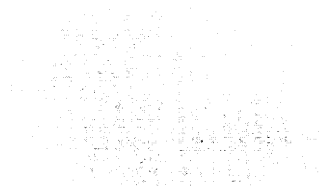


Chapter 5

# The Fundamentals of the Patent System



# The Fundamentals of the Patent System

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## INTRODUCTION

This chapter provides background information on the patent system that will facilitate understanding of the implications of the various proposals for patent-term extension that are discussed in chapter 6.

A patent is the grant by the Government of a right for a limited period of time to exclude others from making, using, *or* selling an invention.

Patents promote the progress of science and the useful arts in several ways:

- they encourage research since they can provide a mechanism for protecting research results from commercial use by others;
- they encourage the development of products since they can provide an exclusive market position or competitive advantage that enables the patent holder to earn a

greater profit and recover his research investment costs;

- they provide a mechanism for the transfer of technology to others who may put the invention to practical use; and
- they enhance the rate at which technology grows by requiring that the invention be promptly disclosed to the public in return for the grant of the patent.

The effectiveness of patents in promoting innovation may vary depending on the other factors influencing the invention and innovation processes. This chapter discusses the patent system in the context of the pharmaceutical industry and examines the role of patents in promoting pharmaceutical innovation. It also provides a brief history of patent law in the United States and examines the practices of those administering and using the patent system.

## THE ROLE OF PATENTS IN PHARMACEUTICAL INNOVATION

As stated earlier, once a drug has been discovered, developed, and marketed by a firm, other firms can produce and sell the drug at a price that is considerably lower than that of the innovator since their price need not include the cost of research and development (R&D) or the cost of creating a market. Thus, if there are no restrictions on market entry, later entrants may have a significant competitive advantage.

In view of these facts, research-intensive pharmaceutical firms consider patent protection as a prerequisite to innovation. From the perspective of these firms, patents are valued most highly because they provide a means for restricting the entry of competitors. But patents are also important to pharmaceutical innovation because they allow for the transfer of technology in a valuable form to those capable of putting the technology to practical use.

Historically, a substantial portion of pharmaceutical innovations have been marketed by firms that did not make the original discoveries but instead obtained licenses (i.e., the rights given by patentees to permit others to practice the inventions) to commercialize the inventions. For example, more than one-third of the new chemical entity drugs are commercialized by firms that hold a license for the new technology but do not hold the patent. ]

The value of a pharmaceutical technology in the business world is significantly influenced by the risk-to-reward ratio and the certainty of the reward. Patents, because of the exclusivity which they provide, may, therefore, be critical factors in corporate decisions to license patents and then complete development of new pharmaceutical technologies.

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<sup>1</sup>Private communication from W. Warden, University of Rochester, July 1, 1981.

## A HISTORY OF U.S. PATENT LAW

From the power vested in it by the U.S. Constitution, Congress has enacted the patent law, which establishes the following general principles:

- an invention, to be patentable, must be useful and must be a process, machine, manufacture, or composition of matter (statutory classes);
- a patent can be granted only for an invention that is novel and not obvious (patentability requirements);
- a patent gives the owner the right to exclude others from making, using, or selling the invention in the United States; however, if the invention is made or used by or for the U. S. Government, the patentee cannot prevent the infringement but can only seek reasonable compensation; and
- a patent term shall run for 17 years.

In the Act of 1790, Congress established a 14-year patent term. The selection of the term was somewhat arbitrary and was said to be equivalent to the length of two apprenticeships. The Patent Act of 1836 permitted the Commissioner of Patents, in certain instances, to extend the 14-year term by 7 years. In the Patent Act of 1861, however, Congress repealed the extension provision and established the 17-year patent term, which stands today. From accounts of the

history of the Act, it appears that the term of 17 years was a compromise between the House bill, which provided for a 14-year term with a possible extension of 7 years, and the Senate amendment, which provided for a 14-year term with no extension.

