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Patents-A Strategic Analysis;Freedom to Operate

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Abstract

Patent is AGovernment Authority or License orARight for a defined period which excludes others from using, making, selling and importing an invention.[1]A patent gives certain legal standpoints, which can deter rival businesses from using and copying the inventions. Producing innovative products and protecting them is an integral part of modern enterprise these days. Patents are granted to encourage disclosure of innovations into the public domain for the common good. If inventors are not given legal protection for inventions, in many cases, they might prefer to keep their inventions as secret. Awarding patents generally mean that the details of new technology are available publicly, for exploitation by anyone after the expiration of patent, and for further improvement by other inventors. In industries once an invention exists, the cost of commercialization is far more than the initial conception cost as it involves testing, tooling up a factory, developing a market etc. One important usage of modern patent is that a small-time inventor, who can afford the patenting process and the patent defense, can use the exclusive rights to become a licensor. This allows the inventor in accumulation of capital by licensing the invention. Modern patenting system also facing some challenges also viz a viz Double Patenting and Evergreening. However, there are many reasons to apply for patents. This article will discuss all related aspects.[2]

Key Words: Patents, Patentee, Novel, Non-obvious, Public Disclosure, Infringement, Law Suit, Claims.

Introduction

We have heard the phrase "**Publish or Perish**", which reflects that thescientific thinking and innovations by one scientist inspires other scientists. If discoveries were kept secret, industries would stagnate, so disclosure of invention is beneficial for society and industry as a whole.

The patent protection was introduced to encourage innovation and disclosure of the new inventions into the public domain for the common good. Inventors are generallyhesitant to publicize their creation because it can be duplicated easily. Patent rights provide an incentive to share ideas with a temporary monopoly on their use.

In industries once an invention exists, the cost of commercialization is far more than the initial conception cost as it involves testing, tooling up a factory, developing a market etc. Thetime period of patent protection allows the inventor to recoup the development cost by:

- Excluding competition for a certain period, thus monopolizing the market by setting a high price
- Licensing the invention to others in exchange of royalty payments
- Suing for damages if a person or business entity infringes the patent
- Selling the invention to a third party

Patent protection is much stronger than other types of IP protection such as Trade mark and copyright. Copyright only protects the way of expressing an idea but does not prevent others from expressing the same idea in a different way.

The patent granting procedure, requirements to get patented and theexclusive rights vary widely between countries according to national laws and international agreements.

United States follow a first to invent patent system, other countries follow a first-to-file system.

A Patent once granted is applicable for a period of 20 years and it is not renewable. An invention or innovation qualifies for a patent only with one rule everywhere:**Novelty, Non-Obviousness & Usefulness** which meansan invention can be patentable when it is new; in other words, must not have been known to any one before the application for grant of patent is filed. It must comprise an "inventive step" means it must not be obvious in the light of already existing invention. It must be of industrial use.

Patents protect ideas. They are providing protection for novel products or processes which have new technical or functional features. These features could be for example, construction of a new product, how it works, or how the product is made.[3]

Discussion& Results

There are so many reasons forapplyingpatent[4, 5]:

- Legal right to claim ownership of the invention
- Help in Acquiring strong market position
- It provides Opportunity to sell or License the Invention.
- High Skilled Image among competitors and other business enterprise.
- Protection of Invention from the time of filing of patent Application.

There are three types of patents which are being granted

- Utility Patents
- Design Patents
- Plant Patents

Utility Patents: These types of patents are granted tothoseinventors who have invented any new and useful machine, article and process of manufacture, or composition of matter, or any new use of existing invention.

Design Patents:These types of patents can be granted to those inventors who have invented an original and new design for an article to be manufactured.

Plant Patents:These types of patents can be granted to anyone who discovers or invents an asexually reproduced distinct and new variety of plant[6].

Trade mark or Service Mark

A trademark may be a word, Symbol, name, or device that is used in trade with goods which is indicating the source of the goods and to distinguish them from the goods of other manufacturers. A service mark is similar to a trademark which distinguishes the source of a service rather than product.

