Chapter 3

Intellectual Property

"The Congress shall have the power. . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

United States (institution Article I, Section 8

"Ingenuity should receive a liberal encouragement."

Thomas Jefferson

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INTRODUCTION

Intellectual property law—which provides a personal property interest in the work of the mind—has its roots in ancient Greece, and developed in the common law of European nations (2). The Framers of the U.S. Constitution assured Congress' broad power to "promote the Progress of Science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" (Article I, Section 8).

Pursuant to its constitutional powers under this clause, Congress subsequently pained statutes providing for the granting of patents and copyrights. Two other areas of law, trademark and trade secret, were enacted to protect commercial use of distinctive marks and secret information. Protection of intellectual property is crucial to all areas of inventive inquiry, including biotechnology. The purpose of this chapter is to explain basic concepts of intellectual property law; specifically, what constitutes a patent, copyright, trademark, and trade secret. Intellectual property protection specifically designed for plant life is discussed in chapter 5.

PATENTS

A patent is a grant issued by the U.S. Government giving the patent owner the right to exclude all others from making, using, or selling the invention within the United States, its territories, and possessions during the term of the patent (35 U.S.C. 154). A patent may be granted to whoever invents or discovers any new, useful, and nonobvious process, machine, manufacture, composition of matter, or any new and useful improvement of these items (35 U.S.C. 101). A patent may also be granted on any distinct and new variety of plant (35 U.S.C. 161) or on any new, original, and ornamental design for an article of manufacture (35 U.S.C. 171).

The first patent act was enacted by Congress in 1790. It embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragemerit." The first patent act provided protection for "any new and useful art, machine, manufacture, or composition of matter. or any new and useful

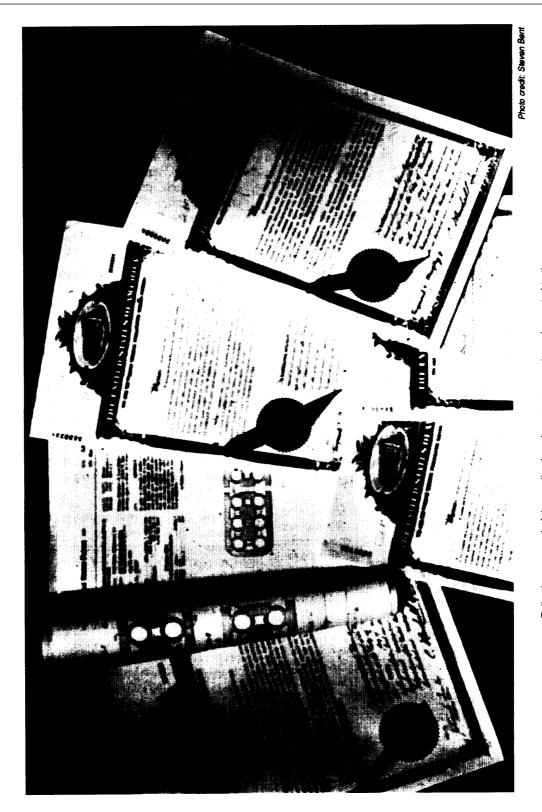
improvement [thereof]." Subsequent patent statutes were enacted in 1793, 1836, 1870, and 1874, which employed the same broad language as the 1790 Act. The Patent Act of 1952 replaced "art" with "process" as patentable subject matter (35 U.S.C. 101). The Committee Reports accompanying the 1952 Act demonstrated that Congress intended patentable subject matter to include "anything under the sun that is made by man." However, the Supreme Court has held that laws of nature, physical phenomena, and abstract ideas are not patentable.

Patents are designed to encourage inventiveness by granting to inventors a limited property right—the right to exclude others from practicing the invention for a period of 17 years. A patent does not grant the inventor any affirmative right to use an invention. Use maybe regulated by Federal, State, or local law. In the United States, patent law is exclusively Federal (35 U.S.C. 1 et seq.; 28 U.S.C. 1338(a)). Of the various forms of intellectual property protection, patents are the most difficult to obtain, since strict examination is required. However, once obtained, a patent is generally easy to maintain, requiring only the periodic payment of maintenance fees during the life of the patent (35 U.S.C. 41(b)).