Since 1861, numerous bills have been introduced to change the patent term: proposed terms have ranged from 5 years to 34 years (17 years with a possible 17-year extension). The first proposal for changing the 17-year patent term was made in 1881 and authorized the Commissioner of Patents to extend patents for which no reasonable compensation had been received; under this proposal, licensing was compulsory and royalties were limited by law. Most of the other proposals for patent extensions provided for a 17-year term which would be extended for 17 years if the patentee, through no fault of his own, had received an insufficient financial return. The determination of the adequacy of the financial return resided, depending on the specific bill, either with the Commissioner of Patents or with the Court of Claims.

Despite these proposals, patent-term extensions had not received serious congressional attention until the patent-term restoration bills S. 255 and HR. 1937 were introduced in the first session of the 97th Congress.

## THE PHARMACEUTICAL PATENT

The cornerstone of the patent system is the patent document. By law, the patent document must provide a teaching of the invention such that others can make and use the invention and contain claims that define the boundary of the invention. To be patentable, the invention defined by these claims can be neither known nor obvious to others.

The portion of the patent application that teaches the invention is commonly termed the specification. The specification serves several functions. First, it describes the invention. Second, it discloses the utility of the invention since

patents are only granted for useful inventions. Third, it describes how to make and use the invention since, in part, the purpose of the patent is to secure a disclosure of the invention from the inventor in exchange for the patent right. Fourth, it discloses the best mode of practicing the invention, insofar as it is known to the patent applicant at the time the application is filed. The specification concludes with one or more claims defining the boundary of the patent rights.

The claims serve much the same purpose as a deed to a piece of land. When a patentee at-

tempts to enforce a patent, the claim is compared with the product or process against which the enforcement action is directed to determine whether an infringement exists.

On the other hand, if other parties can show that the claim encompasses subject matter which was known or was obvious prior to the invention, the claim is invalid in its entirety and no part of the claim can be enforced.

Consequently, patent applications frequently contain a plurality of claims that vary in scope. Some claims may be very broad and encompass many possible products or processes. However, the broader the scope of a claim, the greater the likelihood that the claim will encompass subject matter which was known or obvious prior to the invention. Thus as the scope of a claim increases, so does its chances of being declared invalid. Claims of narrower scope may be adequate to protect the particular aspect of an invention that will be commercialized and may be less vulnerable to attacks on validity.

Claims in pharmaceutical patents may be directed to a product, a method for using the product, or a process for making the product. Product claims may be directed to invented chemicals (chemical claims) or to compositions, i.e., mixtures of chemicals. Claims directed at all of these categories could be made for a single pharmaceutical. To illustrate this fact, an example of each type of claim is provided:

- *A chemical claim.* —A compound having the structural formula  $C_2H_5O - \text{NHC(O)R}$  wherein R is  $-CH_3$  or  $-C_2H_5$ .
- *A composition claim.* —A composition useful for treating headaches when administered orally to a human suffering from a headache in a unit dosage form consisting essentially of 5 to 95 weight percent of phenacetin and 5 to 95 weight percent of aspirin.
- *A process claim.* —A process for making phenacetin comprising reacting a compound of the formula  $C_2H_5O - \text{NH}_2$  with glacial acetic acid at a temperature of 50° to 80°C in the presence of an effective amount of dehydrating catalyst.

- *A method-for-use claim.* —A method for treating headaches comprising orally administering to a human suffering from a headache a therapeutically effective amount of phenacetin.

A headache drug containing 40 weight percent phenacetin and 60 weight percent aspirin is covered by each of these claims. Although these claims might be contained within one patent, it is possible that each of the claims might involve a separate invention and therefore a separate patent. Consider the following hypothetical example:

Inventor A discovered a group of compounds expressed in the chemical claim (when R is  $-CH_3$ , the compound is phenacetin). In A's specification a method was disclosed for making the compounds and a use (as antioxidants to preserve rubber).

Later Inventor B discovered an improved process for making the compound invented by A. B received a patent claiming the improved process (represented by the process claim).

Inventor C subsequently discovered that one of the compounds (phenacetin) invented by A was useful in treating headaches and received a patent claiming the method for use (represented by the method-for-use claim).

After C's invention, Inventor D found that the mixture of phenacetin and aspirin provided a better treatment for headaches than phenacetin or aspirin alone. Inventor D could obtain a method-for-use patent (claim not illustrated) and a composition patent (represented by the composition claim) for his discovery.

