



FENWICK & WEST LLP



Patent Protection

for High Technology and Life Sciences Companies



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Our Offices

Silicon Valley Center	Embarcadero Center West
801 California Street	275 Battery Street
Mountain View, CA 94041	San Francisco, CA 94111
Tel: 650.988.8500	Tel: 415.875.2300
Fax: 650.938.5200	Fax: 415.281.1350

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Understanding Intellectual Property

Intellectual property is the term used to describe the intangible assets associated with a company's technological innovation, "brainpower" and goodwill. If a company's knowledge base, discoveries, ideas, writings, product names and techniques meet certain criteria, the law gives the company a right to prevent others from using those assets. Given the economic importance of these intangible assets, companies must take the appropriate steps to ensure that they qualify for the maximum amount of legal protection available. The first part of this monograph provides an overview of patent, copyright, trade secret and trademark law, the most common techniques used to protect intellectual property.

Patents

The United States Constitution empowers the federal government to enact patent laws and grant patents to promote technological progress. The patent system is at its core an exchange between the government, for the benefit of the public, and the owner of the invention. Patent owners are granted the right to exclude others from practicing their invention for a limited period of time in exchange for disclosing the details of the invention to the public.

The United States Patent and Trademark Office (PTO) is a government agency that receives applications for and grants U.S. patents. There are several different types of patents. Utility patents are the most common, and cover processes, machines, articles of manufacture and compositions of matter. The following discussion focuses on utility patents, but other types of patents include design patents, which cover the ornamental features (*i.e.*, appearance) of an invention, and plant patents.

The PTO also receives "provisional" patent applications, which allow applicants to secure a U.S. filing date without all the formal requirements of utility applications, such as claims or formal drawings. However, the provisional patent application must still describe the invention with the same level of detail that is required for utility patent applications. The provisional application does not receive a substantive examination by the PTO, and a corresponding utility patent application must be filed within one year of the filing date of the provisional patent application to preserve the benefit of the earlier filing date. Utility patent applications are often referred to as "nonprovisional" patent applications.

Not all inventions are determined to be patentable. Three important criteria for patentability are utility, novelty and nonobviousness. An invention generally is assumed to have utility unless there is some reason to believe that it will not work. It has novelty if it differs from previously existing technology, and it is nonobvious if those differences would not be obvious to ordinary practitioners in the relevant technological field. Patentable inventions need not be pioneering breakthroughs. A patent can be obtained on modest improvements in existing technology as long as the improvements are new and useful, and not obvious.

The federal courts have interpreted the patent laws to allow a wide array of subject matter to be patented, including computer software and business methods. The PTO now readily recognizes the availability of patent protection for this subject matter, provided that the invention meets the traditional criteria for patentability introduced above. Patent protection has thus become a more feasible and increasingly popular way for the computer software industry and other industries to protect their intellectual property.

Patents are territorial. Thus, a U.S. patent grants the right to exclude others from making, using, selling, offering to sell or importing the claimed invention in the United States without a license from the patent owner. However, a patent does not necessarily grant the owner the right to practice the invention, because this might require the use of additional technology patented by someone else.

Patents are considered the strongest form of intellectual property. First, the right to exclude may extend beyond the particulars of a product marketed by the patent owner, as coverage extends to what is claimed by the patent. Additionally, independent creation is not a defense to a patent infringement claim. Thus, the patent can be asserted even against a party who had been practicing the invention as a trade secret. Recently enacted patent laws provide a “first inventor defense.” However, this defense is limited to prior commercial users of “business method” inventions and requires reduction to practice more than one year before the filing of the adversary’s patent application to be effective, so its applicability is fairly limited.

Although patents are potentially stronger than other forms of intellectual property, they are time consuming and expensive to obtain, leading many companies to seek patent protection for only those innovations perceived to be highly important to furthering the companies’ strategic goals.

The term for patents filed on or after June 8, 1995, is 20 years from the date that the patent application is filed. (Design patents have a term of 14 years from issuance.) Traditionally, the period of patent protection does not begin until the patent issues, which often takes 3 years or more. Recent patent laws ameliorate the potential loss of term from this delay in two ways. First, the PTO will extend the patent term for certain PTO delays. It is important to diligently prosecute patent applications before the PTO, as applicant delays can negatively offset the extended term.

The PTO publishes patent applications approximately 18 months from their original priority date. The published application can provide provisional enforcement rights for the period between publication and issuance, provided that the published claims are substantially identical to the claims that are ultimately granted in the patent. An applicant can opt out of publication upon filing, but not if the applicant plans to pursue the patent application in another jurisdiction as well.