How does an invention become patented? One Federal judge has spoken of three doors which must be opened in order to obtain patent protection (5). The first door is **subject matter jurisdiction and utility. The** second concerns **novelty.** The third and final "door" to be opened involves the issue of **obviousness.** Once these three "doors" have been opened, a patent (i.e., a grant issued by the U.S. Government giving a property right from the Government to one or more individuals) can result. These three barriers to patentability are covered by 35 U.S.C. 101, 102, and 103 respectively.

Subject Matter and Utility

A patent may issue to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . " (35)



Following approval of the application, the patent, seen here, is granted to the

U.S.C. 101). Known as utility patents, they are divided into three classes by the U.S. Patent and Trademark Office (PTO) for examination purposes: chemical, electrical, and mechanical (see table 3-1). Approximately 1,400 utility patents are granted every week by the U.S. Government (8).

Under section 101, the invention must:

- fall into one of four broad categories-process, machine, manufacture, or composition of matter:
- . be a new invention **or** a new and useful improvement of an existing invention; and
- . be useful.

Congress and the courts have given a wide meaning to subject matter patentability (i.e., what constitutes a process, machine, manufacture, or composition of matter). The expansive terms used in the patent statute have been interpreted to "include anything under the sun made by man" (7). Although the subject matter of things that may be patentable is broad, it is not unlimited. Laws of nature, physical phenomena, and abstract ideas cannot be patented

Table 3-I—Patent Examining Groups

	Group
Chemical examining groups:	
General metallurgical, inorganic, petroleum	
and electrical chemistry, and engineering	
Organic chemistry,	120
Specialized chemical industries and chemical	120
engineering	130
stock material, and compositions	150
Biotechnology	
Electrical examining groups:	
Industrial electronics, physics, and related	
elements	210
Special law administration,	220
Packages, cleaning, textiles, and geometric	000
instruments	
Electronic and optical systems and devices ., , Communications, Measuring, Testing, and	240
Lamp/Discharge Group	250
Design	
Mechanical examining groups:	
Handling and transporting media	310
Material shaping, article manufacturing, and tools	
Mechanical technologies and husbandry personal	
treatment information	
Solar, heat, power, and fluid engineering devices	340
General constructions, petroleum, and mining	250
engineering	350
SOURCE U.S. Patent and Trademark Office, 1989	

SOURCE U.S. Patent and Trademark Office, 1989

(7,11,13,22). The rule that discovery of a law of nature cannot be patented rests not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of discoveries that patent law was designed to protect; mere recognition of existing phenomena or relationships carries with it no rights to exclude others from its enjoyment (22),

In addition to the types of patents permitted under section 101, two other types of subject matter patents are issued under U.S. law:

- Patents for plants (35 U.S.C. 161-164). A patent for a plant may be issued to the inventor of any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state. Plant patents are discussed in further detail in chapter 5.
- Patents for designs (35 U.S.C. 171-173). Such a patent may issue to the inventor of any new, original, and ornamental design for an article of manufacture. Unlike other types of patents (which have a term of 17 years), design patents have a term of 14 years.

Utility or usefulness of an invention is generally an easy hurdle for patent applicants. This cart be shown by experimental data, commercial use, or through the drawings or description of the patent application.

Novelty

Although section 101 requires that art invention must be new, it does not explain what constitutes novelty, To determine the requirement for novelty, one must look to section 102, the second barrier in the path of an invention for which a patent is sought.

In order for an invention or discovery to meet the statutory requirement for **novelty,** it must be new; it should not have previously existed through the work of others (8).

Under section 102, a patent can be denied under several conditions including:

. if the invention was known or used by others in the United States or patented or described in a printed publication in the United States or a

- foreign country before the invention claimed by the application for patent;
- if the invention was patented or described in a printed publication in the United States or a foreign country, or sold or used in the United States more than 1 year prior to the date of the application for a patent in the United States;
- the invention was abandoned; and
- if the invention was made in the United States by another person who has not abandoned, suppressed, or concealed it. In such cases, determining the priority of invention becomes important.