Each of the four patents can affect what the other patentees can do with their inventions. Table 16 is provided to assist in illustrating the activities which each of the patentees can undertake. It is assumed that the patents to A, B, C, and D were issued, and will therefore expire, in chronological order. While all four patents are

Table 16.—Activities Permitted Before and After Patent Expiration

Activity	Before expiration of any of the patents	After expiration			
		A's patent	A&B's patents	A,B,&C's patents	A, B, C,&D's patents
Make, use, or sell phenacetin. . . . .	A	anyone	anyone	anyone	anyone
Use B's process to make phenacetin . . .	no one	B	anyone	anyone	anyone
Use phenacetin to treat headaches. . . .	no one	c	c	anyone	anyone
Make, use or sell combination of phenacetin and aspirin to treat headaches. . . . .	no one	no one	no one	D	anyone

SOURCE: Office of Technology Assessment

in effect, only A can make, use, and sell phenacetin; no one including A, B, C, or D can use B's improved process or C's method-for-use, and no one can make, use, or sell D's composition. B, C, and D cannot practice their inventions since the practice would infringe A's patent on phenacetin, i.e., B, C, and D would be making or selling phenacetin.

When A's patent expires, anyone (including B, C, and D) can make, use, and sell phenacetin. Since B's patent is still in effect, only B can use the improved process, but B cannot use C's method for use nor make, use, or sell D's composition. C, however, can use phenacetin to treat headaches, but he cannot use B's improved process, or make, use, or sell, D's composition. No one, including D, can make, use, or sell D's composition since that would infringe C's patent because phenacetin, albeit in combination with aspirin, would still be used to treat headaches.

When the patents to A and B expire, anyone can practice A's and B's inventions. C's method-for-use patent prevents others from using C's invention and C's patent also prevents use of D's invention. When the patents to A, B, and C expire, D can practice his invention, and exclude all others from practicing his invention. Anyone can practice the inventions of A, B, and C,

Not all types of patents have equal value. Infringements on chemical and composition patents generally are easier to detect than infringements on other types of patents. Infringements on chemical and composition patents occur when manufacturers or distributors make or sell the drugs, and can be readily detected, because neither sales nor distribution can be kept secret. Infringements on process patents take place in

relative privacy and may be impossible to discover.

Additionally, a product made abroad using the patented process can be imported into the United States without providing an actionable infringement of the patent. The patentee, however, does have recourse against the infringer through the International Trade Commission but must prove that the importation of the product results in substantial economic harm to a domestic industry and that the process practiced in the foreign country infringes the patent. Proving either of these points can be quite difficult.

The enforcement of method-for-use patents provides unique difficulties. First, the direct infringer is the ultimate user and not the manufacturer. For the manufacturer to be found liable for infringement, the patentee must prove that the manufacturer induced the user to infringe the patent. Second, except in instances in which the drug has no other use, the owner of a method-for-use patent cannot stop the manufacturer from making and selling the drug. For example, if the method-for-use patent were for the discovery that aspirin could be used as a contraceptive, the patentee could not stop existing manufacturers from making and selling aspirin. Because of the vast number of individuals who may use aspirin for its contraceptive activity, and because enforcement of the patent would involve a suit against each user, the enforcement of the patent would not be financially feasible.

Because of their potential for enforcement, chemical and composition patents are generally preferred by the inventor, but method-of-use and process patents could, on occasion, be sufficient to ensure an innovator an exclusive market position.

## SECURING A PATENT

The progress from an invention to an issued patent is characterized by three stages: the preliminary evaluation stage, the patent application drafting stage, and the patent examination stage.

### Preliminary Evaluation

In the preliminary evaluation stage, the inventor attempts to determine the importance of his invention. For example, once an inventor has discovered a new chemical, he must attempt to discover its utility and determine its potential economic value. The length of the preliminary evaluation stage may range from 1 week to 5 or more years, depending on the perceived importance of the invention and the ability of the inventor to develop the invention to a point that he can sufficiently fulfill the requirements for patenting.