Patent rights may be transferred to others, and such transfers should be recorded in the PTO. A U.S. patent may provide the basis for additional applications in other countries in accordance with provisions of various international treaties.

If a patent is infringed, a court may order the infringer to cease the infringement and pay damages to the patent owner. The patent owner may also grant a license to allow an infringer to practice the invention, in exchange for value.

The process of obtaining and enforcing patent rights is described in detail in the second section of this monograph.

Copyrights

Federal copyright law protects writings and other forms of expression from unauthorized duplication, modification, distribution, display and performance. For works created by individuals, copyright protection lasts for the life of the author, plus 70 years. For works created by corporations, copyright protection lasts until the earlier of 120 years from creation or 95 years from first publication.

Copyright law protects the way an idea is expressed, but not the idea itself. A work need not be novel to be copyrightable, but it must be “original” in the sense that the expression must include at least a minimal level of creativity and not be copied from another source. Computer programs are protected as literary works. During the 1980s, the computer software industry principally relied upon copyright and trade secrets to protect its intellectual property.

Copyright protection arises automatically when a work is fixed in a tangible medium of expression. Neither copyright registration nor copyright notice is required in the United States to obtain protection for works created since 1989. As a result of numerous treaties, works also receive copyright protection in other countries automatically, without any need for international filings such as are required for patent protection. However, the scope of copyright protection received varies widely from country to country.

In the United States, important benefits result from both registration with the U.S. Copyright Office and placement of notice on the work. For instance, registration permits an author to pursue infringers in federal court. By registering within three months of first release of a work to the public, the copyright holder may also obtain statutory damages and attorney’s fees for infringement. Copyright notice tells the public when a work was first published and thereby prevents reduction of damages on the theory that the infringer was “innocent,” or lacked knowledge of the claim of copyright in the work.

In the United States, while the courts may disagree about the test to determine whether one computer program infringes another, the basic principles of copyright generally apply. Thus,

reproduction of computer code can be copyright infringement, whereas copying of the idea or functional elements of a program is not infringement. An amendment to the Copyright Act created an exception that permits buyers of computer programs not only to make backup copies for archival purposes, but also to make modifications necessary for the program to function on a particular machine.

Copyright protection is easier and cheaper to obtain and lasts longer than patent protection. However, unlike patent protection, copyright provides no defense if a competitor creates a similar work independently, *i.e.*, without copying the original work.

Trademarks

A trademark is any word, name, symbol or device used by a company to distinguish its goods in commerce from the goods of others. Service marks, similarly, distinguish the services of one company from those offered by others. Marks function as source identifiers for consumers. They can also be one of a business's most valuable assets.

Trademarks vary in strength. The strongest marks are coined terms, like KODAK, because they are the most distinctive and, therefore, best able to distinguish source. Arbitrary marks, like APPLE for computers and AMAZON for books, are also strong marks. In contrast, a word that is the generic name for a type of product cannot enjoy trademark legal status for that product, because it cannot distinguish the product as originating from a particular source.

Similarly, a word that is descriptive of a product or service cannot enjoy trademark protection, unless and until it has come to function as a source identifier in consumers' minds, through extensive use. Thus, the less a mark reveals about the nature of its product or service, the stronger the mark will be.

Trademarks may be protected under both state and federal law, only in relation to the goods or services on which they are used. Thus, a business that owns LUCKY for cigarettes would have difficulty stopping another from using LUCKY for database software. Trademarks, unlike copyrights, do not protect the expression embodied in a product and, unlike patents, do not protect any underlying invention.

Trademark rights in the United States are gained through use of a mark in commerce. Those rights can be enhanced greatly through registration. Filing an application to register a mark before it is actually used in commerce also provides strong advantages. The rights established in a trademark will last as long as the mark remains distinctive and is used in commerce. Trademark rights may also be assigned, as long as the goodwill associated with the mark is also transferred.

In most countries other than the United States, trademark rights can be obtained only through registration. As with patents, trademarks should be registered in each country

where protection is desired, although some multi-jurisdictional trademarks exist, such as the European Community Trademark. Obtaining a trademark registration is more expensive and time consuming than copyright registration, but much less expensive and time consuming than prosecuting a patent application.

Trademark law has influenced and been affected by the proliferation of Internet domain names. Domain name disputes can now be resolved both through administrative proceedings, like those brought under the Uniform Dispute Resolution Policy promulgated by the Internet Corporation for Assigned Names and Numbers (ICANN), and in courts throughout the world. Domain disputes are fact intensive, and their outcomes sometimes depend on difficult-to-predict administrative panels, but laws have now evolved enough so that trademark owners have strong and clear means for protecting their rights in domains.

