The Patent Process

Introduction

Patents are a form of Intellectual Property (IP) as are trademarks, copyrights, and trade secrets are all considered IP. The purpose of a patent is to turn an idea into property that has rights. Specifically, in exchange for a full disclosure of how to make and use the claimed invention, you obtain the right to exclude others from making, using, or selling the claimed invention for a defined period of time.

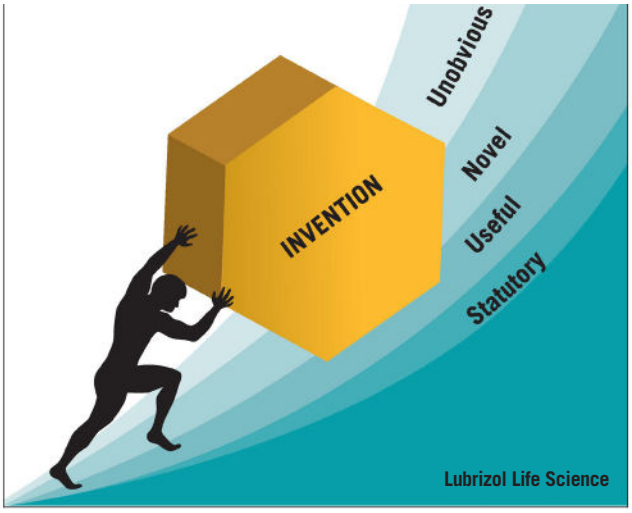
Patents are provided in nearly every country, but patent law is not globally harmonized and is very nuanced. The purpose of this technical brief is to provide an overview of the patent process. We will take a US-centric view, focus on pharmaceuticals, and consider only some of the more common approaches. However, even within this narrow area, the subject is not an exhausted as variations exist.

Many consider the patent system a cornerstone of capitalism and even democracy. Mark Twain noted that "... for I knew that a country without a patent office and good patent laws was just a crab, and couldn't travel any way but sideways or backwards." Systems for protection of IP have been around since at least the 1400s. In the US, Thomas Jefferson created the Patent Act in 1790 which established the Board of Arts that eventually became the United States Patent and Trademark Office (USPTO). He even personally reviewed each application for the first three years of the office's existence.

There are three broad types of patents: utility, design, and plant. A utility patent covers inventions that are methods, apparatuses, compositions of matter, and improvements thereon. A design patent covers a unique shape that is not necessary to the function of the physical article. A plant patent covers asexually reproducible plants. Virtually all patents we will concern ourselves with here are utility patents. These would include, for example, chemical structures, drug delivery systems, formulations, genes, biologics, and medical devices.

Figure 1

PATENTABILITY CRITERIA



To obtain a utility patent, four requirements must be met (Figure 1). Of these, the most difficult hurtle is obviousness. For an invention to be unobvious in the USPTO's view, the idea has to be unobvious to "one skilled in the art". Exactly what is unobvious to this hypothetical skilled person has been the subject of countless debates, numerous court decisions and failed attempts at legislative standardization. It is in the construction of the unobviousness argument that the inventor most needs skilled help, usually a patent attorney.

The actual mechanics of applying for and prosecuting a patent are well laid out. Having said that, there are various routes that can be taken, and the process can be quite confusing to the uninitiated. Integrated into the various paths are associated costs. Paramount among the questions an inventor needs to ask are what costs he/she can support and in what geographies will patent protection be important. The answers to these questions often lie in how the inventor hopes to monetize the invention. A meaningful discussion of this is beyond the scope of this brief but note that, prior to spending the time and money on a patent, the inventor should have a plan to commercialize the invention and some idea as to the value of that invention.

Inherent in the above discussion of the patent rationale is what the inventor is trying to achieve with the patent. Reasons for patenting an invention can range from the desire to prevent others from practicing the invention (blocking) to ensuring that the inventor has the right to practice the invention (freedom to operate or FTO) to establishing a public record of the invention so that others can't "block" the inventor from practicing. Increasingly, companies are primarily concerned with FTO and then, as a secondary matter, blocking. Of course, obtaining blocking IP is always most desirable but many areas of commercial interest are so crowded from an IP perspective that insuring FTO is the first step. If blocking IP is possible, it is often only for a relatively narrow field covering perhaps a specific formulation or compound. The latter approach of using a patent, or simply a published patent application, to establish a public record is used by, for example, not-for-profit groups interested in making sure a given technology is truly in the public domain.