### Drafting of the Patent Application

The patent application drafting stage usually takes between 6 months to 2 years, but this stage can vary greatly. During this stage, the breadth of the invention is investigated. For example, is the invention one chemical or a group of related chemicals? The potential patentability of the invention is also considered. Is the invention novel? Is it obvious? The patent application is prepared according to statutory requirements and the legal, regulatory, and procedural requirements of the Patent Office.

If the invention appears to be of economic significance, substantial incentives exist for pursuing the invention diligently and filing a patent application at an early date. The primary incentive is to reduce the potential of losing the patent right to another who has made the same invention. In the United States, if two or more inventors independently discover a patentable invention, a proceeding termed an “interference” is declared to determine which of the inventors was the first to conceive the invention. If, however, the inventor has not diligently pursued the invention, he may be precluded from using his date of conception for determining

who was the first to invent. Moreover, procedural advantages are provided to the inventor who files the first patent application. The advantage of an early filing is even more important if foreign patents are sought since almost all foreign countries award the patent to the inventor who files the first patent application. By treaty with many countries, if certain requirements are met, the U.S. filing date serves as the critical filing date for this determination in those countries.

A second incentive for speedy filing of a patent application is to enable the technology to be disclosed to others without the loss of proprietary rights to the invention. In most foreign countries, if the invention is disclosed prior to the filing of a patent application, a patent is barred. In the United States, a 1-year grace period exists in which a patent application can be filed after the invention has been disclosed to the public. This secondary incentive is usually most important in the university environment where pressure is placed on the researcher to publish.

### Examination of the Application

Once the third stage is reached, the rate at which the application proceeds is no longer solely dependent on the inventor and his patent attorney but also on the Patent Office.

The patent examination stage is initiated with the filing of a patent application in the Patent Office. The patent application, containing the specifications and claims that the applicant seeks to have patented, is examined by a patent examiner who must determine whether each of the claims defines an invention that is novel and not obvious, and whether the patent application has met other statutory requirements and the regulatory and procedural requirements of the Patent Office. In his examination, the examiner conducts a search of relevant publications and patents. He reports the findings of his examination to the patent applicant. The time between the filing of the patent application and the first report, or “action,” from the examiner ranges from 3 to 18 months.

The examiner often finds a publication or patent that brings into question the patentability of one or more claims. Thus, the first action by the examiner may be a rejection of the questionable claims. The applicant is given 3 months (which can be extended by an additional 3 months) to respond to the action. The applicant may modify the claims to overcome the rejection or may show that the rejection was unsound and should be withdrawn.

Approximately 2 months after the applicant responds, the examiner must act on the application and either allow the patent application or issue what is called a final rejection of the questionable claims. The patent applicant then has 3 months to respond: he may delete or amend claims to overcome the rejection; he may argue that the rejection be withdrawn; or he may appeal directly to the Board of Appeals in the Patent Office. If the applicant responds without filing an appeal the examiner can entirely withdraw the rejection or notify the applicant that the rejection, in its entirety or in modified form, still stands. The applicant must thereafter appeal to the Board of Appeals or abandon the patent application.

Because of the heavy workload on the Board of Appeals, 2 years may pass between the filing of an appeal and a resolution of the appeal. If the applicant is unsuccessful at the Board of Appeals, he may then appeal either to the Court of Customs and Patent Appeals or to the District Court of the District of Columbia, in which case the judicial appeal process applies. Another 12 to 18 months may be consumed.

At any point in the examination period, the patent application may be judged allowable. The Patent Office then requires the payment of a fee by the applicant. After this payment has been made, the patent document is printed and issued. A period of 5 to 12 months may elapse between the allowance of the patent and its issuance.

The period between the filing of a patent application and the patent issuance generally ranges from 18 months to 3 or more years. The average patent-pending period is currently a little more than 2 years. In the mid-1970's, it was

about 18 months, and in the 1950's, it was well over 3 years.

