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Comprehensivestudy on Indian pharmaceutical patent

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ABSTRACT:the term ‘‘intellectual property’’ it means product of the mind or the intellect. this paper gives a comprehensive overview of pharmaceutical patent act in India and how they slightly impact on the growth of Indian pharmaceutical sector. Comprehensive Review on Indian patent system overall history about Indian Patent Act. What is TRIPS agreement and how Its effects on then Indian pharma sector What are the fundamental characteristics of patents and the patent system, as well as information on what can be patented and by whom? Detail information on filling out a patent application, as well as a step-by-step process on how to file a patent in India and what we require.

KEY WORD: Indian patent, invention, trade, intellectual rights, patent restoration, anticipation, novelty

I. INTRODUCTION:

the word “intellectual property rights” can be defined as individual monopoly held by any person over his creation(invention) intellectual property gives legal right in the form of patent, trademark, geographical indication, copy right, & many more. Patent are the rights these right given by the Indian government.now a day’s patent is potential business tool for the Indian pharmaceutical sector to acquire and secure a new invented product or procedure, it helps to gain a strong market position and earn extra profit through licensingThe government grants a patent to an individual inventor for a limited time to protect his invention.patents are like a personal property, patent rights are applicable in a domestic range i.e. if inventor has patent grant by Indian government it is only valid in India, if inventor have to protection in other country, it should requireto file patent application in other country too. Patent confers on the assignee for a specified period of time, the exclusive right of manufacturing, and distributing & disclosure of an invention to the public. Basically what can be patented like new products, new process, new invention, something new or unseen invention. (1)

Intellectual property is playing important role in pharmaceutical sector as well, now a days developing countries have not self-sustained pharmaceutical companies. Many organization and countries made intensive attempt to stablished unite laws governing intellectual property. (2)

India did not accept product patent for pharmaceuticals for many years before joining the world trade organization without patent facilities Indian pharmaceutical sector were able to produce large number of generic medication, and as a result of its commitment under the agreement on trade-related aspects of intellectual property rights (trips), India was required to change its laws in 2005 to extend product patent protection in pharmaceutical products. This legislation is codified in Section 3 of the Patent Act of 2005. (d)). (2)

What can be patented?

According to the TRIPs Agreement (the trade related aspects of intellectual property rights) is one type of international agreement that specifies that patents can be approved for any invention, whether it is a product or a process, as long as the invention is,

A) Anything new or novel
B) Involve or inventive step
C) Have some utility or industrial application. (3)

History of patent law in India:

The first Indian patent related act was passed in the year 1911 with the name of name of “patent and design act 1911” under the British Rule,after post-independence two times of unsuccessful introduced by Indian parliament of patent act bill in the year 1949 and 1965 the bill was finally passed in 1970 on the 20th April the act came into existence. (1) In India the patent system Regulated by patent act 1970(NO 39 of 1970) and patent rule 2003 after in 1974, 1985, 1999, 2002, & 2005 patent act has been amended many times in 2006 rules have been amended. (1)

The first patent rule was passed in 1957, but it wasn't until 1970 that proper patent legislation was passed in the form of the Patent Act

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1970.1856- Act VI of 1856 on invention protection based on British patent law of 1852 grants some exclusive rights to inventors of new manufactures for a period of 14 years. The act was modified in 1859 as XV patent monopolies called exclusive privilege.
The Patterns and Design Protection Act was passed in 1872.The act to protect inventions was passed in 1883.The act on inventions and designs was consolidated in 1888.The Indian Patents and Designs Act was passed in 1911.1999- On March 26, 1999, the Patent Act was amended.
2002- The Patent (Amendment) Act 2002 went into effect on May 20, 2003. The Patents (Amendment) Act of 2005 went into effect on January 1, 2005.

Now a day's Indian pharmaceutical sector, the world's third largest sector in term of volume and 14th in term of value worldwide. Indian has positioned itself as a significant manufacturer of low-cost generic medication worldwide and this lead the Indian pharmaceutical sector worth about US $ 42 billion. Indian pharmaceutical sector totally dominated by MNCs after independence in 1947 and India had some of the world's highest medicine prices. (2)

Procedure:

- **Who can apply for patent?**

The original inventor
Any Single men or that person jointly with other can protect his invention through rights. (3)

Types of patent application:

- **How to apply for patent?**

Patent application can be filled through two modes.
1) Hard copy application format.
2) Online e-filling application format. (3)
The applicant of a patent application can choose any of the above two methods to file a patent but patent office charges an add additional 10% fee for application not filled through online mode. (3)

- **Where to apply?**

Application has to be submitted according to the territorial jurisdiction.

The first-mentioned applicant, site of firm, or location wherein the innovator came originally.

When Applicant does not have any place for business or he has no domicile in India, the office will be as per the address given by an applicant.

