mark is a word or symbol adopted and used by a manufacturer to identify his goods and distinguish them from those manufactured or sold by others. Trademark is written always in capital letters or at least initials in capital with inverted commas. Nearly all pharmaceutical products bear a distinctive trademark, which identifies the company making it (Gottlieb, 2000). Trade mark can be a word or symbol representing distinctiveness of the product of a particular company. If it a word it can be called Trade name. Trade name can be named either by the name of organ it treats like Liv-52 for treating liver or by the principal chemical ingredients like Ciprofloxacin is manufactured by various companies under the several trade names like ALCIPRO, CIPRO, CIPROBID, CIPROLET, CIPROVA (Gottlieb, 2000).

The trade mark should be used in proper sense so that it must be used as an adjective followed by the noun describing the product. The improper use of a trademark as a noun encourages the public to perceive the trademark as

the generic name of the product and not as a protectable brand name. e.g. Xerox made a Photostat machine and gave it the name Xerox so the trademark should be used like Xerox Photostat machine. Xerox Photostat machine has made confusion so that public uses Xerox in place of Photostat.

Similarly Aspirin was the trademark of Bayer for Acetylsalicylic acid, but now it is commonly used name. Dalda was introduced as a trademark for vanaspati ghee but common public uses Dalda as the generic name.

Duration of trademark registration:

Prior to registration the symbol "TM" is used in conjunction with mark. After registration the symbol ® or the phrase trademark registered is written after the mark. Duration of registration of trademark is governed by registrar trademark Mumbai. Initially registration duration was 7 years now it has been extended upto 10 years; after expiry of this period it can be renewed further by paying renewal fees for further 10 years. This renewal process can be done only one time. If the mark is not renewed it will be removed from the register. A mark that has been removed from the register can be restored by filing an application within one year from the date of expiration of registration(Gottlieb, 2000).

Benefits

Trademark is a vital and quickly recognized symbol of cooperation and its products and services.

- They have a lot of goodwill associated with them, which enhances market values of products bearing that trademark.
- It has significant commercial value and must be protected throughout local market or those parts of the world where the company or product may be recognized or found.
- Registration of trademark gives exclusive rights to use it for the goods/services for which trademark is granted.
- It identifies and distinguishes the source of goods or services from that of others.
- If some other person uses a similar or deceptively similar mark for the similar goods/services, the owner will be able to sue for infringement of the trademark and will get compensation money from the unauthorized users.
- It enhances market value f products bearing that trademark.
- It helps to maintain a particular level of excellency for goods /services.

Process of trademark registration (WIPO publication No. 900)

Search

It is recommended to conduct a trademark availability search in order to check if any similar trademark has been filed previously, which may oppose our registration of trademark**.**

Filing

A trademark application is filed to the registrar of trademark office along with the prescribed fees of Rs 2500/- and a power of attorney signed by the applicant or by director of a corporate body. The information required for filing of application are; name of the trademark to be registered, full name, address, nationality, and nature of business of applicant, full name and nationality of the partners of the applicants company, date of the first use of trademark incase if it was being used earlier but not registered till yet or date from which trademark is proposed to be used, list of goods/services for which trademark will be used, translation of non English word appearing in the trademark, exact meaning of the mark (if the language is other than English).

Examination

The trademark office will examine the registrability of the trademark application on the following basis: Distinctiveness of trade mark, No similarity with the prior registered mark, prescribed fees, completion of supportive documents, completely filed and certified application. If satisfied the trademark office will issue an acceptance order to the applicant and trademark is ordered for publication. Examination usually occurs within 3-4 months of filing of application, but if applicant wants rapid examination he can file an expedite application examination request, which costs 5 times more than the normal fees.

Publication

Trade mark applications accepted by the registrar are published in the trademark official journal. Any interested party may file a notice of opposition to the registration of the mark within 3- months from the date of publication.

Opposition

If suppose a third party finds that the published trademark is similar to the trademark used by it, it can oppose the registration within three months from the application date along with full proof. If the published trademark is opposed, then trademark office will request written evidence from applicant party as well as opposing party. If opposition is found to be correct, registration is not granted.