Trademark rights are granted to prevent others from using a similar mark which can create confusion among customers, but do not prevent others from making the same goods or selling the similar goods under a clearly different mark.[7]

Copyright

Copyright is a protection granted to the authors of original works which includes literary, dramatic, musical, artistic, and other intellectual works, which may be published or unpublished. The 1976 Copyright Act generally gives the exclusive right to reproduce the protected work, to distribute copies or phonorecords of the protected work, to perform the copyrighted work publicly, or to display the copyrighted work publicly. The copyright protects the expression rather than the subject matter. For example, how a machine structure is built can be copyrighted, but this will only prevent from copying the description by other inventors; it will not prevent other inventers from writing a description in their own way or making and using the same machine.[8]

Patent Infringement

It is the directive which includes prohibited actsfor a patented invention without permission from the patent holder. Means when a person or business is using parts of a patented idea, method, or device without permission of patent holder it comes under Infringement of patent. Permission may be granted in the form of a license. In other words, we can say unauthorized use or selling of the product by the competitor is a violation of patent right.

There are different types of patent infringements. Whenever a patent holder sues someone in patent infringement case, he must figure out who is at fault? Understanding the types of patent infringement helps to determine who is accountable.[9,10]

Different types of Patent infringement are described below:

Direct Infringement

Using, selling, making, or importing patented product without obtaining a license from the patent holder is considered direct patent infringement. Direct patent Infringement generally occurs when the offender has completed this act wilfully.[11]

Indirect Infringement

When there is no direct infringement by other inventor but persuades another to do the same, or advertise to sell instructions about a patented product then he may be held liable for infringement of a patent which is called inducing infringement. Indirect infringement includes two subtypes of infringement one of which is contributory infringement and second is Induced infringement. Indirect Infringement case may arise even if a company has not originally infringed the patent, that company can still be held responsible for patent infringement.[12]

Contributory Infringement

An infringement is called contributory infringement when it involves the selling, buying, or importation of a portion of information that leads in creation of a patented product. This type of infringement can be claimed when it is proved that the information's main use would be to create a patented product. An off patented or generic product that has additional uses usually doesn't qualify in proving the contributory infringement.[13]

Induced Infringement

When a person or company supportsa patent infringement by facilitating components or helping to make a patented product thenthe infringement is called as induced infringement. Itcan be transpired throughproviding instructions, licensing plans and processes.[14]

Wilful Infringement

It occurs when a person completely neglects for another inventor's patent. Wilful infringement is especially damaging to defendants in a civil suit. The charged penalties are much higher, and typically defendants must pay all attorney and court costs if they are found guilty.[15]

Literal Infringement

If we study Patent infringement in broad spectrum view then infringement generally cascades into two categories: literal infringement and infringement under the doctrine of equivalentsliteral infringement. When each and every element recited in a claim has been copied or duplicated in the apparently infringing device or process the infringement is called literal infringement.[16]

Doctrine of Equivalents

Whena device or method from another inventor doesn't exactly infringe a patent and the patent holderstill revoked a litigation on the basis that the device ultimately producesthe same product with same results, qualifies for infringement under the Doctrine of Equivalents.[17]

Most of the times end-usersare not aware of that theyare using a patented item. Patentee cannot sue all of them for using patented item. Rather than suing end users, it might be best possible option to sue those manufacturers who are eloquentlyinfringing thepatent by manufacturing the patented products.

The doctrine of equivalents is a legal statutefor many cases related to patentinfringement that allows a court to hold a person or an organisationaccountable for patent infringement even though the productor process does not fall within the direct scope of a patent claim, but eventually leads to the production of an equivalent to the patentedinvention.

The intellectual property can be protected in different ways. "Doctrine of Equivalents" (DOE). Is one of these methods which allows a patent holder to sue for infringement in case the product isn't exactly same as the patented product. This preventothers from making slight changes in a patented product in order to evade an infringement case.

In litigation cases under Doctrine of Equivalents, this is toevaluatethat the infringing product is being used for same purpose and is similar in function to the patented product. If the equivalency is proven in these ways, then the manufacturer of infringing will be held guilty for copying a protected item.[18]

Triple Identity Test

Graver Tank & Mfg. Co. vs. Linde Air Prods., Inc. case was the basis of establishment of DOE. This case resulted in decision of making **Triple Identity Test** which were as follows:

- Infringing product should not perform the same function.
- Infringing product should not work in same way.
- Infringing item should not produce the same result or product.[19]

All Elements Rule

Warner-Jenkinson vs. Hilton Davis Chemical Co. case established the all elements rule according to which every element which has been claimed is to be examined instead of whole patented item. The examination of equivalency should be done at the time of filing a patent application not after the grant of patent.[19]

Case Study

Actavis UK Limited and others (Appellants) vs. Eli Lilly and Company (Respondent)

The case revolved around European Patent (UK) No 1 313 508whose proprietor was Eli Lilly & Company. The appeal was made by Eli Lilly that Actavis group of companies has infringed its patent.

