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Patenting the innovation and regulatory considerations

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ABSTRACT

Bringing a medical product in the market is far more complicated compared to any other product due to its sensitivity and direct implication to human life. On one hand, legal protection in the form of patent may be needed and on the other hand the approval to manufacture and sell product should be obtained. In this article, we will discuss the role of Intellectual Property Rights in protecting innovations as well as regulatory requirements, specifically in case of medical products.

Keywords: Patent, Medical, Innovation, Regulatory, IPR

Patent is one of the most popular forms of Intellectual Property Rights, granted by the Government for inventions that are novel, industrially useful, and comprise an inventive step. A patent is granted for a product or process and helps inventors in many ways. These ways include helping inventors gain a competitive edge in the market, securing the validity of the true and first inventors of the innovation, enhance the valuation of their company and become a revenue-generating tool when commercialized. Having a patent also helps inventors to market their product better and strengthen their reputation and goodwill in the market.

The details of the invention must be documented in a prescribed format along with fee and appropriate forms, which then have to be submitted to the patent office in order to obtain a patent. The patent application is published and duly examined (or scrutinized) by the examiner. If everything in the application is in place with respect to the subject matter claimed in the patent application, the patent is granted. Protection extended in the form of a patent usually lasts for 20 years from the date of filing, provided renewal fee by the applicant is paid in time and the patent is not objected by third party (ies).

WHAT IS REQUIRED TO GET A PATENT?

Patents are granted by the Government for inventions (either products or processes) that are novel, industrially useful, and comprise an inventive step. A patent technically comprises a techno-legal document where detailed information about the invention is submitted. Therefore, it is extremely important for the inventor to document the invention in a proper manner right in the beginning. Three main parameters are given prime important when documenting the invention. These are novel elements of the invention, technical problems for which inventor has found a solution through the invention, and lastly, working of the solution or invention [Figure 1].

The invention may be considered to be novel if with respect to the novel elements of the invention, there is no existing prior art in the form of publication or patent. There are various paid and free

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databases to perform a patent search and assess the novelty of the invention. Different search techniques are used to search for relevant prior arts, where the techniques used are keyword searches, assignee searches, and so on. Since novelty plays a very important role in the entire process of getting a patent, the inventor shall maintain strict confidentiality of the invention, at least until after the patent application is filed and date of filing/priority is obtained. Disclosure of the invention in conferences, articles, or any other kind of public disclosures shall be avoided until after the patent application is filed. It's worth observing here that the inventor's own disclosure before the date of filing for a patent can stop him from getting a patent.

If the invention is novel, the inventor must assess if the invention has an inventive step. Inventive step is a feature of an invention that involves a technical advancement as compared to pre-existing knowledge or having economic significance or both, and which makes the invention not obvious to a person skilled in the art.

The third and last criteria to get a patent is that the invention must have industrial application, i.e., the invention must be capable of being used or made in the relevant industry.

Apart from fulfilling the above three conditions of patentability, the invention must further not fall into the category of "inventions not patentable," described in Section 3 and 4 of the Indian Patents Act 1970. Specifically, with respect to medical inventions, Section 3 prohibits patents on any process for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. For example, a method to treat cancer or perform a surgery is not patentable because it is a method for the treatment of human beings. Similarly, any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is also not patentable. An application of substance to the human body purely for cosmetic purposes is not a treatment or therapy and hence may be patented provided it fulfills the criteria of patentability.

PREPARING TO FILE FOR A PATENT

Documentation of the invention in detail is very important before a patent is to be filed. After the documentation is done, patent search is performed to assess novelty of the invention. Since filing of a patent is a tedious and expensive process, it is important to properly perform a patent search and file proceed with the patent only if the invention is novel. Due to its important, professional help may be sought to perform a patent search.

After a patent search is done and the inventor is sure about filing for a patent, the patent specification is drafted. Patent search is one of the ways to assess the novelty and patentability of the invention right in the beginning to increase the chances of getting a patent. Here, the inventor has the option of either filing a provisional or complete patent application. The first application by the inventor is often filed in his own country and thereafter, the application may be filed in foreign countries if it is so desired. If the invention is not ready and inventor needs few more months to complete it, inventor may choose to file a provisional application. In such a case, the inventor can file a provisional application to claim date of filing (priority date) and obtain a patent application number. If a provisional patent application is filed, the complete application shall be filed within 12 months from the date of filing provisional application.