During the patent examination stage, an applicant may file more than one application. For example, after the initial patent application was filed, the applicant may have discovered additional information regarding the invention and may wish to supplement the original application. To do so, he must file a second patent application containing the information in the first application (old matter) and the supplemental information (new matter). This second application is termed a continuation-in-part application and maintains the benefit of the filing date of the first patent application with respect to the old matter and the filing date of the second patent application with respect to the new matter. The identical patent application may also be refiled (a continuation application), perhaps to obtain a reconsideration by the examiner. If a patent application claims more than one invention, the Patent Office can require that applications be filed for each of the inventions (divisional applications). The divisional applications need only be filed before the first application is abandoned or is issued as a patent. There is no statutory limit on the number of times that an application may be refiled as continuing applications.

While sound reasons exist, in most instances, for a patent applicant to file continuing or divisional applications, there is a potential for abuse. So long as no competitor has entered the market, the delays in the issuance of a patent work to the advantage of the patent applicant since the patent expiration is also delayed.

## Interference Proceedings

Interference proceedings are time consuming. Approximately 2.5 percent of all patent applications are involved in interferences, and the figure for important inventions is higher. Interference proceedings can last 20 or more years and most interference proceedings are not completed in less than 4 years. The subject of the interference proceedings might be two or more patent applications or it might be a patent and one or more patent applications.

The time consumed during the interference proceeding will delay the issuance of a patent from an involved patent application and thus delay the expiration of the patent.

## FOREIGN PATENTS

A U.S. patent provides the right to exclude only in the United States and its territories. Patent rights must be sought in each country in which a patent right is desired.

Although many differences exist between foreign patents and U.S. patents, only three aspects will be discussed: the duration of the patent, the types of inventions that can be patented, and the compulsory licensing of patents.

### Duration of the Patent

Virtually all foreign countries have patent terms that begin on the patent application date. The patent term in most industrialized foreign countries is 20 years. The period in which a patentee can exclude others from making, using, or selling his invention is, however, considerably less than 20 years since a portion of the patent term is spent in obtaining the patent. Moreover, in countries in which the grant of a patent can be opposed by the public (opposition procedures), the patent term, may be further eroded. After the patent is granted, however, the patent owner may be able to recover damages for any patent infringement that occurred while the patent application was pending if the infringer knew or could have known of the patent application.

Extensions of patents in foreign countries generally have not been permitted in recent history except to compensate for the patent term lost as a result of war. Some of the British Commonwealth countries do, however, permit extensions (usually up to 5 years) if the patent owner has not been adequately remunerated for his invention. Prior to 1978, Britain had a 16-year patent term that could be extended in cases of inadequate remuneration, but her patent law now conforms with the laws in other European countries: the patent term runs 20 years from

the date of the patent application and no extensions are permitted.

These proceedings have, on occasion, lasted so long that pharmaceutical patents have been issued years after FDA premarket approval was obtained.

### Patentable Inventions

The types of inventions that can be patented in foreign countries are in a state of flux. Many countries do not permit chemical claims, and some that allow chemical claims have specifically excluded such claims for pharmaceuticals. Of the approximately 120 countries that have patent systems, nearly one half do not allow claims to pharmaceuticals. Recently, many of the more industrialized countries have begun to permit chemical claims and to permit claims to pharmaceuticals, but the lesser developed countries are not following suit. In some of the lesser developed countries that do permit pharmaceutical patents, the local courts may not find the patent enforceable because it relates to pharmaceuticals. Method-for-use claims for pharmaceuticals are permitted in less than 20 percent of the foreign countries with patent systems. Some countries (Egypt and India) provide shorter patent terms for pharmaceuticals than for other chemicals.

### Compulsory Licensing

Most foreign countries (including most industrialized nations) have compulsory licensing laws, which allow members of the public to demand that the patent be licensed for a reasonable royalty. The purposes behind compulsory licensing may be twofold: to provide incentives for putting inventions to practical use, and to encourage industrial development in the country. In most foreign countries a compulsory license can be demanded if the patentee is not "working" the patented invention in the country within a certain time after the issuance of the patent. The term "working" varies in definition



from country to country. In some countries, marketing the patented invention in the country is all that is required. In other countries, the product must be manufactured in the country. In still other countries, an attempt to secure a licensee for the patent is sufficient.

Several countries also require compulsory licensing if the patent owner is not meeting national demand for the product, and several countries require licensing if such licensing is in the public interest.