The patent wasrelated to chemical pemetrexed and itsuse. The drug has been proven for efficacy in cancerous tumors, but, when used alone it shows damaging side effects.

The Eli Lilly Patent disclosedthe use of drug and claimed that the administration of drug with vitamin B12 can help in avoiding serious side effects of drugs. Eli Lilly used the pemetrexed Sodium as active ingredient. This medicament was sold under the brand name “Alimta”, by Lilly. Actavis proposed product contained pemetrexed compound as pemetrexed diacid; pemetrexed dipotassium. Actavis proposed the product which do not include pemetrexed disodium, like Eli Lilly.

Judgement

The Supreme Court recognized the fact that the Actavis product will infringe the Patent granted to Lilly's product however, it will not infringe the patent directly and cross-appeal was unanimously dismissed. The Appeal was heard under the Doctrine of Equivalents.[20]

Literal Infringement

When the infringing product accuratelyhas copied everything and possess every feature that has been claimed by the patent. Generally, it has been observed that an infringer will not directly copy and sell the exact same product claimed by the patent holder. Copy-cat cases do occur, only when the infringer is in another country. Whenever infringement disputes involving literal infringement occur, it will be directly escalated to the litigation.[21]

Evergreening

When a patent holder extends his patents by using legal, business and technological strategies or by taking out new patents for the products that are near to patent expiry in order to retain royalties is called Evergreening of patents.

Evergreening is the process of immortalization of an existing patent by pharmaceutical organizations. Theyare obtaining additional patents by minor changes in formulation of the drug without necessarily increasing the therapeutic efficacy of the already protected drug. In one scenario people struggling to afford the high-priced patented drugs, while in the other scenariopharmaceutical companies struggling to give immortal value to their patented products.[21]

30 Month Stay provision

A Generic Drug manufacturer if desires to manufacturer and sell the medicine in US it has to look into provision under the Hatch-Waxman amendment (1984) of the Food, Drug and Cosmetics Act carefully. The application will be submitted to FDA by filing ANDA (Abbreviated New Drug Application) mentioning clearly that the application is being submitted under which certification. Different certifications are as follows:

Para I: The drug is not patented

Para II: The drug patent has already expired

Para III: The generic will enter the market only when the patent expires

Para IV: The patent is invalid or will not be infringed by the generic

If generic applicant files a Para IV certification, then it must intimate to the patent holder. If no action by Innovator Company within 45 days from the receipt of the notice generic

applicant can go forward with the filing. If innovator company decides to challenge the generic application, automatically a stay on further generic approval for the next 30 months or until the hearing is resolved or may be patent lapses.[22]

Types of Patent Application

There are different types of patent applications which are described hereafter:

Ordinary Patent Application

Patent application which may be provisional or complete application and does not claim any priority in convention country or does not refer any other application under process.[23]

Divisional Application

When inventor have more than one invention and cannot include all in main application then applicant can divide the application in different parts and Patent of Addition can be filed subsequently to the main filing for modification or improvement of patent.[23]

Convention Application

An application is called a convention application if applicantrequesting a priority date on the same basis or similar application filed in one or more of the convention countries.[23]

PCT International Application

PCT International Application is governed by the Patent Cooperation Treaty and can be authorized in 142 countries.[23]

Procedure for filing a patent application

Provisional Patents

The invention description can be submitted to patent office ahead of full patent application as per process of provisional Patents. The patent office in return will protect the invention on which inventor is working and trying to raise the funds to file a complete application. The provisional patent application does not require claims and it is less formal than the full application. [24, 25]

Location of filing a Patent Application

An application for the grant of Patent will be filed and further processed in the country where it is filed. There is other application called PCT with help of which we can file patent application in multiple countries.[24, 25]