Nonobvious Subject Matter

Even if an invention is found to be new and useful and is statutory subject matter, a patent may still be denied on grounds of **obviousness**, **the** third door that must be opened. Obviousness is the subject of section 103 of the patent code. In addition to novelty and utility, the statute states that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains" (35 U.S.C. 103).

Obviousness addresses the degree of difference between the invention sought to be patented and that which is known or available (the so-called "prior art") to a person skilled in the relevant field of technology. Evidence of prior art (e.g., existing patents, publications) is evaluated not only for what it expressly teaches, but also for what it would fairly suggest to one of ordinary skill in the relevant field of technology (9), Since an invention may be new but still be obvious, a determination as to whether or not the proposed invention is obvious needs to be made. The test for determining obviousness was expressed by the Supreme Court in 1966 (14):

- . determine the scope and content of the prior art;
- . ascertain the differences between the prior art and the claims at issue; and
- . resolve the level of ordinary skill in the pertinent art.

In addition, the Court stated that secondary considerations such as commercial success, long felt

but unsolved needs, and the failure of others maybe relevant to particular situations.

How a Patent Is Obtained

An application for a patent must generally be made by the inventor, must be in writing, contain a specification, a drawing (where necessary), claims, and an oath that the inventor believes himself or herself to be the original and first inventor of that for which patent protection is sought (35 U.S.C. 111-113, 1 15).

The **specification** is the written description of the invention, describing the manner and process of making and using it "in such full, clear, concise, and exact terms" as to enable any person skilled in the art to which it pertains to make and use the same, and setting forth the "best mode contemplated by the inventor" of carrying out the invention (35 U.S.C. 112). The specification includes one or more **claims**, which particularly points out and distinctly claims the subject matter which the applicant regards as the invention. The claims represent the metes and bounds of the property to be protected. As in a title to real property, the claims stake out the patent holder's territory, and any encroachment on that particular territory constitutes infringement (4). For biotechnology -related inventions, particularly microorganisms, it is sometimes impossible for the applicant to fully describe the invention as required by statute. In such cases, the applicant may be required to deposit a specimen of the microorganism to meet the enablement requirement (35 U.S.C. 114). Issues related to deposit are discussed in chapter 9.

The patent application can be made by the individual inventor, by two or more inventors jointly, by legal representatives of deceased or incapacitated inventors, or under certain circumstances by a person to whom the inventor has assigned a proprietary interest in the invention (35 U.S.C. 116-1 18). The actual filing date of the application is important, for that date becomes the **presumed date of the invention**, or the priority date. The presumption is that patent applications and documents published after the priority date do not constitute prior art for purposes of the filed patent application.

Once the application is filed, it is referred to a primary examiner at PTO, who makes the determination as to whether a patent should issue (35 U.S.C. 131) (table 3-1). After the application is filed, there is generally give-and-take written correspondence between the patent examiner resigned to the application and the applicant. Often, the examiner will find several prior art references in addition to those found in the patent application that limit or preclude patentability of the claimed invention. These are provided to the applicant, who may in turn respond with amendments to the claims, information, or arguments to distinguish the claimed invention from the prior art. This procedure whereby the applicant attempts to demonstrate the patentability of the claimed invention is called "prosecuting" a patent application (8).

If, after examination, the examiner determines that any claim of a patent application is unpatentable, the claim is rejected and the applicant is so notified with reasons for the rejection. The applicant has a right to automatic reconsideration of the rejection of the claims, as long as a request is made within 6 months (35 U.S.C. 132-133). An applicant whose claims have been finally rejected may appeal the decision of the primary examiner to the Board of Patent Appeals and Interferences, which consists of the PTO Commissioner, Deputy Commissioner, Assistant Commissioners, and the examiners-inchief of the various examining sections. Each appeal is heard by at least three members of the Board of Patent Appeals and Interferences, as designated by the Commissioner (35 U.S.C. 7, 134).

