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Patent Application Preparation and Filing

Mohamad Taleuzzaman and Iqra Rahat

Abstract

The issuance of a patent by the government office is basically done by a patent application record that is an agreement between the inventor and the government office. Correspondingly, a patent application is in many ways like a contract. Preparation of a standard patent application is curious because it sets out in a transparent way, the terms and condition by which the patent owner and others will be bound. These criteria of the patent application make it different from writing a scientific paper. The technical subject matter that is available in the patent application have bear some similarities to a scientific or technical paper, although it does not usually need to rise to the level of a blueprint for making the invention protected by the patent. Public officials of government take a long time to review the patent as examiners and judges and business partners. Therefore it is necessary that a patent application should be drafted with these important audiences in mind. The parts of the patent application typically include the Background, Summary, Detailed Description and Drawings, Claims, and Abstract. The patent agent is unlikely to draft the patent application in this order and should ordinarily draft the claims first.

Keywords: application, patent, filing, government official

1. Introduction

From last many decades, national and international organizations have made to try with best efforts to homogenize the laws governing intellectual property. To attempt the standardization, the little bit restriction always comes it is either infrastructure or capital, especially in pharmaceutical industries. That is the reason a continuous tension exists in multinational pharmaceutical companies (MNCs) in developing nations. Intellectual always give their maximum efforts to overcome these problems which the easier business environment worldwide. In the World Trade Organization (WTO) earlier, India does not recognize product patents in pharmaceutical. Without product patents, Indian pharmaceutical companies were able to agitate countless generic drugs. In the world, India contributes to leading manufactures in generic drugs. Results of these are that the relative moderate of these generic drugs as compared to patented drugs not only provide chief drugs but also made India the de facto pharmacy for many developing countries [1].

The basic object of the Intellectual Property Right (IPR) to deliver unquestionable absolute right over the fabrication of the mind and to finite exploit it for a fixed duration of time, in order to enable them to gather commercial benefits from their creative efforts.

The application and filing is the first step to patent the drugs for trade world-wide, which provide a platform for the exclusively business without a doubt or question regarding the quality of drugs and its efficacy. The evolution of innovation can explain by the diagram [1, 2] (**Figure 1**).

The Intellectual property known as IP, gives the right to the people to own their innovation, invention, and creativity in the same way as they own their physical property. In can cover the different forms like **Figure 2**.

In a general way, IPR plays an important role in two principal areas which impact in the Pharmaceutical Industry. First, the pricing and access where the focus on securing competitive marketing which creates the problems in the pricing of drugs. Second, is an issue related research and development incentive, which is the marketing of the new medicines and its price? The consequence of IPRs on R&D expenditure and its grant across the different disease, countries, and organization.

The IPRs patent application preparation and filing, the right of legal work it might be sold, uses, offers for sale and/or imports any technology can be protected by the IPR documents, that gives the power to trade in an authentic way. The inventors are completely satisfy if he/she has legal documents of IPR. For this, there is a process which is followed by the regulatory bodies in every country.

Before, the patent approved a step that is called the provisional application in some country like the United State of America. The provisional patent application duration is 1 year and it provides smoothly, rapidly and affordably got the pending status. The patent is ownership for creativity or innovation product protected by the patent's claims. Before revealing the innovative idea the patent application filing is necessary. The patent should persuade all legal requirements it covers like time limits related to how long the invention was disclosed to the public. Before filing a patent application if the inventions communicate in public it will be denied without any grace period [2–4].

A detailed audit is a must before filing the application itself. From this consequence the broader concept or the principle which are important for the public and it will be drafted in very well manner. The application prepares on the facts of the principle or new idea that is highlighted in the drafts, its importance, and scope in that respective field.