With answers to the above questions, the inventor can determine the proper patent strategy and map that against the available resources. Usually, the first step is to search existing patents and literature, referred to as prior art, for previous descriptions of the supposed invention or things closely related. Once a thorough understanding on the prior art exists, the patent can be drafted to distinguish the invention from those things previously described. Patent and other literature resources are so deep at this point that it is rare that no relevant art is found with a good search. It is important to realize that just because some relevant prior art is found, obtaining patent protection can still be possible. The skill lies in the ability to craft the patent in light of existing data in such a way that meets the inventor's commercial needs. Or, if not possible, to determine that as early as possible so that a minimum amount of resources is expended. Last, as prior art is inventoried, one should always keep in mind the possibility of in-licensing prior art as a way of obtaining the desired IP position.

The following summarizes several of the most common approaches for US inventors / companies to seek patent protection. To understand the global patent system and the US system in the global context, a few organizations and treaties must be explained.

The Paris Convention signed in 1883 was one of the first IP treaties and now has over 170 signatory countries of which the US is one. The fundamental benefit of this treaty is that the filing date of a patent application filed in any one of the convention countries can serve as the priority date for patent applications filed within one year in any other member country. There are other treaties with similar reciprocal priority rights. The US, for example, has one with Taiwan.

Members of the European Union (EU) are included in the European Patent Convention (EPC). The EPC allows you to file a single patent in the The European Patent Office (EPO) and name the EU countries you want coverage in. Also, the EPC is considered as a single country under the Paris Convention for purposes of examination. Ultimately, for enforcement in a given country however, each individual country must have a patent. There are the African Intellectual Property Organization (OAPI) and African Regional Industrial Property Organization (ARIPO) as well.

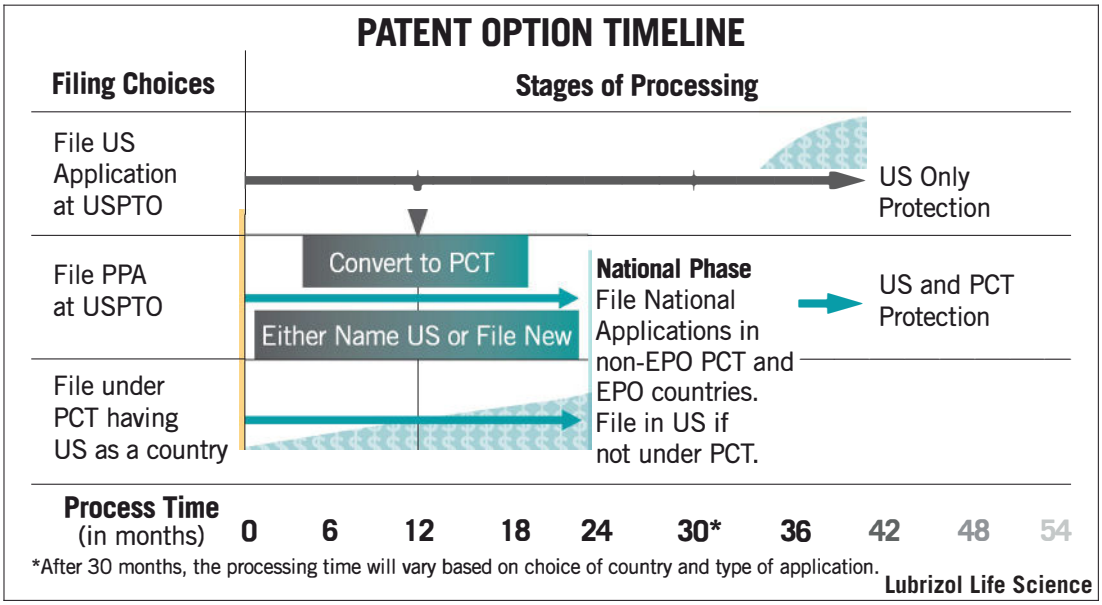
The Patent Cooperation Treaty (PCT) is perhaps the most important treaty when it comes to common pathways US entities use to gain international utility patent protection. The PCT is a searching authority administered by the World Intellectual Property Organization (WIPO). WIPO is an agency of the United Nations and has as its mandate to promote the protection of intellectual property around the world. The PCT, entered into in 1978, allows US residents to file in the US and then, within one year, file a single application searched for patentability by the PCT which reserves the right to file an application in all PCT countries. These include those covered by the EPO as well as most other industrialized countries like Canada, Australia, China, Brazil, India and many others. Note the PCT process does not cover plant or design patents.