All businesses are wise to protect their trademarks and corresponding domains, as the Internet has become a powerful marketing channel. Each business, however, must consider which domains are most important to its success. With the addition of new generic top-level domains (*e.g.*, .biz, .info, .name) and hundreds of country-code domains, a unified trademark and domain protection strategy is beneficial to all companies.

Trade Secrets

A trade secret is any device or information (such as a formula, database, method of operation or material) that is used in a business and that gives the owner an advantage over competitors who do not know or use it. Trade secret protection requires that reasonable steps must be taken to protect the secret, such as limiting access to the secret and obtaining signed nondisclosure agreements from individuals or entities to which the secret is disclosed. No state or federal filings or registrations are required for trade secret protection. In addition, federal law protects trade secrets by allowing criminal prosecution of individuals and organizations involved in the theft of trade secrets. Further, if the theft of trade secrets involves a foreign government, instrumentality or agent, the act becomes economic espionage and results in potentially stiffer fines and penalties. Trade secrets may last indefinitely, but are lost when the information becomes generally known to the public.

Unlike patents, copyrights and trademarks, trade secrets are protected primarily by state law. Therefore, the scope of protection varies from state to state, even though almost all of the states have adopted the Uniform Trade Secrets Act.

Many technology companies rely on trade secret law as one of the primary means of protecting their intellectual property. However, trade secrecy is the most fragile form of intellectual property protection, and companies that count on trade secrecy must be ever vigilant in guarding against disclosure. Trade secret protection also has significant limitations – it does not cover those who independently discover the secret, or legitimate reverse engineering efforts.

In one sense, trade secret protection runs counter to the policies underlying patent law, where protection is conferred in exchange for a full public disclosure of the invention. However, despite recent changes regarding the publication of patent applications, U.S. patent law continues to allow trade secret protection to be retained under certain conditions during the pendency of the application.

Obtaining Patent Rights

The process of obtaining patent protection for an invention is known as patent “prosecution.” The following section describes a typical U.S. patent prosecution and highlights the most important factors in deciding whether or not to pursue patent protection for an invention.

Domestic Patent Applications

A typical U.S. patent prosecution entails significant cost and typically takes two to four years to pursue from start to finish. As a result, most companies only seek to patent inventions that have a market value that can justify such costs, and that are likely to remain in need of protection for a long time. Companies should establish a review process for all inventions by which technical and business managers, as well as patent counsel, evaluate each invention to determine if it is cost effective to seek patent protection.

As a first step in this process, an in-house or outside patent attorney should review with any potential inventors the basics of patent law and the required contents of invention disclosure forms. An invention disclosure form includes questions regarding the development of an invention that will enable a patent attorney to determine if the invention is novel and not obvious in light of existing technology (often referred to as the “prior art”). Technical personnel should be required to fill out an invention disclosure form for each significant new development.

For an invention to be novel, someone other than the patent applicant cannot have invented it before. The invention is not novel if it already exists in the prior art. An invention also can cease to be novel (and therefore cease to be patentable in the United States) if the inventor fails to file a patent application within a grace period of one year after first publicly using, describing or commercializing the invention. Since even beta releases and confidential product proposals can sometimes be triggering events for the one-year “statutory bar,” many companies lose their U.S. patent rights by failing to file a timely patent application. As discussed below, many other countries do not provide any grace period at all. Therefore, to avoid a loss of valuable patent rights, particularly outside the United States, a patent application should be filed before any public disclosure, use or commercialization of the invention.

Even if the invention is novel, it may not be patentable if it would have been obvious to one of “ordinary skill in the art” at the time of invention. Engineers typically find it difficult to determine whether their inventions are obvious and frequently overlook inventions that are made up of known elements. In fact, a novel combination of known elements or steps may be patentable. Additionally, actual reduction to practice of the invention is not required in order to file a patent application. Thus, a patent application can be filed when the invention is ready for patenting, but before the invention is ready for the market. Inventors should check with a patent attorney to evaluate their potential inventions for novelty and nonobviousness, and should do so throughout the product development process.

If, after the market value, durability, novelty and nonobviousness of the invention have been received, the invention merits pursuit of patent protection, then a patent attorney will prepare a patent application based upon the invention disclosure. The application will include a specification that describes the invention and how it is made and used, and claims that detail the protection sought for the invention.

In exchange for the grant of patent rights, the government requires inventors to provide the public with a complete description of the invention. The patent specification must provide a clear written description of the invention that enables someone skilled in the art to make and use it. The specification must also describe the “best mode” known to the inventor for carrying out the invention. Since courts do not enforce issued patents where the written description, enablement and best mode requirements have not been met, it is important for the inventor and the patent attorney to ensure that the specification is accurate and complete.