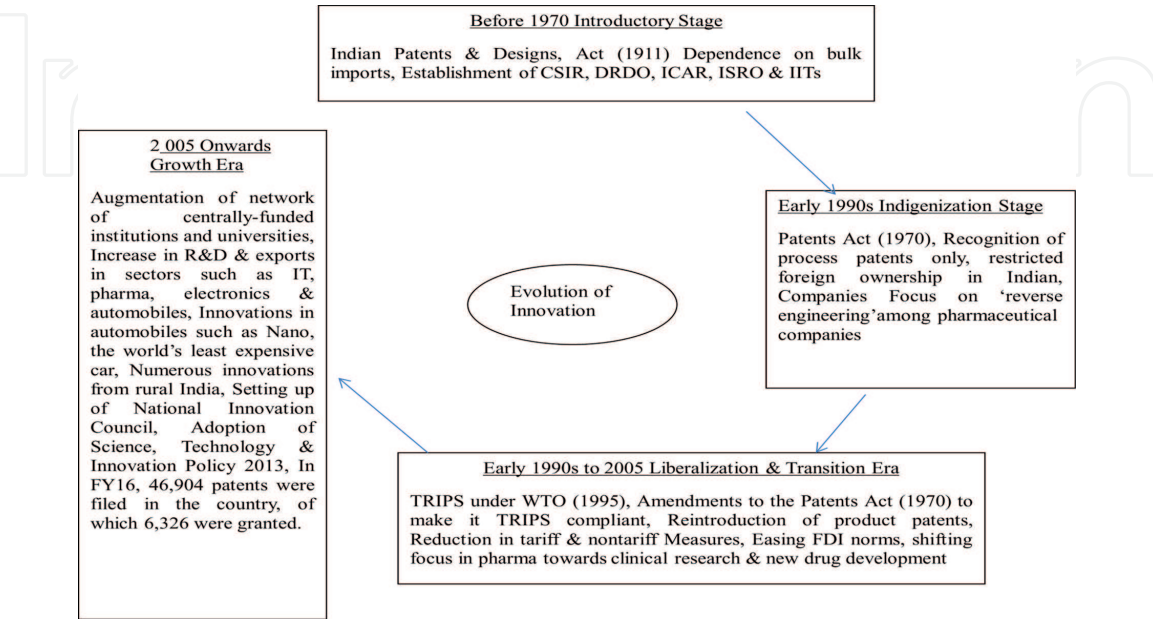


Figure 1.
Evaluation of IPR.

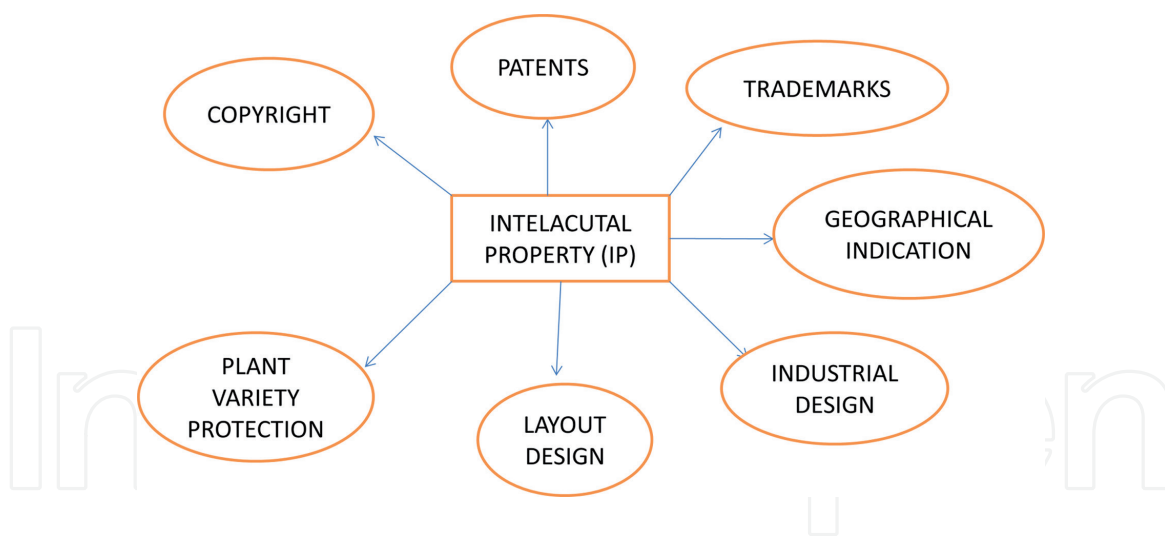


Figure 2.
Different types of IPR.