An applicant dissatisfied with the decision in an appeal to the Board may either file an appeal with the U.S. Court of Appeals for the Federal Circuit or file a civil action against the Commissioner in the U.S. District Court for the District of Columbia (35 U.S.C. 141, 145). Appeals of interference actions (establishing the priority of an invention) operate in a similar manner (35 U.S.C. 141, 146). For the applicant who chooses to appeal to the District Court, a trial de novo (i.e., a new hearing) is conducted (15). One advantage of a trial de novo is that the applicant may be able to introduce additional evidence into the prosecution record (3).

The Patent Term

Once obtained, a patent has a term of 17 years, assuming that maintenance fees are paid (35 U.S.C. 154) (see figure 3-1). Maintenance fees are not required for design and plant patents. Exceptions to this general term of 17 years are design patents, which have a term of 14 years, or certain utility patents where the term has been extended for up to an additional 5 years (35 U.S.C. 156). Where a patent claims a product (limited to a human drug product, medical device, a food or color additive) that has undergone regulatory review prior to approval for commercial marketing or use by the Food and Drug Administration, the patent may be eligible for an extension of the patent term for up to 5 years if certain conditions are satisfied,

Protection of Patent Rights

Patents have the attributes of personal property (35 U.S.C. 261). Property is generally viewed as a bundle of legally protected interests, including the right to possess and to use, to transfer by sale and gift, and to exclude others from possession. Property can be tangible (e.g., animals, furniture, merchandise) or intangible (e.g., copyrights, stocks, annuities). Patents are intangible personal property; a violation of that personal property right constitutes **infringement**, which is defined in the patent statute as the making, using. or selling of any patented invention without authority of the patent owner (35 U.S.C. 271).

The remedy for patent infringement is by civil action (35 U.S.C. 281). Monetary damages may be recovered, and an injunction may also be granted in order to prevent the violation of any patent right (35 U.S.C. 282). In awarding damages for infringement, a court must award at least the amount of a reasonable royalty; a court may, at its discretion, award increased damages up to three times the level found or assessed. In exceptional cases, attorney's fees can be awarded by the court (35 U.S.C. 285).

A patent that has been issued can be **reexamined.** This can occur at the request of any person citing prior art and paying the requisite reexamination fee or by the initiative of the Commissioner (35 U.S.C. 302, 303). Once initiated, patent reexamination follows the procedural steps of an initial patent examination. All reexaminations, however, must be

LIST OF PATENTEES OF DECEMBER, 1988 PATENTS WERE ISSUED ON TH PLANT PATENTS GRANTED DECEMBER 27, 1988 299,087
KNOCKDOWN ROCKING CHAIR
nce, 3538 Lomas Serenas Dr., Escor

Figure 3-1—All Patents and a List of Patentees Are Published Each Week by PTO

conducted by PTO with "special dispatch" (35 U.S.C. 305).

Patent Rights in Inventions Made With Federal Assistance

Beginning in 1981, a uniform patent policy went into effect regarding ownership of inventions made using Federal funds by small businesses and nonprofit organizations. The purpose is "to promote the utilization of inventions arising from federally supported research and development, to encourage the maximum protection of small business firms . . . [and] to promote collaboration between commercial concerns and nonprofit organizations including universities . . . " (35 U.S.C. 200). This law, the Government Patent Policy Act of 1980 (Public Law 96-517) and additional amendments added in 1984 (Public Law 98-620), replaced 26 different agency policies then in effect (24).

Under the law, nonprofit organizations (e.g., universities, nonprofit scientific or educational organizations) or small businesses (i.e., independently owned and operated with fewer than 500 employees) can elect to retain title to any invention resulting from any funding agreement (including grants, contracts, or cooperative agreements) with any Federal agency. In order to retain title, such election must be within a reasonable time, normally 2 years. If the contractor does not elect to retain title within the appropriate time, the Federal agency may take title (35 U.S.C. 202(c)(2)). If the contractor retains title, the Federal agency retains a nonexclusive license to practice the invention worldwide (35 U.S.C. 202(c)). The Federal agency also retains march-in rights (i.e., the ability to intercede) to require the granting of a license if the invention is not practiced within a reasonable time. Such marchin rights are limited (35 U.S.C. 203) and have not been used by a Federal agency nor interpreted by the courts (23). In 1983, a Presidential Memorandum extended the policies of the patent statute to contractors other than nonprofit organizations and small businesses (i.e., large businesses), thus allowing almost all contractors to retain title to inventions created with Federal support (21).