The patent claims define the scope of coverage granted by a patent, just as the metes and bounds description in a deed to real property describes the physical boundaries of the land conveyed. Unlike most real property claims, however, the scope and validity of a patent claim is often uncertain. Under U.S. law, the patent claims in a granted patent are presumed valid. However, someone accused of infringement can later prove that a patent claim is not valid. For example, evidence can show that a claimed invention was not novel or was obvious. If another person previously made the invention, or if a prior publication of similar subject matter would have made the invention obvious, the corresponding patent claim may be held invalid. Accordingly, a patent attorney typically drafts a set of several claims, some broader in scope than others. If it later turns out that the inventor was not the first to develop the invention as most broadly claimed, the narrower claims may still be valid.

To illustrate, a patent attorney drafting claims on an electronic mousetrap might include the following two claims:

Claim 1: A mouse-trapping device, comprising a platform and a spring bar pivotally attached to the platform for engaging a mouse, responsive to the mouse stepping on the platform.

Claim 2: A mouse-trapping device as in Claim 1, wherein the platform comprises a capacitive detector circuit coupled to the spring bar, the capacitive detector circuit releasing the spring bar responsive to a change in nominal electrical capacitance representative of a mouse stepping on the platform.

If, after this patent issues, someone else is discovered to have previously invented a mousetrap with a platform and a spring bar, but had not used a platform with a capacitive detector, Claim 1 might be declared invalid, but Claim 2 would remain in force. Claim 2 is called a dependent claim because it refers to Claim 1 and incorporates all of its recited features. As this example illustrates, it is extremely important for the patent attorney and the inventor to discuss various ways to claim the invention by using a combination of independent and dependent claims.

In addition to the specification, most patent applications include a set of drawings illustrating the invention and its use. These drawings may include block diagrams of circuits, flow charts, timing diagrams and molecular structures. An inventor can simplify and reduce the cost of patent prosecution by providing the patent attorney with clear and understandable diagrams at the outset. Production level schematics do not have to be provided. Rather, as described above, the patent application must teach one with skill in the art how to make and use the invention.

After the inventor and the patent attorney have reviewed and revised the specification and drawings to their satisfaction, the patent attorney prepares the patent application for filing in the PTO naming the inventor as the applicant. The patent application typically includes the specification, drawings, inventor's oath or declaration, filing fee and an assignment of rights to the inventor's employer.

Under U.S. law, patents must be applied for in the name of the actual inventor(s). Most companies ask their employees to sign written assignments of inventions at the start of employment. By signing this agreement, the employee/inventor agrees to transfer to the company that employee's rights to any inventions and associated patents. It is highly desirable to also have the employee/inventor separately assign each patent application to the company. For an assignment to have full effect and be valid against other possibly overlapping assignments, the assignment should be recorded in the PTO within three months of its execution. Some states, such as California, limit the extent to which employers can claim rights to employee inventions and require that employees be notified of these limitations.

Without such assignments, both the inventor and the employer may have certain rights to the invention, depending on the circumstances. In some cases, the employer may claim "shop rights," an equivalent to a limited license to the invention. Unless there is an assignment or written agreement to the contrary, joint inventors share an undivided interest

in the patent, and each may exploit the patent without having to account to the co-owner or having to share profits.

Most PTO fees, including the initial filing fee, are on a two-tiered structure, with “small entities” (having not more than 500 employees, among other things) paying half the fees of larger organizations. The filing fee depends upon the number of claims in the application, and is typically between \$1,000 and \$2,000. The attorney fees involved in preparing the application vary widely depending upon complexity of the invention, adequacy of the written invention disclosure initially received from the inventor(s) and other factors, and generally range from about \$5,000 for simple inventions to over \$20,000 for more complex inventions.

The process of preparing a patent application for filing, including back-and-forth communications between the inventor and the patent attorney to properly describe and claim the invention, typically takes six to twelve weeks. The actual time required may vary depending upon inventor availability, number of inventors, company management structure and the complexity of the invention. Given the time necessary to prepare the patent application and the “statutory bars” discussed above, it is critical that an early decision be made regarding whether to apply for a patent. The lack of a decision or a slow decision may result in forfeiting rights to patent protection in the United States or elsewhere.