Registration

In the absence of opposition the trademark is registered and the certificate of registration is issued for 10 years from the date of filing of application. Generally 24-30 months are

taken for final trademark registration without the case of opposition.

4. Industrial design

It refers to specific shape, configuration, surface pattern, colour or combination of colours, shades that produces an aesthetic impression of the article. The main purpose of industrial design registration is to see that the aritisa, creator, originator of a design having an aesthetic look gets his monopoly right benefits for a limited time. Under WTO obligations, protection must be provided by the member countries to new or original industrial design having aesthetic look (Mayer, 2003).

E.g. Design of a particular bottle used for packaging a pharmaceutical product, design of a new packaging method for tablet and capsules.

To make Indian laws complaint with WTO obligations for industrial design, the Indian parliament enacted the "Industrial design act 2000" for protecting the new and original industrial designs. The maximum period for which industrial design protection is valid is 15 years. Its registration process can be made by writing an application to registrar of industrial design Kolkata.

5. Layout design of integrated circuits

Semiconductor integrated circuits are product having transistors and lead wires that are connected to perform an electric circuit function. The act for the protection of layout design of integrated circuits came into force on 4th September 2000 and is called "SICLD (Semiconductor integrated circuit lay out design) act 2000". This act provides the exclusive rights to the registered proprietor of layout design. Its registration is done by writing an application to registrar SICLD New Delhi. Its term is valid for 10 years from date of filing (Mrudula et al., 2009).

6. Geographical Indications

Geographical indication is defined as that aspect of intellectual property which is related to goods/products of a particular geographical region. The product must be of the good quality and must have some distinctive property that designates specific region. ***E.g.***: Darjeeling tea, Nagpur oranges, Bikaneri bhujia, Agra petha, Mathura peda.

India as a member of WTO enacted "Geographical indications of goods registration and protection act 1999". The registration can be obtained only by official bodies, societies and associations and not by the individuals. It is applicable for 10 years. Its registration is done by writing an application to registrar of geographical indications New Delhi.

7. Plant Breeders rights

These are legal rights granted by the government for the protection of plant varieties as well as rights of farmers and plant breeders. In most of the WTO members countries crop varieties can be protected as the intellectual property. But the present IPR system is not designed to promote the protection of the diversity of whole ecosystem or unmodified plants and only the plant varieties having same medicinal value are protected. Plant breeder's rights are granted for inventing new variety of already existing plants (Henson, 2002).

Protection of plant varieties is covered in India under the "Plant varieties and farmers rights bill 1999" which got the status of act in 2001 under the name of the protection of "Plant varieties and farmers rights act 2001". This act safeguards the interests of the farmers to save, use, share, or sell his product. Its term is valid 15 years for annual crop, and 18 years for trees and vines. Its registration is done by writing an application to registrar of Plant varieties New Delhi.

8. Trade secret

It refers to proprietary information having a commercial application and use, e.g. biotechnological information and useful microbial techniques can be protected as trade secrets. Under WTO regulations it is required that all member countries must provide rights to protect trade secrets, but in India three is no such right or act to protect trade secrets. However common tool used till now is "Non-disclosure agreement (NDA)" or "Confidentiality agreement (CDA)".

IPR related treaties

GATT (General agreement on trade and tariff)

GATT was formed in 1947 with 23 member countries including India. It was made for promoting international trade. Under GATT, 8 rounds of negotiations took place between the member countries to reduce trade barriers. These negotiations were held at Geneva, Switzerland 1947; Annecy, France 1949; Torquay, England 1951; Geneva, Switzerland 1956; Geneva, Switzerland 1960; Geneva, Switzerland 1964; Tokyo, Japan 1973; Urugguay, South America 1986.