When a patent application is filed through a patent agent, then location of the office of patent agent becomes deeding factor for jurisdiction of patent application.
Patent offices; perform the function whatever are related in granting of patent for new invention renewal of patent, amendments, restoration under Indian patent act 1970. (3)

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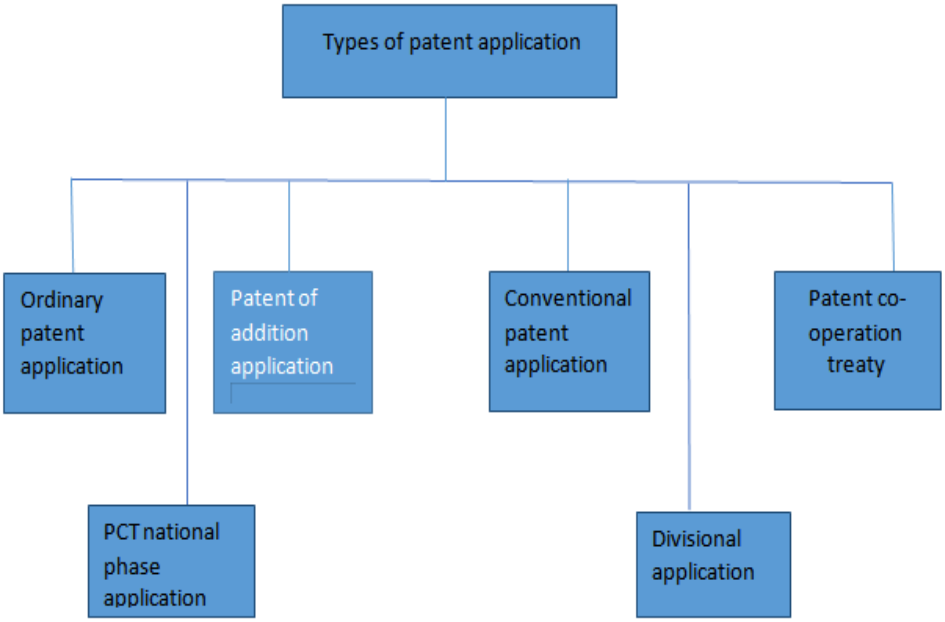

A) Ordinary patent application:
This is made under the provision of Indian patent act and then accompanied with provisional or complete specification.
B) Patent of addition application:
Patent of addition can be filed for any kind of modification of an inventor which is under the provision of Indian patent act.
C) Conventional patent application:
Foreign country applicants which are declared as conventional country by Indian government can Apply for patent in India, under reciprocating arrangement claiming priority date of original filing in conversion country.
D) Patent co-operation treaty (PCT) or (IPA):
PCT provides a system for filing patent application in multiple countries as it is an international treaty it provides a system on the basis of a single patent application and allow you to obtain patent in multiple countries.
E) PCT national phase application:
Applicant may decide the states in which he wants to proceed further with international application.
F) Divisional application:
They are the type of patent applications which have been derived from another patent application which contain more the one in application which contain more the one divisional application. (3)

Patent application content:

1) A patent application must be filed on form 1 and include a provisional/complete specification, as well as the fees listed in the first schedule.
2) Fees apply to applications with up to thirty pages and ten claims; however, if the specification exceeds thirty pages or there are more than ten claims, additional fees must be paid.
3) A patent application should include the following information:

a) Form 1 application for patent grant
b) In order to file the inventor's application form, the applicant must first obtain a professional license.
c) Form 2 provides a provisional or complete specification.

4) Statement and undertaking of section 8 in form 3 only if application is made or within 6 months of the application date. (3)
5) For applications accompanied by a full specification, a convention application, or a PCT application, a declaration as to inventorship must be made in form 5. Form 5 must be filed within one month of the date of filing the application if it is asked in form-4.
6) Attorney-in-fact (Form 26) If a general power of authority has already been filed, a copy of it may be filed in another application, and if the original general power of authority has already

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been filed, it may be referenced in the self-attested copy. (3)

7) In some circumstances, certain documents are necessary.

A) Use of the Convention Application (under Paris convention)

B) In the case of a request for early publication, a PCT national phase application must be filed before/along with the request if the requirements of rule 17.1 (A or B) of the PCT regulations have not been met. (3)

8) Every application must include the signature of the applicant or an authorized person / patent agent, as well as the applicant's name and date, in the relevant place specified on the form.

9) Applicants/agents must sign the specification i n the bottom right corner on the last page with the applicant's signature in the right hand corner.

10) The application must clearly disclose the geographical origin of any biological material obtained from India. Any Indian biological material must get permission from the national biodiversity authority.

11) In case of an application being filed offline or though physical mode a list of document has to be submitted during filling of a patent application to patent office.

12) The patent application must be file in the authorized office based on the applicant's or patent agent's location. There are patent offices in India in which is located in Delhi, Kolkata, Mumbai, and Chennai. (3)

Process of Granting patent:

Step 1: application for filling a patent

The first step is to submit an application for patent grant.