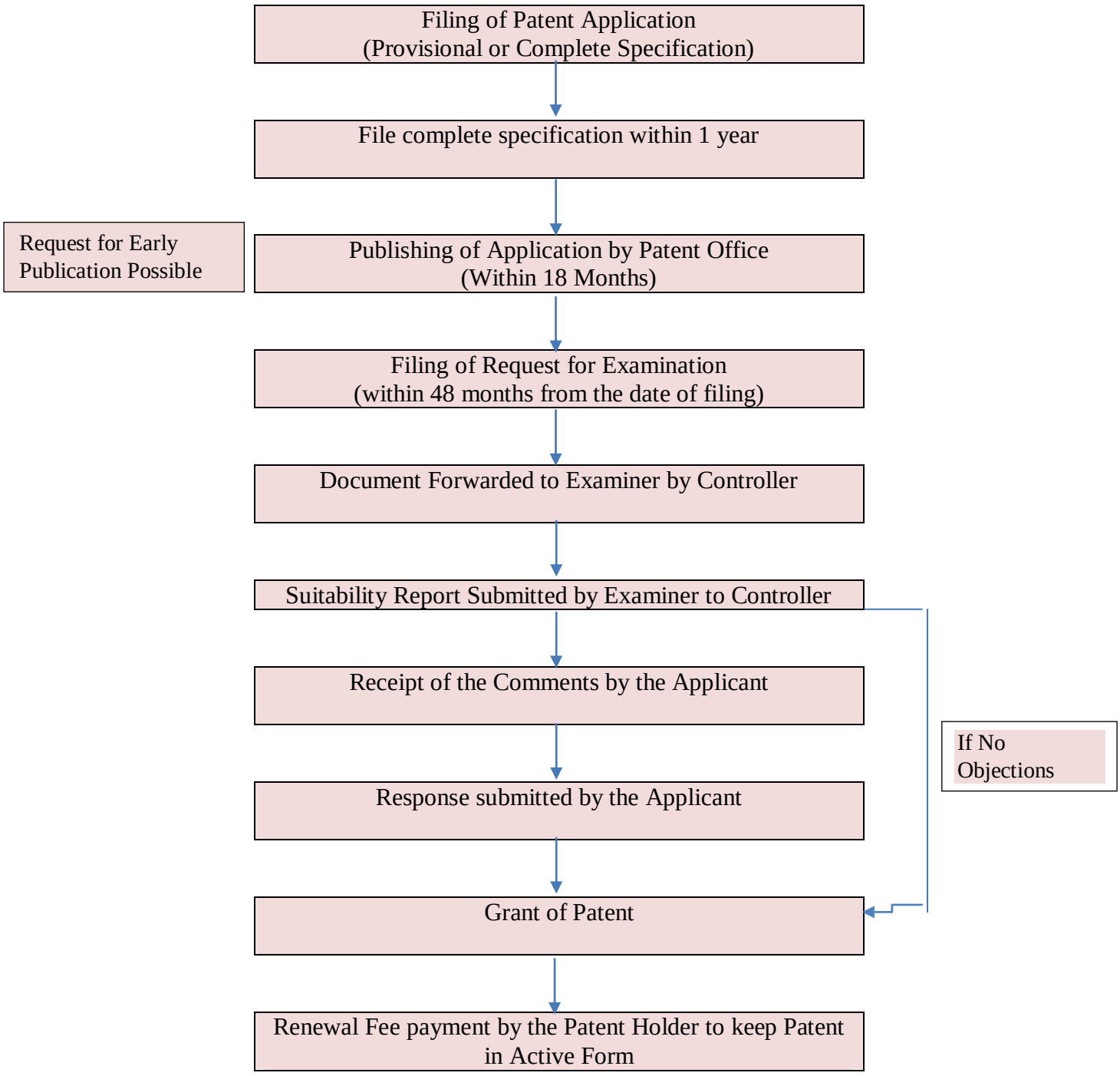
Term of A Patent

The maximum period granted to applicant during which patent will remain in force. The term of patent is always calculated in number of years. It can be calculated from date of filing patent application or from the dayon which patent was granted. Applicant has to submit Patent Renewal Fee after a certain period to keep the patent in active form. In case there is delay without reason or the fee not paid intentionally there is lapse of patent term before time. A patent application can be invalidated completely or any single claim also can be curtailed if invalidated in court.[24, 25]

International Harmonization

Earlier every country was pertaining its own rule and term of patent which were valid on national level only. In 1990 WTO's TRIPs Agreement was introduced and as per TRIPS agreement it was implemented that the patent term shall not end before 20 years counted from date of filing the application. Consequently, most of the countries follow the decision of patent term of 20 years from the filing date of the application. There are some other short-term patent rights also exists like utility patents which are generally granted for 6 to 10 years.[24, 25]

Flow Chart for Patent Filing Procedure



Procedure

1. Patentee will file application by himself or any authorized person called assignee can file patent application.
2. An Important part of patent application is specification which will be submitted along with Patent application. If a patentee is filing provision application then complete specifications are not required initially. Separate application will be filed for multiple inventions.