In facts, patents are “regional” its consideration only on those countries where they have been applied for and granted. Every country has its own legal office where it documented that the patent applicability is worldwide or it is only to its own country. Patent acceptability and its innovative idea can be challenged and if it’s finding any demerits should be rejected. To maintain the discipline and hierarchy in the legal office the team must examine the whole content of the application properly, so further it is no possibility of challenge.

After World War II, The international pharmaceutical Industry grows rapidly. The demands of antibiotics create a challenge for the company in the research and development division. As the year gone following the wars saw the rapid growth in number industry and establish as MNCs by infiltration in many countries. The headquarters of such MNCs established in developed countries from where business manage. Due to the lack of trained skill human source in developing countries as well as a necessary technology for which big capitals are required to developed a new molecule make not a possibility such corporation.

After independence India was faced many challenges like as one of the poorest countries in the world, with also increase problems in the health sector to overcome this government takes any initiative for the amendment in patent law which make the business easy. For this government of India appoint two committees one is the Patent Enquire Committee (1948–1950) and the Patents Revision Committee (1957–1959). The object was to review the patent law and ensure that the patent system was more conducive and interest for the nation.

India by 2020 reached as a global leader in the field of the pharmaceutical industry. This country established as a leader of generic drugs manufacturers. India passed its first patent law in 1856 under the British colonial rule and it is based on the British Patent Law of 1852, here inventors have right for 14 years duration privileged. In 1911, the British government introduces the Indian Patents and Design Act with removing the Inventions and Designs Act of 1888 which is effective till 1972.

Worldwide the developing countries as a consumer for the many products its importance partly increase, in 1994 all members of the World Trade Organization were required to adopt the Trade Related Intellectual Property Standards (TRIPS).

By growing the Pharmaceutical MNCs worldwide, The World Trade Organization came into existence on 1 January 1995, and along with it came the Trade-Related Aspects of Intellectual Property Rights TRIPS Agreement. Covering the international instruments for strengthens the IPR. India initially not in favor

of TRIPS as other developing countries. As a member of WTO India modifies its domestic intellectual property laws in order to comply with the agreement.

In the world, the most difficult aspect of the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) is over the issue of patents for pharmaceutical drugs. From 1 January 1995, The TRIPS agreement came into effect, this agreement stretches the scope of intellectual property rights. Patents shall be available for any invention it declared in article 27, whether the products or process in all fields of technology. In India Parliament granted by act 1970 that patent rights only to manufacturing processes, rather than to the end products themselves,"

In the world, India is the country which not only a chief exporter of drugs but also the primary producer of drugs for its own population. Generic drug share market is large portion covered by this country [1–3].

2. Patent basic

The basic aspects of the patent system must know very well and it is outlined before to practical aspects. The primary logic behind the generation of a patent system was to honor an inventor by a full right to the invention of duration for a number of years it depends upon the country legal authority. The new inventions which support to stimulate and promote the further technological process and innovation, it is fruitful when the patent has public access. The countries or group of countries have legal authority that patent is the exclusive rights for the innovations. In a trade or commercial business, a patent provides their owners which stop from the making, using, offering for sale, selling or importing a product or a process without their permission (a license). By the patent system, it is clear that how the inventor can protect their patent and also it is necessary that how to respect other innovation by participating in it. Keep in mind that the patent itself is a regional right, it workable in limited either in a country or a group of countries. Patent never is "world patent" as it only territorial. Therefore the filing of a patent is a choice of the territory and the region where the patent protected. The desire of territory is based on the country market potential, manufacture's competitor place, research center place, and various other places. It is a fundamental part of the patent application filing. The basic criteria of patentability—Must be patentable subject matter in US geography, Unity of invention, capable of industrial applicability. In most of the countries, the primary object is the novelty, in some countries also seen the double standard of novelty depending on the place of the invention it is inside the territory or outside the territory. The comparison of novelty and art of skill in the invention should be superior to the existing patent in the same field. In a patent, the non-obviousness is one of the most difficult things to define. Its contribution to defining the level of technology. The examiner of the patent has the ability to disclose in the prior art but also identifies the art of the skill in the innovative person. In the Pharmaceutical world, patent protection is very important which uplift the development of the new medicine for disease those consequences these countries. The patent protection boosts the pharmaceutical industry for the investment of the billion to develop the new molecules, making sure that the product sale [3, 4].