An early application filing date can help to establish “priority” of invention. Occasionally, two unrelated inventors seek a patent on essentially the same invention. U.S. patent laws award patent protection to the first to conceive and diligently develop an invention, rather than the first to file a patent application. Nevertheless, if a contest arises between two or more rival patent applicants, the first inventor to file is accorded a presumption of seniority. Contests over priority of invention are known as “interferences.” Aside from the patent application, other documentary evidence can be crucial to establishing dates of conception and development. For this reason, many companies require their technical staff to keep technical notebooks, with entries being signed, dated and witnessed on a regular basis. Archives of engineering drawings, computer programs and R&D memos provide further evidence. Filings on the PTO can also be used to archive disclosure documents for the same purpose.

Simplified “provisional” patent applications can be filed in order to obtain an application filing date. Informal documents that do not include claims or formal drawings are often filed as provisional patent applications. The provisional application preserves a filing date that may be relied upon by a subsequently filed utility patent application, provided that the disclosure in the provisional application is adequate and the utility patent application is filed within one year of the filing date of the provisional patent application. Adequacy of disclosure for provisional patent applications is governed by the same statutory standards that are applied to utility patent applications, so applicants must be careful to ensure that their provisional patent applications are technically accurate and complete.

Once the nonprovisional patent application is filed with the PTO, it is assigned to a patent examiner trained in the area to which the invention pertains. Because of the backlog of applications, one or two years may pass before the examiner actually reviews the application.

Typically, after reviewing the application, the examiner sends an “office action” to the patent attorney involved in the application, citing previous patents and other prior art documents relating to the field of the invention, rejecting some or all of the claims and objecting to informalities.

The patent attorney reviews the office action and likely consults with the inventor regarding the examiner’s arguments and the cited prior art. A patent applicant’s response to the office action usually includes claim amendments and arguments to overcome claim rejections. The examiner may agree with the reasoning in the response and “allow” the remaining claims, or may initiate another round of examination, rejection/objection and response from the inventor and the patent attorney. If the applicant and the examiner reach an impasse over an issue, the examiner issues a “final” action, forcing the applicant either to file an appeal in the application to a special board of the PTO or drop the argument. If the applicant decides not to pursue the argument, the applicant can start the process over with slightly different claims using various “continuation” procedures, or can abandon the application.

Traditionally, unlike patent authorities outside the United States, the PTO maintained patent applications in strict secrecy until issuance. However, the United States recently harmonized its laws with the laws of other countries somewhat by enacting an application publication law. The PTO now publishes patent applications approximately 18 months from their original priority date by default, as described above. The applicant can opt out of the new publication requirement by filing an appropriate request at the time the application is filed. However, this option cannot be pursued (and an existing request not to publish must be rescinded) if the applicant pursues any international applications that have such a publication requirement. Publication can be beneficial to the patent applicant, as provisional enforcement rights for the period between the dates of publication and patent grant are potentially available, provided that the published claims are substantially identical to the claims ultimately granted in the patent. Publication also offers other parties the opportunity to submit references to the PTO that are directed at the published application.

Where an application will not be published, and it appears that the PTO will disallow all claims or only allow extremely narrow claims, the applicant may decide to abandon the application in favor of continued trade secret protection.

In most cases, the PTO ultimately allows one or more of the claims in an application. Shortly after allowance of the claims and payment of an “issue fee,” the patent issues.

The result of all this effort is a grant of rights to exclude others from making, using, importing and selling the claimed invention for a set period, for a term that typically begins on the date that the patent issues and ends 20 years from the date on which the application was originally filed. For countless companies, the return is considered well worth the effort.

Once a patent issues, maintenance fees must be paid periodically to maintain the patent in force. Maintenance fees are due six months before the end of the fourth, eighth and twelfth years following the issuance of the patent, in increasing amounts ranging from about one thousand dollars to several thousand dollars.

Once the patent issues, the patentee can mark products incorporating the invention claimed with the word "Patent" or "Pat." and the patent number. A patent notice is typically placed directly on a patented article in a permanent manner. This marking notifies the public that the article is protected by a patent. Patent marking is not mandatory but can help the patentee recover money damages from infringers of the patent. Multiple markings can be made. For example, for software inventions an original program CD and the program's sign-on or splash screen can be marked.

International Patent Applications

With limited exceptions, a U.S. patent grants rights only in the United States. Thus, many companies choose to file patent applications in other countries where there is a significant market for their inventions or where the inventions are likely to be manufactured, especially by known competitors. Patent rights are typically granted on a country-by-country basis, and each country has its own rules for determining patentability, which often differ significantly from comparable rules of the PTO. For example, whereas the United States awards patents on a "first to invent" basis, other countries award patents on a "first inventor to file" basis. Similarly, the United States allows one year after first public disclosure within which to file a U.S. application, but in most other countries the right to patent protection is lost unless a patent application is filed before the first public disclosure or sale of the invention. On the other hand, these countries do not allow mere offers to sell an article containing the invention to trigger the one-year clock, as in the United States.