   Content of the specification will include:

   - Title
   - Abstract
   - Description
     a. Description containing most important information i.e. background, working and details of the invented product and drawings.
     b. The inventor must follow the rule of Enablement which means a person with ordinary skill is able to understand and use the invention.
     c. The inventor must file the patent application which describe the invention, its working and use in itsBest Mode.
     d. The inventor must summarize the limits of claims.
     e. If inventor has made use of any micro-organisms, it has to be deposited at a recognized collection point.
     f. Priority Date: The day or first date of filing the Invention which is used to determine the patentability of the invention.
3. The Applicant need to file Patent Application with complete specification, background and other details along with Authorization Letter of Patent Agent or Patent Attorney to Patent Office.
4. The Patent application with completespecifications and attachments will be published for comments from public. Generally, the publication will be done within 18 months of filing application. On the request of the applicant publication can be done earlier as the patent rights commence on publication, but applicant benefitted commercially after the grant of patent.
5. A request for examination of suitability of patent will be submitted by the applicant andfurther sent to the examiner. First of all, it will be evaluated by the examiner that the patent can be granted or not for invention. It will be evaluated that whether the

subject matter is patentable or not, then a search for prior art will be conducted from previous invention claimed. Then the analysis is made whether invention fulfils the patentability requirements. The examination report will be provided within 3 months of request. In-case the application does not fall under scope of patentability, the applicant may be provided the opportunity to the applicant for correction or amendment in the patent application.

6. An opposition may be raised when the publication is done before the grant of the patent on the basis of non-patentability, non-disclosure of traditional knowledge or resources.
7. A committee called opposition board will be constituted and the both applicant and opponent are given reasonable opportunity to present their case. The board members may evaluate the case and they can issue referral to opponent or may ask for amendments in patent application.
8. When A patent application gratifiesthe requirements of patentability, it will be granted a patent. The publication of granted patent in the official gazette will take place and valid throughout the country from the date of publication.
9. An applicant will be granted full rights to use, sell, make and license the product.
10. After the grant of patent any opposition on various grounds viz a viz sale, import, public use or display of the invention can be filed. Post grant opposition can be filed within 12 months of the grant of the patent. The process of filing Post Grant Opposition is same as in pre-grant opposition. If the opposition is found to be true the patent is invalidated, or there may be a requirement for amendments.[26, 27]

PCT

The Patent Cooperation Treaty (PCT) benefits the applicant who is seeking approval in many countries simultaneously. Applicant needs to file single International patent application. PCT application can be filed by any national or resident of a PCT Contracting State. PCT application is filedin Receiving Office (RO) in one language.