1) Form 1: application for great of patent section 7,54, 135 & rule 20(I).
2) Form 2: provisional or complete specification section 10 and rule 13.
3) Form 3: Section 8 Rule 12 requires a statement and an undertaking.
4) Form 5: Section 10(6) and Rule 13(6) require a declaration as to the inventor ship.
5) Form 26: power of attorney in original section 127, 132 and rule 135.
6) Certified true copies of priority document (if claimed)
7) Certified copy of convention application if require in case the form 2 is being submitted along with complete specification or complete information being submitted at a later stage it should comprise of

- Title
- Field and the history of the innovation
- Utilization of invention
- Prior art in the said field and the drawbacks in it
- Comparison of The prior art and the current invention
- Abstract/ summary and current invention
- A Statement of current invention
- brief explanation of the drawing accompanying the specification

8) Detailed description of the invention.
9) Best method of working of invention.
10) Claims defining the scope of protection being sought through the patent.

The submission of application is completed when payment is done online or offline. (3)

Step 2: Publication,

1) Till 18 months of date of filing the application is kept secret. 19 months' application is published on official website on weekly basis (every Friday)
2) From 0-18 months file is under secrecy period after that it comes under public domain. If anyone wants publication before 18 months he can file request for early publication under rule 24A along with form 9

Step 3: Request for examination (RFE)

1) Application is examined only on request either by applicant or any third person.
2) The applicant gets 48 months' time period to file an application to be examined.
3) Within one month, the controller sends the application to the examiner.
4) The examiner looks whether invention is prohibited for grant of patent or not.

Step 4: Issue of first examiner report (FER)

1) Examiner takes time period of 1-3 month to submit examination report to controller.
2) Further one month to examine report.
3) The FER containing list of objection issued to applicant within 6 months of date of filing a request.

Step 5: Response to first examiner report (FER)

1) Upon receipt of first examination report applicant has 12 months' time period to make changes to the application and recommended in first examination report.
2) This 12 months' time is given to applicant is also provided and opportunity of being heard by controller.

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3) Response then submitted by applicant to the controller. In case controller is not satisfied he may refuse the grant.

Step 6: grant of patent

1) After applicant submit response to the first examination report and provided controller is satisfied the controller under section 43 orders for the grant of patent.
2) In register of patent the date of grant of patent is noted and certificate carrying the official seal of the patent office and the date of patent grant is issued to the applicant.

Step 7: Maintenance and renewal of patent

1) Patent given for a term of 20 years from the date of application and expires after 2 years from the date of grant of patent.
2) It needs to be renewed regularly in case patent is not renewed then it is liable to get lapsed and applicant cannot claim damages during the period it was not active. (3)

The Trade related aspects of IPR (TRIPS):

The agreement on traderelatedaspects of intellectualproperty rights is an globalagreementruledwith the aid of usingglobaltradeagency that establishes minimalrequirements for numeroussort ofintellectualpropertyrules as they practice to nationals of different WTO member it become negotiated in 1994 on thecease of the Uruguay round of the overallagreement on tariffs and trade. (1)

To make Indian patent law consistent with TRIPS, the Indian patent act was revised to add a "product patent" system and also the Indian pharmaceutical sector focus switched away from generic pharmaceuticals and towards Research based "NEES" novel drug delivery products in the post TRIPS period India experienced a surge in patenting activity. (4)

Impact on Indian pharmaceutical sector:

In 1970, the Indian parliament passed the Indian Patents Act, which allowed only process patents for medicinal compounds and new chemical substances. Indian Patent Act of 1970 played a significant role in the country's pharmaceutical sector's rapid and consistent rise. Prior to 2005, there was no significant activity in patenting in India because the Indian pharmaceutical business was focused on generic product development.(4)

Pharmaceutical "generic drug" business in India is one of the most developed in the world as one of the world's fastest expanding industries with the pharmaceutical industry on a worldwide scale its located in India's science based sector are at the top the ranking with a divers set of skills in complicated sector of pharmaceutical technology and manufacturer.(4)

In 1959, the patent law amendment commission, led by shri justice N. rajagopala ayyangar, submitted a report on the revision of a patent law, which stated that foreigners held 80% to 90% of Indian patents at the time, and that 90% of patented products not manufactured in Indian territory. Foreign businesses could restrict manufacture of their proprietary pharmaceuticals in India, as a result, the commission believed that multinational businesses had manipulated the patent system to monopolies the market, particularly in the food, pharmaceutical, and chemical industries. Market monopolies also lead to high product prices, which is why the commission recommends that only methods or processes be able to obtain a patent, as opposed to the Indian Patent and Design Act of 1911, which grants patent for both products and designs.(5)

II. CONCLUSION:

This article gives you the detailed information regarding the patent filing and its submission. The patented drug is referred as a generic drug at one point. How the patent is granted in a country and what is the impact of patented drug in the market. As India is the third ranked patented sector and the hub of generic market.

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