

Review Article

## PATENT FILING AND DRAFTING PROCEDURE IN INDIA FOR A NEW PHARMACEUTICAL PRODUCT

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### ABSTRACT

**Background and Aim:** A patent is a legal right to grant of Patent to the Patentee for his new idea, method, product, etc. for a limited time period by the government. The patent law in any country provides safety to the inventor for his discovery. Patent safety means the other person cannot manufacture and distribute the product without taking prior permission from the patentee. **Methods:** In this work the Patent law for Patent grant in India is discussed. The patent law is quite similar in all countries. The difference is mainly in the patent filing procedure. **Result:** The patent system is divided into two parts, first is patent filing procedure and the second is the patent grant procedure. The procedure starts with the filing of an application for the grant of patent. This is followed by the second step which includes the search, publish and examination. If the application fulfills all the requirement of the patent law, then the patent is granted. **Conclusion:** In different countries there are different criteria for an invention to be a patentable, but in all the countries the clause of novelty is there. The clause novelty states that "the invention must be new" if your invention is already known you cannot get a patent despite being fulfilled criteria, such as industrial application and must be non-obvious.

**KEYWORDS:** Patent, IPO, ISA.

### INTRODUCTION

A patent is a legal right for any discovery, ideas approved for a narrow period of time to the patentee by the government in exchange of his discovery. A patent gives safety to the patentee for his new discovery. The safety is approved for 20 years. Patent safety means the other person cannot manufacture and distribute the product without taking permission from the patentee. When the patent time limit expires the production also comes to an end and the patentee no longer holds the right to the discovery. Any discovery, related to the product and process that is useful for industrial application and is new can be patented. The patent filing procedures differ from one country to another. [1]

#### PATENT FILING PROCEDURE IN INDIA

**What is Invention-** Section 2 (1) (j) of the Patent Act, 1970 (the Act) defines the invention as "Invention means a new process and product which is non-obvious and useful for industry". [2]

**What is novelty-** Section 2 (1) (1) of the Act defines new inventions as "new invention means any technology and invention which is not available in any country or any published document before the filing of patent application" is known as a novelty.

**What is inventive step** –Section 2 (1) (a) of the Act defines inventive step as "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".

**What is industrial applicability-** Section 2 (1) (AC) of the act defines industrial applicability as "industrial applicability means that any method or technology being made which is useful to the industry."

**Invention not Patentable-** Section 3 of the act mention different types of invention which will not qualify for a patent even if they satisfy the requirement of section 2 (1) (j) of the act namely. [3]

- Any invention which is against the natural law
- Any invention which produces harmful effect to plant, animal or human life
- Any discovery related to abstract theory and scientific principle
- A technique of agriculture

- Any method for the surgical, medicinal or other care of human beings
- Presentation of information
- Topography of integrated circuits

Any "invention falling within subsection (1) of the Atomic Energy Act, 1962 (33 of 1962) are not patentable under section 4 of the act

#### TYPES OF PATENT APPLICATION

The application for patent can be of following types:

- Ordinary application
- International/PCT application
- Convention application
- Application for addition
- Divisional application

#### Ordinary application

It is also called non-provisional application. This application contains the claims and the complete specification. It is submitted in the patent office without any reference to other application. In the patent application, name and address of first and true inventor must be given. [4]

The important documents of the patent application are:-

Form 2 "Complete or Provisional specification"

Form 3 "Statement and undertaking"

Form 5 "Declaration as to inventor ship"

- Priority document
- Power of attorney

#### International/PCT application

PCT application is also known as international application. It was introduced in the year 1970. The main purpose of this application is to give safety to the inventor for his idea or discovery in the world. In PCT, there are 148 countries. Instead of filing several regional or national application the applicant can file a PCT application and protects his invention in these 148 countries. [5]

In PCT national phase application the applicant must attach a complete specification which includes title, drawing, abstract description and claims. 31 months' time period is fixed for entering into the national phase from the priority date. PCT national phase application can be examined any time before this time limit.

#### Indian Patent Office (IPO) as Receiving Office

- The receiving office sends the search copy of the applicant to the **International Searching Authorities (ISA)**.
- An applicant can file an international application in a language other than the language which is accepted by the ISA for carrying a search.
- A dialect acknowledgment by the ISA
- Publication Language
- A dialect acknowledged by the receiving office under rule 12.1 (a), unless the global application is documented in a published language.
- The office is competent only if the international search has been carried out by Swedish patent office or by Austrian patent and registration offices. [6]

#### IPO as International Searching Authorities

- ISA notifies the applicant that the search copy has been received in form PCT/ISA/202 and sends a copy of the notification to the international bureau (IB).
- The Language accepted for international search is English. The other important points are:
- The topics indicated in subsection (i) to (vi) of PCT Rule 39.1 are not searched.
- There is no need to submit the separate power of attorney.
- ISA must create the international search report (ISR) and written opinion within 3 months from the date of receipt of the search copy.