In past some countries protected their inefficient firm production by giving heavy subsidies, so that their products become artificially cheap. This depressed international prices. As a result other countries did not get good price for their products. However under GATT these subsidies are reduced to maintain satisfactory prices. In past developed countries had to suffer loss because their product got copied by other countries. Hence a protection for IPR on global basis was ensured by bringing uniformity in patent laws among the member countries. Under GATT, an attempt was made to remove tariff related barriers that hindered the world trade. Tariffs are basically the custom duties, surcharge etc. They are to be paid for trading in other

countries. Under GATT, member countries can freely perform trading with each other without tariff barrier (Beier and Schricker, 1996).

WTO (World trade organization)

WTO was established on 1st January 1995 after the discussion of 8th GATT round at Uruguay. WTO accounts for over 97% of world trade. WTO is responsible for administering and implementing multilateral trade agreements. It helps to solve dispute between member countries pertaining to trade and also cooperates with other international institutions involved in global policy making (Shamsi A, 2002).

WTO has 150 member countries. India is one of its members. WTO contains 29 legal texts which cover various things like agriculture, textile, intellectual property, services, government procurement, pharmaceuticals, medicines and other industries. WTO has following committees:

a) **Ministerial conference:** It is the highest body of WTO, composed of the representatives of all member countries. It meets at least after every two years. All major decisions related to multilateral trade agreements are taken by this body.

b) **General council:** It carries out day to day function of WTO as well as takes expenditure related decisions, meeting places decisions etc. Under this council there are other bodies like: Dispute settlement body, Trade policy review body, council for trade in goods, council for trade in services, council for trade related aspects of IPR.

DOHA declaration

DOHA declaration is a legally binding agreement that was adopted by WTO Ministerial Conference at DOHA on 14th November, 2001.

Salient features of DOHA declaration

- It provides IPR protection for the development of new medicines.
- The other areas that can be protected are pharmaceutical products, process, surgical, therapeutic and diagnostic methods, medical equipment, diagnostic kits etc.
- It specifically mentions that each member country has the right to grant compulsory licences and the freedom to determine the ground upon which such licenses are granted.
- Compulsory license is a permission granted by the government in public interest to non patentee to make a patented product. It can be granted on the following grounds-
  - A circumstance of natural emergency.
  - In case of epidemic condition in which a drug that is patented is required.
  - If some patent has been granted, but that product is required by general public but not being manufactured by the patentee in surplus amount.
  - If a drug being patented is very useful for a particular disease but its price is very high, government can grant compulsory license to others.

TRIPS (Trade related intellectual property rights)

The member countries of WTO have to amend their IPR laws to be in conformity with the minimum provisions written in TRIPS a specified period. India has also adopted the principles of TRIPS in 2005 (Subramanian, 2002). Following provisions has been adopted under TRIPS:

- TRIPS agreement provides that patent shall be granted foe any invention whether products or process in all field of technology. The invention must be new, involve an inventive step and must be capable of industrial application.
- Certain inventions that are very necessary for public health, human being, animalor plant life have been excluded from patenting because they are considered indispensable for human life so can be exploited.
- Patenting of microorganism has now been accepted.
- Term of patent made uniform and it is increased to 20 years, previously some countries used to grant patent for 14 years.

Hatch –Waxman Act

It is also called Drug Price Competition and Patent Term Restoration Act 1984. It is an act dealing with the approval of generic drugs and listing of such drugs in the patent offices in orange book. Generic drug refers to a drug that is chemically equivalent to brand name drug but dispensed under its generic chemical name and not as a brand name. Thus generic drug has same chemical moiety as branded drug but it is cheaper because it is sold under chemical name, so advertising cost is not included (Mayer, 2003; Glasgow, 2001).

According to this act generic drugs can be approved and manufactured only after expiry of the patent of branded drugs. E.g.: Phenytoin, Diazepam, Haloperidol and Cimetidine are generic names of brand drugs Dilantin, Valium, Haldol, and Tegamet respectively.

This act states that all the generic drugs can be approved by evaluation of their bioavailabity studies and clinical trials are not required for them. For bioavailability studies it is stated that generic drugs should show an absorption rate of ±20% as that of branded drug in particular time duration. Approval of generic drugs will be listed in a book called "orange book". Generic drugs of a particular chemical can be manufactured and sold only when patent term for original branded drug of same chemical formula is expired.

