

Chapter 6

INTELLECTUAL PROPERTY PROTECTION

A life sciences company's intellectual property (IP) is generally among its most important assets, and the state of an emerging company's IP is of critical importance to its ability to obtain financing. There are different types of protection your Company can use to protect and defend its IP assets—patents, trade secrets, trademarks, and copyrights—each of which can be used to protect various aspects of a life sciences company's business. While patents are generally the predominant form of IP protection relied upon by life sciences companies, other types of IP protection and exclusivity can also prove extremely valuable.

As a side note, there are other types of exclusivity that are available to products of life sciences companies. For example, the Food and Drug Administration (FDA) confers different types of exclusivity, such as granting an additional period of exclusivity if a drug is tested in children. Such protections and exclusivity periods are a part of a life sciences company's "life cycle management" tools.

This chapter provides a short summary of the protection afforded by each form of IP protection and exclusivity, and describes what each can offer a life sciences company.

Patents

Patents can be granted to inventors who invent a new and useful process, machine, article of manufacture, or composition of matter (all defined by statute as "patentable subject matter") to exclude others from benefiting from an invention or discovery for the term of the patent. The right granted is the right to exclude others from making, using, or selling the claimed invention. Importantly, as discussed more fully later in this section, the issuance of a patent does not grant the patentee the right to make, use, or sell his or her own invention, as others may have dominating patent rights.

The term of a patent runs from 20 years from the date of filing of the first application—the "priority date." In order to be granted a patent, the invention must fall under the criteria of patentable subject matter, and it must be novel (e.g., no one else has invented it before) and nonobvious.

"Patentable subject matter," as defined by 35 U.S.C. § 101, comprises a process (e.g., methods of making or methods of using a composition), machine, or an article of manufacture or composition of matter. The Supreme Court has excluded certain subject matter from its definition of patentable subject matter, including laws of nature, natural or physical phenomena (e.g., a new mineral

discovered in the earth or a new plant found in the wild are not patentable subject matter), and abstract ideas. While the rules seem straightforward, the application is more complex, particularly in the life sciences area. The scope of patentable subject matter has evolved over time as new technologies have arisen. As each new technology develops, the courts must decide whether the subject matter is patentable by a categorization of the technology as (i) fitting the definition in 35 U.S.C. § 101 or as (ii) an area excluded by case law. Sometimes this categorization changes over time.

For an invention to be considered nonobvious, the subject matter cannot be obvious to a person of ordinary skill in the art based on the prior art at the time the invention was made. “Prior art” is a term referring to subject matter that was known, including through documentary and non-documentary references that were available. Further, the patent must include a written description of the invention in full, clear, concise, and exact terms to enable a person skilled in the art to make and use the invention.

Inventions in the biotech and pharmaceutical fields are generally eligible for patent protection in several statutory categories, including (i) articles of manufacture, (ii) compositions of matter, and (iii) processes.

Patenting organisms is an area of ongoing controversy in the life sciences area. Although the courts have declared naturally occurring organisms unpatentable, in the seminal Supreme Court case *Diamond v. Chakrabarty*,¹ the Court found patentable a claim to a genetically engineered bacterium useful in breaking down components of crude oil, rejecting arguments that living organisms could not be patentable. Further, the Court found that the bacteria were patentable as either articles of manufacture or compounds of matter. The Court held that they were not unpatentable products of nature because the bacteria were not naturally occurring, as the natural characteristics of the organisms had been altered.

Courts have also found that a compound existing in nature can be patented if claimed in isolated or purified form. Applying this rule, courts have upheld claims to, *inter alia*, purified Vitamin B-12 and purified prostaglandins. In 2003, the Federal Circuit seemingly affirmed this result in a case involving a patent on a metabolite produced by the ingestion of a prior art pharmaceutical compound.²

Following this line of reasoning, claims to isolated and purified DNA molecules have been eligible for patenting as articles of manufacture or composition of matter. Pursuant to the requirement that an invention include a sufficient written description, courts have required that claims to genes detail the exact nucleotide sequence of the gene, and have disallowed claims that described the gene generally by its properties.

1. 447 U.S. 303 (1980).

2. *Schering Corp. v. Geneva Pharmaceuticals*, 348 F.3d 992 (Fed. Cir. 2003).

An earlier Supreme Court case, *Diamond v. Diehr*,³ addressed the distinction between a patentable process and a law of nature. Citing established case law, the Court noted that transformation of an article to a different state or thing was the touchstone of patentability of a process claim that does not include a machine. The distinction the Court made was between a law of nature, which is not patentable, and application of the law to create a new and useful structure, which may be patentable.

With regard to life sciences companies, there are instances in which unpatentable discoveries can lead to patentable subject matter. For example, the discovery that protein X and protein Y interact in a disease pathway is not in itself patentable subject matter. However, understanding what happens when this interaction is interrupted can lead to useful method claims; for example, “a method of treating disease by adding a compound that interferes with the interaction of protein X and protein Y.” Understanding the different statutory categories allows inventors to plan a robust claiming strategy to exploit research inventions.