#### Convention application section 135 of the act

According to the act, convention application is defined as the application filed by the applicant in one or more convention countries. After filing the application in convention country the applicant again files the same application at the patent office of India within 12 months. [7]

#### Application for addition section 54 of the act

The application is filed by the applicant in the IPO if any improvement or modification is made to the invention. The time period is the same for granting the patent and it is not extended. [8]

#### Divisional application section 16(1) of the act

This application is used when the applicant claims more than one invention and law does not allow multiple patent in one invention. The applicant sends a request application to the patent office before the grant of patent and divides the application in two parts. [9]

Following this approach, it is not mandatory for the applicant to submit the complete specification in the first part of application. In the second part of application the applicant must submit the complete specification within the specified time period. If the applicant does not submit the complete specification in a given time period then the application is rejected by the IPO.

#### Person entitled to apply for patents section 6 of the act

- A) According to the section 134, application seeking the grant of patent can be filed by the following person:
- First the true inventor of the invention
  - First and true inventor assignee a person who represent the invention on his/her behalf.
  - Legal representative of the inventor
- B) Under sub-section (1) of the act the applicant can make a patent application either alone or joint with other person. [10]

#### TYPES OF PATENT SPECIFICATION

There are two types of specifications

1. **Provisional Specification :section 9 of the act**
2. **Complete specification: section 9 of the act**

#### Provisional Specification

This is filed when the applicant feels that his discovery/idea has reached the stage that it can be disclosed in the form of a written report. In this case provisional application is submitted to the patent office and it helps to preserve the priority date of the application.

After receiving the provisional specification, the patent office gives an application number to the patent application. [11]

#### Complete Specification

It is very important document in a patent application for the grant of patent, the applicant must submit it within 12 months from the date of filing of provisional application. In this application, applicant gives a complete description of his invention. The submission of complete specification period can be extended by 3 months.

#### Content of specification section 10 of the act

1. **Title:** The title of the patent should describe the subject matter in the patent application.
2. **Field of Invention:** The field of invention is a general wide statement telling about the technology of the invention.
3. **Background:** The background is used to describe the statement of the technology, the known prior art, the disadvantage/needs that are being overcome before the invention described in the patent. The background identifies the key feature of the invention that were lacking in the prior art. [12]
4. **Summary:** The inventions are represented in a summarized form in this section. The information in this section is related to the step taken to solve the problem which was discussed in the background of invention. This section also describes the advantage of the invention.
5. **Description:** It starts with the background of previous invention and also includes information about the present invention like process and products or its parts. It must be written in detail as per the rules of the act.
6. **Claims:** Claims must be clear and brief.
  - It must describe the technical features of the invention.
  - Important features of the invention must be stated in the independent claims.
  - Use Arabic numerals for numbering the claims.
  - Only one independent claim should be present in the same category of the application
7. **Abstract:** It is short summary of invention and its uses. It should preferably be written in 150 words and should consist of following.
  - Invention description
  - Description of the important component and their work
8. **Drawing:** The drawing of a patent specification describes the invention by using chemical or mechanical structures, charts and detailed relationship of features. The drawing contains references as (numeric and alphabetic) that relate the features described in the specification to the features or portion shows in the drawing.

#### FEES FOR FILING

There are two types of filing that e-filing and physical filing. The fees are based on the type of filing. [13]

For e-Filing\*:

Table 1: Patent Filing Fees in India

Number of entry	On what payable	No. of form	For natural person(S)		For person other than natural person(S) either alone or jointly with natural person(S)	
			Rupees		For small entity Rupees	For other except small entity Rupees
1.	On application for a patent under section 7, 54 or 135 and rule 20(1) accompanied or complete specification.	1	1600		4000	8000
	I. For each sheet of specification in addition to 30		I. 160		I. 400	I. 800
	II. For each claim in addition to 10		II. 320		II. 800	II. 1600
2.	On Filing complete specification after provisional up to 30 pages having up to 10 claims.	2	No fee		No fee	No fee
	I. For each sheet of specification in addition to 30		I. 160		I. 400	I. 800
	II. for each claim in addition to 10		II. 320		II. 800	II. 1600
3	On filing a statement and undertaking under section 8	3	No fee		No fee	No fee
4	Declaration as to inventor ship	5	No fee		No fee	No fee
5	On request for examination of application for patent	18				
	I. Under section 11B and rule 24(1)		I. 4000		I. 10000	I. 20000
	II. under rule 20(4)(ii)		II. 5600		II. 14000	II. 28000