Most of the world's industrialized countries are parties to an international treaty known as the Paris Convention. The Paris Convention entitles a patent application filed within one year from the original filing of a corresponding application in another member country to carry the filing date of the original application. For instance, if a U.S. patent application is filed on January 1, 2006, the Paris Convention will permit corresponding applications, each having an effective date of January 1, 2006, to be filed in other member countries until January 1, 2007. For a U.S. application filed before any publication or commercialization of the invention, the Paris Convention generally allows one year (six months for design patent applications) from the U.S. filing date to file patent applications in other countries. However, to obtain patent protection in countries that are not members of the Paris Convention, a patent application

must be filed directly in those countries prior to the first public disclosure or sale of the invention, unless there exists a legislative agreement in those countries that honors the one-year grace period. For example, Taiwan is not a member of the Paris Convention but has entered into an agreement with the United States that grants priority rights based upon U.S. filings.

In addition to the Paris Convention, there are other international treaties that harmonize patent protection among countries. For instance, the Patent Cooperation Treaty (PCT) provides a two-stage examination process for applications, first at an international level and then in the individual countries from which patents are sought. Another treaty, the European Patent Convention, established the European Patent Office (EPO) to provide a single examination covering applications in approximately 17 European countries. Thus, a single EPO application can be filed for protection in some or all of those countries. The application is examined by the EPO in any of the three official languages and, if granted, the specification is translated into the languages of the designated countries for issuance as patents of the selected countries.

Typically, companies initially file a U.S. application and take advantage of the one-year period under the Paris Convention to determine whether the invention is important enough to warrant the expense of seeking patent rights in other countries. If so, a patent attorney typically will prepare and file an application under the PCT based on the U.S. application, or may directly file applications in other countries. Most other countries publish patent applications, so filing therein prevents the applicant from opting out of early publication of their U.S. application, as described above. These cost and disclosure factors justify review of the value of each U.S. application before filing corresponding applications in other countries.

Inventions Related to Software and Business Methods

Many years ago, it was believed that patent protection was not available for software. While that may have been true in the early years of the software industry, patent protection is now commonly sought and obtained for a variety of software related inventions. Indeed, the courts have broadly defined patentable subject matter to include a variety of types of inventions including not only those that relate to software, but also to business methods.

In one notable case, *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, the Federal Circuit considered whether a financial data processing system was patentable subject matter. In rejecting the notion that the system was an unpatentable “mathematical algorithm,” the Federal Circuit noted that an invention constitutes patentable subject matter if it includes a practical application evidenced by the transformation of data, or “a useful, concrete and tangible result.” All that is generally necessary is a practical application that produces a useful result. Any transformation, including that of information or just numbers, suffices.

Significantly, regarding what had previously been thought of as a “business method exception,” the Federal Circuit took the opportunity to note that there was no such exception to invalidate a patent. Instead, cases in which the court had invalidated patents involving business methods had been decided on other issues, such as obviousness, the lack of novelty or the attempt to patent an abstract idea. The court clarified that determining whether something is patentable subject matter does not turn on whether the claimed subject matter does “business” instead of something else.

Strictly speaking, there is no special category in the patent law for software patents. The term “software patent” is conveniently used to describe patents related to computer software. However, patents pertaining to the traditional categories of processes, machines and articles of manufacture variously protect software. Particularly, computer programs can be claimed as processes or methods implemented by computers in which they reside. Machines that operate with processors to control the flow of data between various computer components, to retrieve, store or otherwise transform the data according to program instructions, can also be claimed. Patent protection is also available for data structures to the extent that they are claimed in combination with some form of computer-readable memory, so as to configure the memory or improve the operation of the computer. However, data structures as mere logical arrangements of information are likely not patentable. Finally, a computer-readable memory (*e.g.*, a CD or floppy disk) that stores patentable software can be claimed as an article of manufacture. This allows patent holders to sue entities that ship or manufacture infringing software for direct infringement and to prevent offshore companies from importing infringing software.

The disclosure requirements for software patents are also governed by the same principles that are applied to all utility patents. Thus, the patent application must provide sufficient, detailed information to allow others in the field to practice the invention. Notably, an applicant is not generally obligated to disclose source code to satisfy the above-described “enablement” and “best mode” disclosure requirements. Rather, the software patent applicant must describe the invention using a textual description of the invention, and preferably flow charts, tables or other illustrative information about the invention. Where desired, source code can be included with the patent application as an appendix.