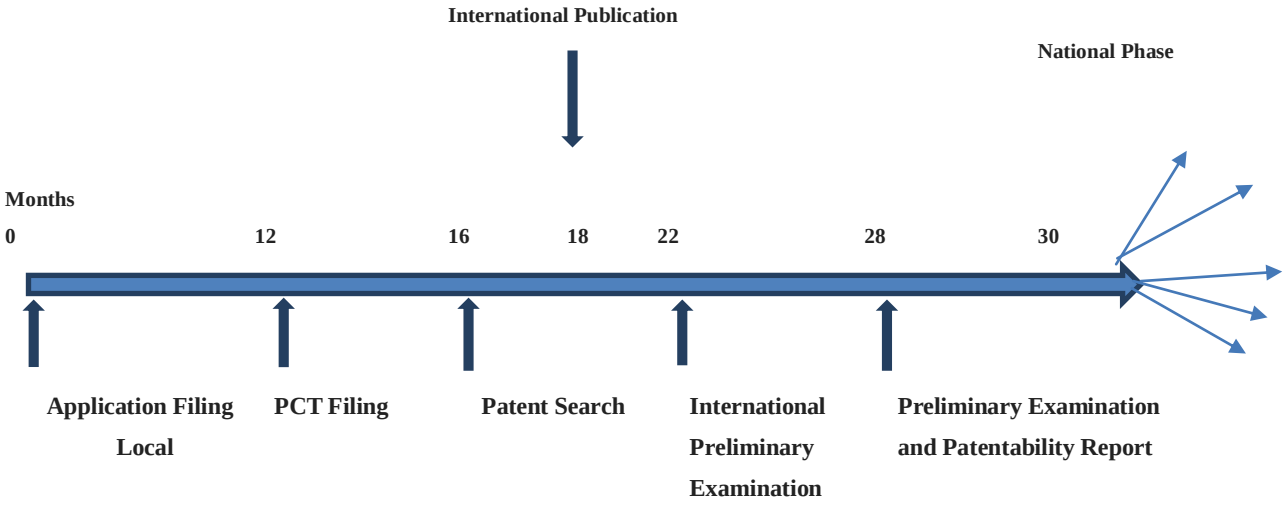
Filing of A PCT application does not mean that the patent has been granted.There is no such term as an "international patent", and the patent will be granted by regional authority of each country selected in application. By filing a PCT application, same date of filing will be recognized in all contracting states.After that the application will enter into national phase and proceed towards grant of patent.

A PCT application can be acceptable or may be rejected individually by contracting members according to lawin each jurisdiction.

The member states to the PCTconstitute the **International Patent Cooperation Union**.

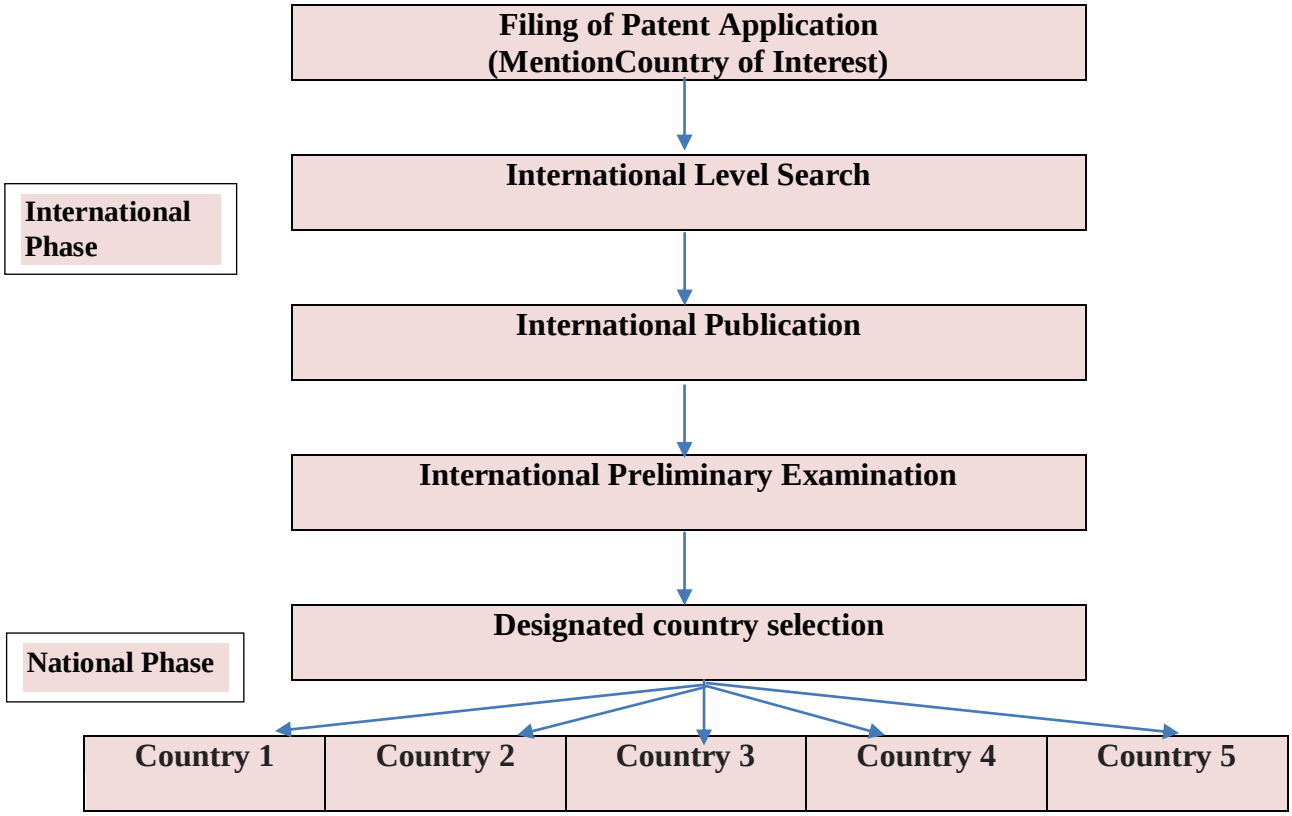
A PCT system enables filing of patent applications in many countries under a single umbrella and facilitates simplified procedure for examination and search of applications. India became a PCT Contracting member state on December 7, 1998. Therefore, India can be designated in PCT applications and can be elected for preliminary examination.[28,29]