Trade Secrets

As an alternative to patent protection, your Company can seek to protect its confidential information as a trade secret under state common law. Unlike a patent, a trade secret need not be novel and nonobvious. Rather, to obtain trade secret protection, a company must show that it has taken reasonable precautions to keep the information confidential and that the information has not been published and is not otherwise publicly known. Trade secret protection may be an attractive option when, for example, the subject matter to be protected is not likely to be found patentable.

In contrast to the limited term of patent protection, a trade secret may be protected as long as it remains secret. However, if the information is developed by a competitor independently, or through reverse engineering, it is no longer protected. Furthermore, it is often difficult to maintain the confidentiality of information over time, and once the confidentiality is gone, the protection is gone. In any suit based on a claim of theft of trade secrets or unfair competition, proving that a competitor obtained the trade secret as a result of a breach of confidentiality rather than from independent development may be challenging.

Considering the intensity and importance of research in the biotech/life sciences area and the potential rewards at stake from the fruits of that research, companies may prefer to patent their inventions rather than choose the riskier option of trade secret protection.

Trademarks

A trademark is a word, phrase, design, color, and so forth used to designate the origin of a product or service. In the life sciences area, a key trademark is the brand or proprietary name of a pharmaceutical composition. For example, Advil® is the trademark of the tablets containing the active ingredient ibuprofen made by Wyeth. Typically, the brand name is simple and, therefore, easier

3. 450 U.S. 175 (1981).

to remember than the name of the chemical composition. To a certain segment, the brand name product represents a certain quality level that gives it a commercial advantage over generic products.

However, because of the third-party payer system, the life sciences area is somewhat unusual regarding the advantage of a known trademark, and trademarks may not offer the same benefit that they do in other industries. Third-party payer programs, such as Medicaid and HMOs, may mandate that once there is generic competition, only generic drugs may be used to fill a prescription, and patients who want the proprietary medicine may have to pay far more than they would for the generic. Thus, there will remain a residual brand business based on patients who are willing to pay the higher costs, but such business will be reduced in those areas where counterbalanced by insurance coverage.

Copyrights

Copyrights protect the written, pictorial, graphic, or musical expression of an idea, but not the underlying idea. A copyright is infringed if the accused work is substantially similar in its expression to the copyrighted work.

One area in which life sciences companies have sought to use copyright protection against competitors is labeling. For example, an effort to protect a generic from copying the copyrighted labeling for an over-the-counter product for smoking cessation failed when an appeals court found that the language of the labeling was mandated by FDA.

Exclusivity Periods

FDA provides approved drugs several types of “exclusivity” periods during which certain or all competing products may not be approved.

To obtain FDA approval for a drug, your Company will submit an application called a new drug application (NDA). Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, a generic drug is permitted to reference and rely upon the safety and efficacy data of the proprietary drug’s NDA as long as the generic is the same drug and is proven to be bioequivalent to the proprietary drug. This generic application is called an abbreviated new drug application (ANDA). The ability to file an ANDA is subject to certain exclusivity periods granted to the approved NDA drug. For example, a “pioneer” drug—one that has never before been approved for any indication—is entitled to a five-year period during which no generic applicant may be approved. No generic may even file an ANDA during the first four of those years. If additional clinical data is submitted for new indications for a previously approved drug, there is a three-year moratorium on generic approvals for that new indication. Exclusivity of this type is termed “marketing exclusivity” or “data exclusivity,” the latter because the exclusivity suit is based on use of the proprietary safety and efficacy data to obtain approval for the generic. The safety and efficacy data from the NDA may not be considered by FDA in approving an ANDA during the exclusivity period. There is no prohibition against the approval of full NDAs for competing products or uses, i.e., where the applicant submits an NDA with its own safety and efficacy data.

Outside of the United States, similar periods of exclusivity vary in length. There has been a move in the United States to extend exclusivity in the United States to as long as 10 years to match the longest time frame available in the European Union.

Another period of exclusivity is granted by FDA to those drugs it determines to be orphan drugs.⁴ An orphan drug is one that is targeted toward a rare disease or condition, defined as one that affects a patient population of 200,000 or less in the United States, or where there is no reasonable expectation that the costs of developing and making the drug available in the United States will be recovered from the sales in the United States. With certain exceptions, when a drug is granted FDA approval as an orphan drug, the same drug for the same disease or condition may not be approved for a seven-year period. With small-molecule drugs, two drugs are considered the same if their active moiety is the same. For macromolecules, there are separate definitions of what is considered the same drug, depending on the type of molecule.⁵ However, with both small molecules and macromolecules, the second drug is not regarded as the same drug if clinical superiority over the previously approved orphan drug is established.

These periods of exclusivity are separate from, and do not preclude, patent protection.

Conclusion

A biotech/life sciences company must protect its IP portfolio using carefully selected and maintained IP protection. Given the remaining uncertainties in the law, companies should continue to monitor developments in IP protection and modify their portfolios accordingly. Biotech and life sciences companies must consider all available forms of protection including patents, trade secrets, trademarks, and copyrights, and any available exclusivity periods.

4. 21 U.S.C. § 360bb.

5. *See* 21 C.F.R. § 316.3.