Having effectively conceded that software and business methods are among the types of things that can be patented, the PTO now properly focuses its scrutiny on whether these patent applications are well described, clearly claimed and sufficiently distinguished from the prior art, just as has been done in other technology areas for many years. The overall result should be better, more useful patents that contribute to the knowledge base in the software industry and other industries.

Inventions Related to the Life Sciences

The life sciences industry depends upon the patent laws to protect often enormous investments in new discoveries and to justify the value placed on these discoveries in public securities offerings and mergers. For some sectors of the life sciences industry—such as traditional pharmaceutical compounds and medical devices—patents have long been granted subject only to the usual novelty, nonobviousness and disclosure requirements.

Biotechnology inventions have posed more problems. Unquestionably, recombinant compounds and genetically altered organisms are patentable under the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*, wherein the Supreme Court also found that Congress intended statutory subject matter to broadly include "anything under the sun that is made by man." However, as the PTO and courts have evolved patentability standards for biotechnology inventions, some special requirements have come and gone. For example, the PTO previously applied special utility requirements to claims to bioengineered therapeutic compounds, requiring some applicants to demonstrate that their invention was a safe or fully effective drug in humans. Further appellate guidance and new PTO guidelines now provide a uniform analysis so that the same standards of utility and operability apply to all inventions.

Biotechnology inventions nevertheless continue to raise special issues. Stringent description and enablement requirements sometimes limit claims to classes of compounds that are actually derived by the inventors, and preclude claims to all degenerate nucleic acid sequences encoding therapeutic proteins. These limitations require special consideration of alternative claiming strategies to assure adequate protection for biotechnology inventions. Similarly, PTO practices particular to biotechnology, such as the deposit of biological materials, and disclosure of a nucleotide sequence and amino acid sequence in required formats (including computer-readable form), must be considered.

Inventions related to the life sciences increasingly use other patentable technologies, such as software. Medical devices often embed software and information databases as part of a diagnostic system. Bioinformatics heavily relies upon software algorithms to support drug screening and design, manufacturing processes and automated sequence identification. The patentable aspects of such technologies must be considered along with the primary inventive combination and sometimes contain the most important discoveries.

Enforcing Patent Rights

Companies find patent ownership useful in two distinct ways. Patents can be used offensively to prevent a competitor from using patented technology. They can also be used defensively. The mere act of applying for a patent creates a record that can be used to disprove another company's later claim that it was the first to invent a particular technology. Furthermore, companies holding significant patent portfolios often can mitigate liability for

infringement by counterclaiming infringement by the accuser, or by offering part of their portfolios as settlement. Typically, companies in such situations cross-license each other's patents. Thus, patents are helpful in defending a company against the patent claims of others.

Patent infringement results from the unauthorized making, using, importing or selling of patented subject matter, from contributing to another's infringement or from inducing a third party to infringe.

Patent infringement may be found either literally or under the so-called doctrine of equivalents. An accused device or process literally infringes a patent claim if each element of the claim, as literally set forth, is found in the accused device or process.

For example, consider the following simplified claim:

Claim 1: A bicycle, comprising a front wheel, a rear wheel, a frame connecting the front wheel and the rear wheel and a drive train coupled to the rear wheel.

This claim literally covers any bicycle having the four recited elements in the recited configuration. Thus, the patent would cover a bicycle having two wheels, a frame, a drive train coupled to the rear wheel and disc brakes, even if the patent made no mention of disc brakes.

On the other hand, if a bicycle differed from the claim in only one of the recited elements, that bicycle would not be covered by that claim. For instance, the above claim would not "read on" a front-wheel-drive bicycle, which would therefore not infringe the simplified patent claim.

A "doctrine of equivalents" is used in situations where an accused device has elements that are not literally identical to the claimed elements, but that perform substantially the same function in substantially the same manner to achieve substantially the same results as the claimed elements. The critical test is that there be no substantial differences between the accused device or process and each element of the patent claim.

Recent judicial decisions have limited the availability of the doctrine of equivalents. Claims that are amended during their prosecution are often limited to their literal scope. This makes the scope of protection offered by patents more predictable, for both patent holders and others. Amending claims during prosecution is sometimes unavoidable. However, inventors and attorneys preparing their patent applications can lessen the potential for such amendments by thoroughly articulating the differences between the invention and conventional technology, and by providing corresponding sets of independent and dependent claims in the original application.

Because knowledge of a patent is not a prerequisite to infringement, it is common to unknowingly become a patent infringer. To reduce this risk, some companies undertake occasional searches of issued patents before commercializing a new technology. Such searches are often helpful, but the lack of an effective index to patent claims, the time lag for publication of applicants and the secrecy of some pending applications reduces the reliability of any such search, no matter how extensive. To reduce the cost, many companies restrict the scope of their searches to patents owned by specific competitors.