10% surcharge on physical filing

FLOW CHART OF FILING APPLICATION IN INDIA

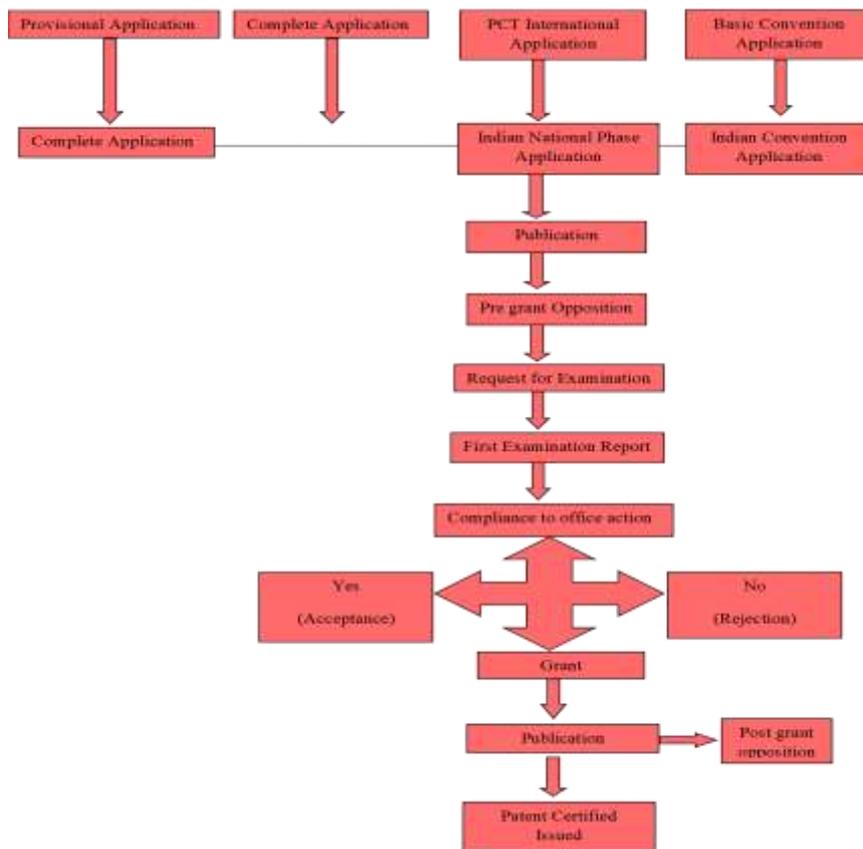


Fig. 1: Patent filing procedure in India

## PUBLICATION

After filing the application form, the applicant is required to publish a journal which contains name, address, abstract, abstract and procedure of invention to the patent office. This should be done within 18 months after filing the application form or from the date of priority, to the patent office. After this procedure the patent application is open for public inspection. Before publication it is not open for public inspection. [14]

## EXAMINATION

The applicant who has filed for the patent undergoes the procedure of examination in which all the documents, application forms, claims forwarded by the applicant are tested. After testing of the reports, a First Examination Report is published and sent by the patent office to the applicant or his agent stating the objection to which the applicant or his agent has to reply within 6 months. In case the applicant fails to reply to the report and an extension of 6 more month is given to the applicant. [15]

## OPPOSITION TO THE PATENT

After the First Examination Report the patent office search for the same patent type in their offices to ensure that the patent applied for invention is valid there is no other claim or there is no other patent holder of that invention already in the past. [16]

## GRANT OF PATENT

When all the criteria are met the patent is issued to a person for 20 years. If there is opposition to the patent another can file within a year of publication of patent. [17]

## DRAFTING OF A PATENT SPECIFICATION

**First Step:** Information/document required from inventor, invention disclosure form which should include all information. [18]

**Second Step:** Prepare strategy for drafting and figure out the relevant method of drafting such problem-solution, Could-would, Teaching suggestion motivation etc.

**Third Step:** Confirm your understanding with the inventor.

**Fourth Step:** Prepare claims of the specification and confirm the scope and technical disclosure with inventors.

**Fifth Step:** Draft the description, abstract, drawing/s of the specification.

**Sixth Step:** Share the full petition with the inventor to confirm.

**Seventh Step:** File a patent application based on the drafted patent specification.

## CONCLUSION

The patent law in any country provides safety to the inventor for his discovery. Patent safety means the other person cannot manufacture and distribute the product without taking prior permission from the patentee. In different countries there are different criteria for an invention to be a patentable but in all the countries the clause of novelty is there. The clause novelty states that "the invention must be new" if your invention is already known you cannot get patent despite being fulfilled criteria, such as industrial application and must be non-obvious. The patent filing procedure is first step in which the applicant drafts the specification which provides complete information about the invention. This includes title, drawing, description, abstract and claim. The patent application acceptance

and rejection depends upon the drafting. The patent protection term in India is 20 years from the priority date. In India there are two type of patent which are product and process patent. Patent grant procedure is the next step after the filing of application, in which includes search, publication, examination and opposition.

## CONFLICT OF INTEREST

There is no conflict of interest

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