During the 5 years following passage of the 1980 patent law amendments, patent applications by universities and hospitals for inventions involving

human biological increased more than 300 percent as compared with the preceding 5-year period and constituted 22 percent of all patent applications filed by these institutions (25).

COPYRIGHTS

Copyrights, as patents, find their domestic roots in the Constitution, "... securing for limited Times to Authors . . . the exclusive right to their . . . Writings." Historically, the term *'writings" has been interpreted broad] y. The copyright statute(17 U.S.C. 102(a)) defines a writing as that which is "fixed in any tangible medium of expression. now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device." Copyright protection is expressly provided for eight categories of works: literary; musical; dramatic; pantomimes and choreographic; pictorial. graphic, and sculptural; motion pictures and other audiovisual works; sound recordings; and computer programs (see figure 3-2).

A copyright does not protect an idea. but rather the expression of the idea. Copyrights also do not extend to any procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied (17 U.S.C. 102(b)).

Copyright protects the writings of an author against copying, and protects the form of expression rather than the subject matter of the writing. Copyright protection, for example, would extend to a writing that describes a machine. Such protection would prevent others from copying that description; it would not prevent others from writing a description of their own or from making or using the machine itself (26).

One writer on intellectual property law has suggested that DNA molecules are copyrightable as express information, comparing DNA molecules to computer programs; both are sets of instructions (18). The U.S. Copyright Office, however, has unofficially stated that DNA molecules and gene sequences do not constitute copyright subject matter, a position that would likely extend to engineered proteins (6). Even if such information was copyrightable, the protection afforded would arguably be inferior to that provided by a patent, since under

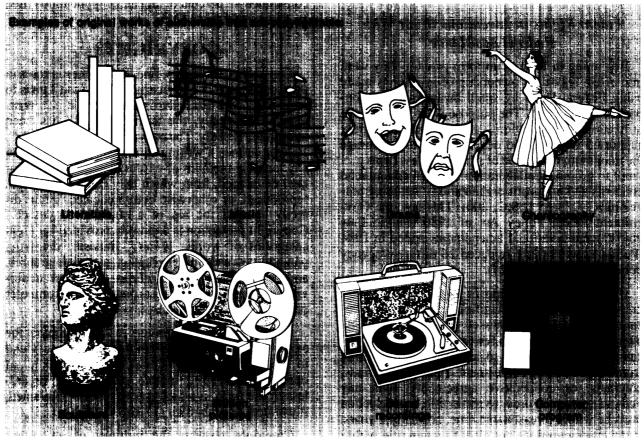


Figure 3-2-The Eight Categories of Copyrightable Subject Matter

SOURCE: Office of Technology Assessment, 1989

copyright law, the author of such information could not prevent others from independently making or sequencing the same information (12).

TRADEMARKS

A trademark is a distinctive mark, motto, device, or emblem that a manufacturer stamps, prints, or otherwise affixes to goods so that they may be identified in the market and their source or origin be vouched for. The law of trademarks is governed by both Federal and State law. Federal trademark law stems from the Trademark Act of 1946 (15 U.S.C. 1115-1127, popularly known as the Lanham Act), as amended in 1988 (Public Law 100-667). Each State has an administrative registration system that is generally parallel to but autonomous from the

system in other States and from the Federal system (10). For those marks which qualify, Federal registration is preferable to State registration because it provides nationwide protection; State registration only affords protection within the State of registration.

Trademarks are designed to protect the public against false and deceptively marked goods and to secure to the owner of the mark the good will of the business (27). For example, "Sanka" designates a brand of decaffeinated coffee. "Bib" the "Michelin Man" is the symbol for a brand of tires. A stylized penguin designates those books published by Penguin Books; and the color pink is a trademark for residential insulation manufactured by Owens-Coming (16,20) (see figure 3-3).