The pharmaceutical product takes a very long time to develop and enter the market for human use. A new dosage form an average takes around 10–15 years during this period medicine efficacy and safety must be proved by a different phase of a clinical trial. A significant period lost the new drug before entering the market that is a disadvantage in the pharmaceutical field. On innovation

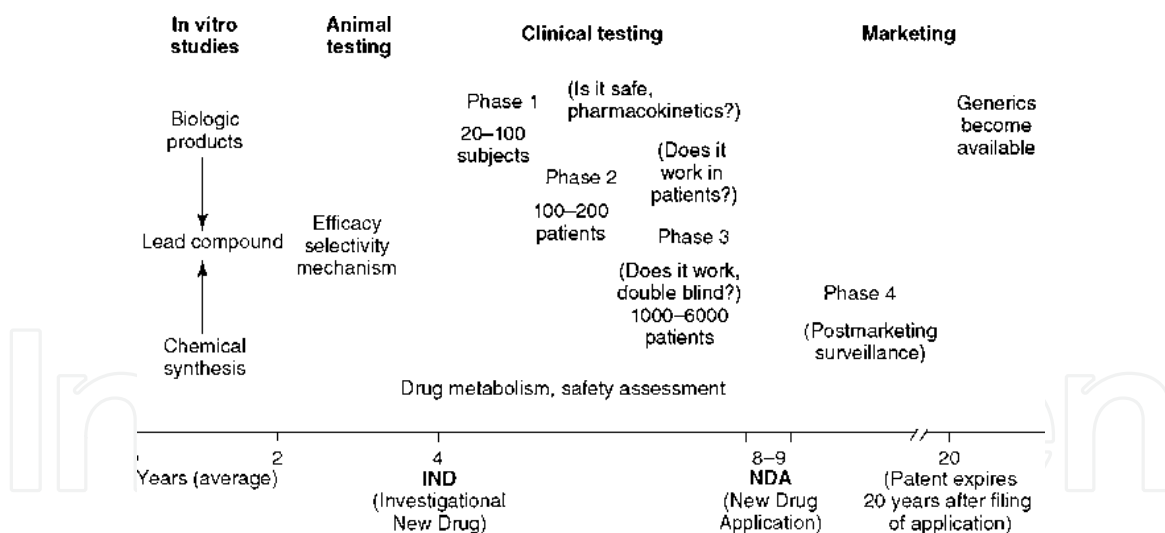


Figure 3.
New drug development.

patent role is that it protect the innovation it either territorial or global, but in case of pharmaceutical product, there must be some extent of flexibility by which the monopoly right decrease so that it does not affect the cost of medicine. The world moving towards the differential pricing of medicines, making the cost of medicine cheaper in developing countries. From the developing countries, the revenue generated is very less and around 1% as compared developed countries. Developing countries contribute the minimum incentive to the research, it comes maximums from the developed countries. To provide the health patent is not only the obstacle along with it has other factors like poor infrastructure lack of sanitation and shortage of funding for even generic drugs **Figure 3** (New drug development).

The concept behind the patent for innovation is a contract on a temporary basis, where society agrees to the monopoly that allowing a high level amounts that doing so provide will provide a strong incentive for innovation. Creating revenue from manufacturers and production give the strong back up to research and development also encourage in the interest in development for the new molecule in pharmaceutical. A balance is necessary between the research and development in aspect to economic, because from research and development there is no scope to generate direct revenue from the customer. Indirectly it gives very strong revenue to the market [4, 6].

3. Structure of application

For filling of application, the ideal requirements of the patentability and also the application must be filed by the competent authority for a certain country or a group of countries. A quick focus must be given when filing the application and try to cover the application with the following parts.

- Claims
- Detailed description (or specification)
- Drawings
- Background

e. Abstract

f. Summary

Who that file the application; the title must be itself descriptive and creative. The title properly indicates the subject matter of the application. The patent application itself should also include all priority information, such as the identification of related applications. The audience for the application basically is the judges and patent examiner. Also, apart from these the patent agent's client and the inventor are also audiences.