If one is only interested in obtaining US protection, there are two common choices for filing. The first is to simply file an application with the USPTO. This is most often done with the aid of a patent attorney although many inventors do this alone. The construction of a patent and its claims is an acquired skill. The quality of the work often only comes to light if the patent is of value and is challenged or attempts are made to circumvent it. Once the patent application is filed one receives a series of office actions (OA's) which are formal reports from the USPTO indicating what is and isn't allowable and the reasons for each indication. The inventor or their attorney replies to each OA and argues the case seeking granting of the patent. At the time of this writing, the average time from submission to the first office action and final decision is roughly 18 months and 3 years, respectively.

The second route to US-only protection is to first file a provisional patent application (PPA). A PPA is a document filed with the USPTO establishing a filing date for priority purposes. Within one year of filing a PPA, the inventor either converts it to a regular utility application or abandons it. At that point it is treated just like a regular utility application. However, the priority date is the date of the PPA filing. A PPA does not have to be in the same form or as complete as a patent application. It is generally cheaper and easier to prepare. However, it would be a mistake to assume a PPA does not have to be a well thought out and constructed document for it lays the foundation of the utility application.

If international patent protection is desirable, there are several common paths to achieve this (Figure 2). First though, one must carefully consider if protection abroad is worth the considerable effort and cost required.

Figure 2



As outlined in Figure 2, for a US entity to gain non-US patent protection, one can start with a USP TO patent application, PPA or go straight to a PCT application. Most commonly, one first files at the USPTO. Then, within 12 months the inventor files under the PCT or in individual national countries. At 30 months post USPTO filing in the PCT process, the patent enters the "national phase" where the inventor needs to select the PCT countries in which to pursue the application. The EPO will generally be selected as a "country" in this scenario covering all EU countries. Non-EU countries are named separately. There is an EPO filing fee as well as filing fees for each other selected country. This stage can be quite expensive ranging from $5,000 to several $100,000 depending on strategic decisions and the resulting geographic coverage being sought. Additionally, the ongoing expense at this point increases substantially since one is answering OAs from multiple patent offices.

Increasingly, PPAs are being used as a first step in obtaining international patent protection. Under this scenario a PPA is filed and 12 months later the inventor files a PCT application using the PPA filing date as the priority date. The US can be named in the PCT or a separate US application can be filed at the same time. At 22 months post PPA filing or 3 months after receipt of the International Search Report and Written Opinion on Patentability, one can elect to obtain examination at either the USPTO or EPO PCT Receiving Office. Advantages to starting with a PPA is the lower initial cost and the extra time to better document and develop the invention. However, since most financial clocks start ticking at the PPA filing, there is, ultimately, little savings or postponement of fees.

Not all countries are covered under the PCT. For instance, Taiwan is not. In general, you may file non-covered countries at any time prior to your invention being made public. Note that publication of a patent application is viewed as making the idea public.

Once a patent application is filed, there are limited ways to expand the coverage. Common in the US is a Continuation-in-Part (CIP). A CIP claims priority based on the filing date of the parent application. A CIP is substantially the same as the parent, but some new and related subject matter is added providing basis for expanding the original claims. Other countries do not provide for CIP applications. Thus, if international patent protection is desired for new claims, the expanded claims must be novel and unobvious over the disclosure in the original application.

Conclusion

Patents are a key part of any commercialization process. Obtaining patent protection is complicated and costly. In fact, IP support often becomes a significant portion of the overall budget. Properly integrating an IP strategy into the product development timeline / budget is fundamental to success. This is true whether the goal is to sell the technology, license it or bring it to market. However, each goal might dictate a different patent strategy thus the earlier the options are considered, the better.

For more information, visit lubrizolcdmo.com or call us toll free at +1 610-861-4701

LUBRIZOL
LIFE SCIENCE

9911 Brecksville Road
Cleveland, OH 44141-3201 USA

The information contained herein is believed to be reliable, but no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end-product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the user. Lubrizol Advanced Materials, Inc., shall not be liable for and the customer assumes all risk and liability for any use or handling of any material beyond Lubrizol Advanced Materials, Inc.'s direct control. The SELLER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Nothing contained herein is to be considered as permission, recommendation nor as an inducement to practice any patented invention without permission of the patent owner. Lubrizol Advanced Materials, Inc., is a wholly owned subsidiary of The Lubrizol Corporation.

©2019 The Lubrizol Corporation, all rights reserved. All marks are the property of The Lubrizol Corporation.
The Lubrizol Corporation is a Berkshire Hathaway company.

HEALTH_RX_TB_PATENTPROCESS
NO1620 OCT 2019