RIGHT OF THE PATENT HOLDER

It is interesting to note that a patent does not give the inventor any positive rights but rather, negative rights. The patent holder or the patentee can prevent third parties from making, using, selling, offering for sale or importing the patented invention, in the country where he has patent protection. For example, if the patentee has an Indian patent, he can prevent third parties from making, using, selling, offering for sale, or importing the patented invention in India. However, if he do not have a patent in the USA or China, people in these countries can use his invention without his consent.

RIGHT TIME TO FILE FOR A PATENT

After performing the patent search and carrying out initial due diligence, patent application should be filed without any delay. If the product is not ready, provisional application may be filed to secure the priority date and application number, and complete specification may be filed later once the product is ready. In the entire system of patenting, the priority date or the date of first filing is very important as patents are granted on a first-come-first-serve basis.

The invention is also required to be novel on the date of filing. Considering these factors, it is highly recommended to file a patent application at the earliest, taking help from a registered patent agent. The Indian Patent Office (IPO)[1] has a list of registered patent agents who authorized to draft and file patent applications on behalf of inventors in India as well as PCT. The list of registered patent agents may be obtained from the official website of the IPO. A patent agent is a person who is at least a graduate in science and has cleared the Indian Patent Agent examination following which, his name is registered in the register of patents as a registered patent agent. Since technology is evolving day by day, it is becoming increasingly more important to select a patent

agent who is capable enough to handle invention from a particular scientific domain.

When patenting a product, it must be checked if a design patent is also attainable for the invention. The design of an invention, also called as Industrial design refers to the aesthetic look and feel of the invention and requires formal registration of the same. Brand name of the product or trademark is a valuable intangible asset and often includes the name, logo, and tagline of the brand name. In order to ensure that the trademark does not imitate any existing marks, a trademark search should be performed before registering the trademark. Further, the trademark should not be suggestive or descriptive in nature with regards to the product it is being used for, and hence arbitrary trademarks are generally easy to register.

STEPS TO REGISTER A PATENT

As soon as a patent application is filed in India, the receipt of the filed application containing the priority date and application number is obtained. Almost all timelines are calculated from this date of first filing, also called the priority date. Publication of the application on the official website of the IPO takes place after passage of 18 months of time, starting from the priority date. However, there are provisions to expedite the publication of the application if it is required for the application to be published sooner [Figure 2].

After publication, the application is taken up for examination where the Examiner examines it and issues first statement of objections, to which the inventor must reply within 6 months from the date of issuance. After the Controller is satisfied with the application, the patent is granted. To keep the patent enforced, the inventor must pay a renewal fee periodically. If required, foreign filing is initiated within expiry of 12 months from the priority date.

FILING FOR A PATENT IN FOREIGN COUNTRY (ies)

As patent rights are territorial in nature, patent applications should be filed in every country that the inventor desires to have their invention patented. However, the first patent application must be filed in the inventors' home country to obtain the priority date. There are two ways to file a patent application in foreign countries, and are as given below:

Convention application route

This route is preferred when a patent application is be filed in only two or three foreign countries.[2] The patent application may be filed in countries that are part of the Paris Convention, and the patent application so filed is called a convention application. For example, a resident of India wants to file their application in the United States and Japan. Both of these countries are part of the Paris Convention, so the inventor may opt to go for the convention route to proceed with the foreign patent applications. The resident of India must first file their invention in India to obtain a priority date, where the application filed in India is called a Basic Application. The convention application must be filed in the countries of Japan and the United States within 12 months from the priority date. The application filed in these countries is called Convention Application and in this way, it becomes possible for the inventor to seek patent protection in convention countries. As of now, around 168 countries are members of the Paris Convention, covering all important jurisdictions. It must be noted that the Indian patent agent who filed the patent application in India is not authorized to file and prosecute patent application in foreign countries and it is up to the inventor to engage with local patent agents or attorneys in foreign countries to file their application in the respective countries.

Patent cooperation treaty (PCT) route

PCT[3] route is helpful when an inventor wants to file their application in multiple countries. PCT route is a cost-effective way to file their application in multiple countries and gives additional time to the inventor to decide about the countries where they want to file their application. Similar to convention filing, the PCT route requires the inventor to file their application first in his country and obtain a priority date. Within 12 months from the priority date, a single PCT application must be filed. PCT application can conveniently be filed online by the India patent agent. After the application is filed, it is examined by International Search Authority (ISA) and a comprehensive report on patentability is generated, which assesses novelty, non-obviousness, and industrial applicability of the invention. The comprehensive report is a good document for reference as it helps inventor to understand how strong his invention is. Within 30 or 31 months from the priority date, the inventor can file his application in any member states of PCT, and this application is called PCT-National phase application. It is to be noted that PCT is only patent filing platform and it does not grant patent. PCT only enables filing of patent application in its member states and helps inventor assess patentability of their invention. Additionally, PCT provides a time of 18 months from priority date to enter PCT national phase, as opposed to 12 months of time that the convention route provides.