3.1 Claims

In the patent filing, the claims for the inventor prepared by the agent that is first it must be easy in language and plan should be in at least three. The patent agent outlines a diagram in the first disclosure meeting and discusses with the inventor. The language or the terminology used for the filing the might be difficult to understand by the inventor. So, the agent explains it in pictures or another diagram by which it is easy to understand.

In practice, the agent prepares the several drafts for the communication and select the best one for further proceeding. The claim is the legal part of the application. For the preparation of quality contents draft, the agent must give the time and during writing focus on that, it is concise and explanatory. In any case, it is seen that due to short of time the ideal paper not prepare and such situation the technical paper of the inventor consider a claim. For convenient the claim may present in a picture that is easy to understand. By pictures language the novelty of the paper is high.

As the claims completed the patent agent require to check the specification to verify and confirm that the claim terms appropriately explain in the paper.

The detailed description section, sometimes known as the "preferred embodiment of invention" section or the "disclosed embodiment of the invention" section breathes life into the claims and provides a sufficient explanation of the invention for an ordinary person skilled in the art to make and understand the invention. In some jurisdictions, the term "specification" is also used to refer to the description in addition to the summary and background sections of the application; suffice to say that "detailed description" and "specification" are generally the same for purposes of patent drafting.

The detailed description section must be closely tied to the drawings. This section cannot be substantively amended once the application has been filed. Consequently, the patent agent must make sure that the detailed description section provides an appropriate degree of technical disclosure on the day that the application is filed as he won't have a second chance to alter this part of the application. The patent agent cannot amend his application to include new technical disclosure during prosecution.

If the patent agent uses a highly abstract term in the claims he should consider using the term in the detailed description section, but in a manner that ties the abstract term to a specific embodiment of the invention. For example, if the claims use the term "warning device" for automobile horn, the specification could either say: "One example of warning device 10212 is an automobile horn. Other warning devices may be used, consistent with the spirit of the invention," or, "Automobile horn 102 constitutes a warning device. Many other such warning devices may be used consistent with the spirit of the invention."

As mentioned above, the detailed description section cannot be substantively amended once the application is filed. Thus, a patent agent should take care that

the patent application (1) reflects the disclosure material provided by the inventors, (2) provides sufficient information to enable an ordinary artisan to reproduce the invention and (3) provides sufficient depth so that the claims can be narrowed during patent prosecution to avoid close prior art. Further considerations about the scope and importance of the detailed description section will be discussed below and are also illustrated by the following example [2, 5, 6].

3.2 Detailed description (or specification)

For the preparation of filing, the specification should be full filling the basic requirements. The condition as per the country rule regulation. For example, Canadian practices are more or less different from those of American practice. But worldwide the American practice is more considering that the Canadian practice regarding the specification.

The specification discusses in three parts:

- I. Describing the Invention: The first object is to give a hint of what to be claimed. Explain the patent by the inventor through the electronic circuit compromising a combination of a logic gate. In such a way if the inventor wants to file another one application need to only change the logic gate where the microprocessor change. Therefore, all claimed elements must be shown in the specification. In specification there is no limit, it must be broad and require covering most of the points in a general way, where it full fill all terms that cover the patent application.
- II. Professional Person enables to explain Invention: It is in the concern to update software have full knowledge to a patent agent. For convenient, the agent explains all the content of the application in drawing with the help of updated version of the software. By block diagrams, is easy to understand the whole contents of the patent.
- III. The Best Mode by the Inventor: The inventor discloses his best knowledge at the time of filing of the application. Two ways by which it explains. First, the invention carries out as claimed, not disclose invention for commercial in the market. The second is subjective here; the inventors may be not disclosing the proper knowledge in such case some aspects of the invention in dilemma.

3.3 Drawings

In this part, the presentation of the invention is the best way of drawing which makes easy to understand the facts of the invention. The patent agent describes the innovative idea with good visual supporting materials. It is found that the drawings are the most important of the patent after the claims. The preparation of the picture itself an innovative idea, the patent agent first read all the contents of the application and thick on the designing of the picture. Some time it is very difficult to explain the principle or innovative idea by drawing a picture. During the explanation of innovation by drawing the agent focus on the using of minimum words and that itself explanatory, use in some way a reference in the picture.