BRITISH AIRWAYS Napco **Tektronix** You're somebody special at <u>GM</u> Toolsmith Series arc RAMADA CONTEL Allstate Computerland RIGGS Bankers To The Most Important Money In The World. Ω OMEGA ATST digital Van Kampen Merritt BEST @ C&P Telephone **BANK EMHART** American Airlines A GREAT NUDGE FORWARD AVIS A MITSUBISHI ELECTRIC FLUKE **CITICORP** Beckman Industrial

Figure 3-3-A Sampling of Trademarks

soulRCE Office of Technology Assessment, 1989.

A Federal trademark may issue to persons who use or intend to use a trademark in commerce (prior to the 1988 amendments, only trademarks already in use could be registered). Trademarks, unlike patents, must be **used** in order to maintain registration. Federal trademark registration has a term of 10 years, which can be renewed if continuous use of the mark is shown.

As applied to biotechnology proprietary rights, trademarks can be useful to indicate the source of commercial products, but such marks do not prevent a subsequent competitor from lawfully developing the same product and marketing it under a new trademark that is not confusingly similar to the trademark of the original manufacturer (6).

TRADE SECRETS

Trade secret protection extends to information used in one's trade or business that is maintained secret by its owner and provides a competitive business advantage over those not having the information. A plan, process, tool, mechanism, chemical compound. customer list, or formula are all examples of information that can be maintained as trade secrets. Affirmative steps must be taken by an employer to keep information secret (e.g., by limiting access or by contract). Once the information becomes publicly known it loses its status as a trade secret.

Trade secrets are the subject of State law. The theft of a trade secret is a tort and action lies against the "thief' for misappropriation. It is not considered a misappropriation if one obtained trade secret information and did not know that such information was a trade secret. However, the trade secret owner may have a cause of action against the disclosing party for wrongful disclosure of the trade secret.

Trade secret law in the United States has been fashioned to promote two beneficial ends. It encourages commercial morality and fair-dealing, and it encourages research and innovation. It does not, however, promote disclosure to the public, which is one of the end results of a patent.

In Kewanee Oil v. Bicron Corp. (19), the Supreme Court found trade secret law to be compatible with patent law, stating that:

Certainly the patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention. In this respect the two systems are not and never would be in conflict.

In support of its decision in *Kewanee*, the Court in 1979 held in *Aaronson v. Quick Point Pencil Co.* (1) that a contract for royalties on a product was enforceable even though the product was unpatentable. The Court was seeking to prevent the suppression from the market of innovative products which do not achieve the level of patentability, and thereby encourage trade secret law where it is not inconsistent with the aims of the patent system. Quick Point Pencil Co. had placed great value on an innovation disclosed to it in confidence and paid for the right to be the first in the marketplace, knowing that a patent might not issue.

Trade secret rights require that a trade secret be disclosed in confidence only to those having a reasonable need to know (e.g., employees). These rights require that measures be taken to prevent disclosure of the trade secret to the public or to competitors. Companies generally identify what information constitutes trade secrets so that it will have enforceable rights. A person entering into a confidential relationship with a trade secret holder, therefore, must know what is considered to be a trade secret. If a trade secret is disclosed in a nonconfidential manner, it is lost forever.

Patent applications are held in confidence and nondisclosure rules apply during the pendency of an application (35 U.S.C. 122). A member of the public must obtain permission from the owner of a patent application to obtain access to the file. Abandoned patent applications are similarly not generally available to the public, except under special circumstances. Confidential patent information can be maintained as a trade secret. However, once a patent issues, the information contained in it is made available to the public, in order to encourage further innovation.

SUMMARY

Various forms of American law protect the intellectual property rights of inventors, authors, and holders of commercially useful trademarks and secrets. Of primary relevance to this report is one area of intellectual property law—patent law—

which is of increasing importance to biotechnology research and development. Subsequent chapters will address the patentability of micro-organisms and cells, plants, and animals.

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