Significance of generic drugs

There is no need of clinical trials for generic drugs. These drugs only have to be proved as therapeutically equivalent to brand name drugs because clinical trials and drug development studies have already been conducted by the original innovator company. So expenses in generic drug approval are much less as compared to original brand name drug approval. Almost 40-60% reduction of prices is obtained in generic drugs. This is very helpful to geriatric patients who have to take more medicines but have less economic resources to spend money on medicines.

Generic drugs have same efficacy and safety as brand name drugs because active ingredients are similar in strength and purity in generic drugs. Only active ingredients/excipients like colour, additives or packaging materials and design may differ. The Government regulations relating to manufacture and selling of generic drugs are similar to brand name drugs. So their effectiveness is comparable to brand name drugs.

Case studies

There are many incidences of conflict between original branded and generic drug manufacturers during the patent term of branded drug. In 1986, patent was granted to Pfizer for antihypertensive drug Amlodipine under name "Norvasac". In 2002, DRL tried to get approval for the generic drug of Amlodipine but since patent term of Pfizer was till 2006, Pfizer sued DRL for patent infringement and won the case.

In 1983, Pfizer was granted a patent for antifungal drug "Diflucan". When Ranbaxy in 1987 initiated for a launch of generic version of this drug it was sued by Pfizer on the ground of patent infringement. Thus Ranbaxy could not launch the generic version of Diflucan till 2003.

As per the trademark act 1999, if two trademarks are similar or somewhat similar the owner of the mark can sue for infringement of trademark. USV Ltd manufactures antidiabetic drug "Pioglitazone" under the trade name PIO. Systopic laboratories also manufacture Pioglitazone under the name PIOZ. USV Ltd sued against Systopic lab in madras highcourt in 2004 for infringement. The court focused on the point that the drug is prescribed by registered medical practitioners and dispensed by qualified pharmacist, so the chances of confusion are considerably reduced. Moreover some similarity is allowed because word PIO is a part of the chemical name Pioglitazone so court gave the decision that no company can have sole right on the name. Hence it has been decided that no person can claim exclusive use of the tradename that is derived from chemical name of the drug. So there is no monopoly over chemical name, which is a descriptive of particular ingredient(Ghai, 2010).

The Delhi High Court granted an ex-prate injunction to SmithKline Beecham Ltd which was the registered owner of the mark Crocin for paracetamol tablets. The word Crocinex was used by Cyper Pharma (Delhi). The Court felt that the words were so similar that the attempt was to mislead the public (Ghai, 2010).

On the other hand, in Calida Lab vs Dabur Pharma Ltd, Calida alleged that Zexate was deceptively similar to Mexate in respect of a particular injection used to treat cancer. The Court based its conclusions on the fact that the drugs were specialized drugs which could be purchased by showing the prescription of a cancer specialist. Since prescriptions are made by specialist doctors who are knowledgeable and capable of distinguishing the names, so court held that the trademarks can be allowed (Ghai, 2010).

The same logic was followed in the case of Biopharma vs Sanjay Medical Store; the question was with reference to Flavedon and Trivedon for a drug that was prescribed for heart disease. The court noticed the fact that the drug was a Schedule H drug under the Drugs and Cosmetics Act, which meant that the drug cannot be bought off the counter. The Court decided that the two drugs can't be considered to be deceptively similar (Ghai, 2010).

Conclusion

There are various registered and unregistered rights which can be used in protecting intellectual property arising from drug development. Effective utilization of the registration systems and legislation available can provide effective monopolies, which should ensure adequate return for investment in the research and development necessary to obtain marketing approval for a therapeutic entity. Key considerations in the creation and maintenance of useful intellectual property rights are to plan the strategy for protection with the routes of exploitation in mind; to ensure that these evolve as product development evolves; and to maintain competitor awareness and evaluate any threats to commercialization. These simple steps, if executed effectively, should help ensure competitive advantage is maintained.

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