3.4 Background

This part is very less important for the filing of the application, the patent agent focus on that very least at last. If the background of the application prepares first the

value of the draft it finishes. The patent agent trying to explain the background in brief. If the background of the patent application describes in detail it is not good for the inventor, so some practitioners intentionally not saying too much about the innovation in the background section, in the way patent can be protected in public space.

3.5 Abstract

This section is not necessary here, generally it is described in first or some time not requires in a patent application. The innovation idea expresses in very few words where it is smartly explained. In some countries, the court demand first abstract, by study the abstract the patent application can be understood very easily if it is discussed in properly. The preparation of abstract after completing the draft of the patent application, if it is prepared earlier, there is a chance of mistake my it is poorly written or not completely explanatory. But the drawback of this section is that here, some time the innovation specification explains.

3.6 Summary

In most of the country National Law did not ask the legal authority to submit the summary, but it comes in practice by the patent agent. Patent agent prepares the summary parts with the help of the expert, so it is helpful for the jurisdiction to understand what the inventor wants to say. In this section avoid putting the picture or explaining the contents thoroughly. The patent agent focuses to write the summary that it does not explain the parts of the whole claim. The words used in this section are not very turning to mean and try to complete in one paragraph [4–6].

4. Patent filling strategy and tools

As it discussed that patents are territorial rights, the designing of the application explains itself how the patent protection would be preferable. The filing of the patent application is a basic requirement for each country. The grant of a patent and thus patent protection is necessary. The filings of application in many countries are a financial resource for legal bodies, some it is the uncertainty of the potential success of the invention.

During filing the patent agent has the responsibility and accountability to present all the information in the given specification that the inventor ownership uses their best mode of mechanism to develop for easy access. The chronicle must not contain incorrect or confusing statement calculated to cheat the person to whom the specification is addressed and make it hard for them, by not considering proper tests and experiments, to understand and construct the invention. From the filing of the patent, it must be clear that it is useful, certain points relating to its utility must be in the specification. The Chronicle may be invalid if it is not properly completed.

It is the duty of the inventor that he or she provides the all information very properly to the patent agent of its invention and not hide any information which it may be lead to the lawsuit later, which should be legal during the duration of the patent. The inventor whatever the content submits to the patent agent either it's in drawing from or in the very good language, the patent agent drafts his or her application based on that. The patent agent when preparing the application should demand the artwork or the facts from the inventor prior to his work, it may be helpful for the agent to draft the application properly. The patent agent put the proper address, correct affiliation and place of work in the application. Which must appear in the application? The right of the invention may be individual or its transfer to the

company or another one, for such things the patent agent must be written with very effectively in the application latter it is not questionable [7, 8].

5. Development and importance in pharmaceutical industry

India's modern pharmaceutical industry was primarily shaped by Patents act 1970. Before that Indian market dominated western Multinational Corporation that controlled over third fourth market basically through imported drugs. At that time most of the pharmaceutical product was held by foreign companies and domestic drug price was among the highest in the world. An important point of the 1970 patents act was the special delivery connects to the pharmaceutical that allowed patent protection only for a new method or process of manufactures in the synthesis of a molecule in the Indian market. This patent protection was provided for only 7 years for pharmaceuticals.

This robust domestic manufacturing industry for pharmaceuticals stems, in part from the 1970 Patents Act effectively encouraging the reverse engineering of internationally patented products. If the large price increases that some predicted following the adoption of TRIPS were realized, they should be evident in the aggregate data. Our primary identifying assumption is that the timing of patents being granted was orthogonal to other events that might also have affected the market outcomes of newly patented products. To further address concerns regarding heterogeneity in the strength of patents or the importance of the patented molecules in the Indian market, we next examine the subset of patent applications identified. Perhaps the most direct is a decrease in the number of producers due to the increased exit rate of incumbent firms or a lower entry rate of new firms. The change in prices can occur without any actual difference in the observed market structure. As evidence of the existence of this phenomenon, we note that some of the firms receiving patents for molecules never appear in the retail sales data. India has granted hundreds of patents to both domestic and multinational firms. This represents one of the first attempts to apply an entirely new patent system to an existing market of this size and scope. Prior to the new patent system, there were many products being sold containing molecules that were patented outside of India but were domestically manufactured and sold by a large number of firms [9, 10].

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