PRODUCT LAUNCH AND INFRINGEMENT RISK

Having a granted patent does not necessarily guarantee that the invention is safe to be launched in the market by the

inventors. In order to launch the product, it is important to assess if any feature of the product is infringing patent rights of others or not. If performed in the beginning, appropriate due diligence can save the inventor from lot of disputes later on. It is generally called clearance search or Freedom-to-operate search, wherein patents disclosing features about each novel element of the invention are analyzed, and assessed to give opinion on patent infringement risk.

REGULATORY APPROVALS NEEDED TO BRING PRODUCT IN THE MARKET

The purpose of filing for patent is to extend legal protection and prevent third party (ies) from making, using, selling, offering for sale, and importing the patented invention. However, in the case of pharmaceutical or medical products, it is required to seek permission from the authorities to ensure that the product is safe to be used and to verify the product has undergone required tests to prove the same. Medical products need to comply with India's medical device regulations before they can be sold in India. The Central Drug Standards Control Organization (CDSCO) is India's main national regulatory body for pharmaceuticals and medical devices. Within CDSCO, The Drug Controller General of India (DCGI)[4] is the key official responsible for the approval of the manufacturing of certain drugs, vaccines, blood products, specific medical devices, new drugs, etc. The CDSCO is responsible for regulating clinical trials of drugs and the manufacture, approval, and sale of medical devices and drugs in India. It is also responsible for providing expert advice on health issues and the enforcement of the Drugs and Cosmetics Act.

The manufacturing, import, sale, and distribution of medical devices are regulated under India's Drugs and Cosmetic Act and Rules.[5] On a whole, only 40-50 medical devices require formal registration in India. However, for all other medical devices that do not require registration, the manufacturer of the medical devices is required to obtain a No Objection Certificate (NOC) from the DCGI. NOC issued by the DCGI states clearly that the said product does not require registration in India and can be imported freely into India.

At the time of filing application for registration, the right class for the product needs to be identified and specified as below:

- Class A – Low Risk (example: thermometers, tongue depressors)
- Class B – Low-moderate Risk (example: hypodermic needles, suction equipment)
- Class C – Moderate-high risk (example: lung ventilator, bone fixation)
- Class D – High Risk (example: heart valves, implantable devices).

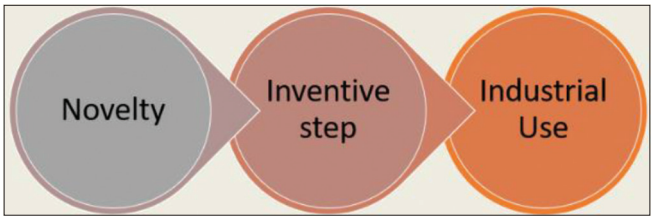

Figure 1: Criteria of patentability.

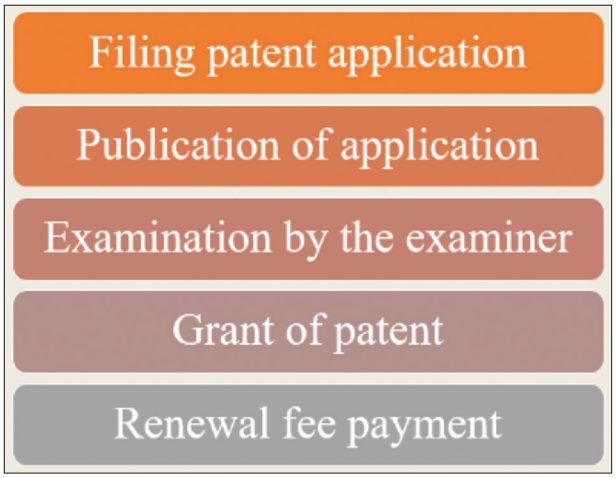

Figure 2: Main steps to register a patent.

CONCLUSION

Bringing a medical product in the market is far more complicated compared to any other product due to its sensitivity and direct implication to human life. On one hand, legal protection in the form of patent may be needed and on the other hand, the approval to manufacture and sell product should be obtained.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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