Patent Corporation Treaty Filing Procedure



If applicant has selected India as a designated country in the PCT application and also elected for preliminary examination which has been submitted within 19 months of the priority date, then the target entry into the National Phase in India is 31 months from the Priority Date. If applicant has not selected India for preliminary examination the target entry into the National Phase in India is 21 months from the Priority Date.[28,29]

Process Flow Chart



Procedure Details

First of all, the applicant will**file the patent application**in receiving office.Generally, application is filed with receiving office in the home country of applicant.However, it can be another national office or a regional office and may be international bureau in Geneva. But it is not very common that the international bureau gets involved at this very early stage.

Once the patent application is filed, next step will be **International Search**.In present scenario, there are only eleven offices specifically established by PCT assembly which areauthorized to carry out international searches. These offices are called international search authorities. These search authorities have been established based on certain criteria, and these offices render services to applicants as per PCT system. These all search offices are not available to all PCT applicants those who file PCT applications as these offices work in specific languages. For example, the Japanese search office is not available to the applicants who file their applications in French, German and English. Another example is Spanish patent and trademark office, this office works only in Spanish. There are some offices which are working in three, four different languages.

After International search the next step will be**Publication**, which will be handled by the **International Bureau** in Geneva. This is the only step where WIPO actually takes part and is exclusively responsible for it. WIPO will publish all PCT applications, no matters the place from where they belong and in which language they have been filed.

Next step is international preliminary examination, for this purpose WIPO will consult to the International search offices. This is the last step of the international phase. It has been observed that the international bureau has indirect involvement in the overall procedure, however do not participate in direct way. It facilitatesavailability of certain documents to offices andapplicant. The international bureau directly not carrying out much of the substantive work, butremained involve in this phase. The international bureau relies on the concerned offices to provides all necessary documents and then acts on the information once they are received.[28,29]

A comparative study was carried out by WIPO for number of patents filed in different countries in 2018 comparison to 2017 which is illustrated below:

Numbers of PatentsFiled in Different Countries in 2018				
Country	**World Wide Rank**	**Applications Submitted**	**Advancements**	**% Share World Wide**
US	**1**	**56142**	**-1**	**22.2**
CHINA	**2**	**53345**	**9**	**21.1**
JAPAN	**3**	**49702**	**3**	**19.6**
GERMANY	**4**	**19883**	**5**	**7.9**
S. KOREA	**5**	**17014**	**8**	**6.7**
INDIA	**15**	**2013**	**27**	**0.8**
Total 253000			**Source: WIPO**	
Comparison with 2017 Data				

Conclusion

From the above discussion it is clear that Patent rights are need of today. Invention may be of any type must be protected. Government of every Country is promoting its inventors to save invention from duplication not only in country, at international level too. In present scenario

awareness is at its peak and fully equipped tools are available to identify infringement cases. Awareness regarding patent rights has made its way to every nook. We have observed in above discussed case studies that if enterprise has hardly improved an existing product then this improvement does not fall under the scope of patentable Invention.

It is highly advisable for SMEs to engage more in inventive activities and consult patent databases to find out existing technologies. To avoid duplication more and more emphasis should be on searching licensing partners for existing technology. More comprehensive analysis and patent searches should be done to avoid complicated litigation cases.

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