If a company determines that one of its patent claims is infringed by a competitor's product, the company can either negotiate a patent license with the competitor or charge the competitor with patent infringement in civil litigation.

Licensing

Patent licenses are an increasingly valuable business asset, particularly for high technology companies. Companies commonly use their patent portfolios strategically to increase their revenues through aggressive licensing programs, and also use such patents as leverage in negotiating cross-licenses with other companies.

Patent licenses may grant different rights in the same patented technology to many different licensees. The patent law allows most of the basic rights granted to a patentee to be individually licensed. For example, the right to use a process internally may be granted to one company, while the right to sell products manufactured by the same process may be exclusively granted to another. Generally, licenses may be exclusive or nonexclusive and may be for general application or limited to a particular field of use.

There are some legal constraints on patent licenses. For instance, a patent license cannot extend beyond the duration of the patent, because the invention enters the public domain and is free for general use once the patent expires. The right to patented technology cannot be tied to requirements that the licensee also acquire nonpatented technology from the patent owner. Patents can be "misused" by attempting to extend their effects beyond the limits provided for in the patent law, in which case a court may hold the patents unenforceable.

Patent licenses and cross-licenses are sometimes quite complex, with worldwide coverage considerations, indemnifications against patent claims by third parties and the like. Although such complexities can lead to considerable drafting expense, well-considered patent licenses can be of great value to both the licensor and the licensee.

Litigation

Under U.S. law, a patent owner is under no obligation to license a patent to anyone, or even to practice the patent itself. Whether the patent is licensed to anyone or not, the owner may

take legal action against others who make, use, sell, offer to sell or import into the United States the patented subject matter without the owner's authorization.

Patent infringement actions are initially tried in federal district courts, with appeals taken to a special Court of Appeals for the Federal Circuit, or "Federal Circuit" for short. The Federal Circuit has found patents to be valid and infringed more frequently than its predecessor regional courts of appeal had found, and many credit the Federal Circuit with the resurgence of interest in patents since the 1980s. While the U.S. Supreme Court is the court of final appeal on patent matters, it does not choose to hear patent cases very often.

In some circumstances, parties may agree to have patent disputes decided by a panel of arbitrators rather than in a court of law. In other instances, involving importation of infringing products, it may be possible for patent disputes to be resolved in the International Trade Commission (ITC) of the U.S. Department of Commerce. Finally, questions of patent inventorship, validity and enforceability are sometimes determined in the PTO using procedures such as an "interference" or a "reexamination." Traditionally, reexamination procedures primarily limited participation to the patent owner, only allowing nonowners to request a reexamination and make an initial submission. For this reason, nonowners often elected not to pursue reexamination for fear that it would only give the patent owner an opportunity to strengthen their patent. Recently, *inter partes* reexamination procedures have become available that increase nonowner participation. Whether any of these options make sense in any particular situation calls for serious discussion between a company and its legal counsel.

Where infringement is found, the patent owner is entitled both to an injunction preventing future unauthorized use of the patent by the defendant, and to damages. The measure of damages is the profits that the patent owner has lost by virtue of the defendant's infringement, or, if there are no lost profits or they cannot be proven, then at least a reasonable royalty. The amount of a reasonable royalty generally depends upon the rate charged by the patent owner to others (if the patent owner grants licenses) or rates charged under similar circumstances by others in the industry, the importance of the patent to the infringing product, the expected profit of the defendant and other factors.

In some cases, the patent owner may obtain a preliminary injunction that can be requested fairly early in the case and, if granted, prevents the defendant from using the patented technology while the case is pending. In many instances, the granting of a preliminary injunction essentially determines the outcome of the case, because the defendant is out of the market until either the district court or the Federal Circuit removes the injunction, which may take months or years. On the other hand, the patent owner may have to post a bond to compensate the defendant for its lost sales while the preliminary injunction is in effect if it turns out that the preliminary injunction was improper.

In cases where infringement is willful rather than unintentional, a judge may order the infringer to pay up to three times the actual damages caused to the patent owner, as well as the patent owner's legal expenses. Because the stakes are so high, accused infringers must take claims of patent infringement very seriously.

Today, patent infringement suits are invariably followed by counterclaims of invalidity, "inequitable conduct" (fraud) in obtaining the patent, patent misuse and a variety of other defenses. For these reasons, and because of the complexity typically involved in proving or disproving patent infringement, patent litigation is expensive. Companies that have been through patent litigation correctly view it as a last resort to dispute resolution.

The Patent Practice of Fenwick & West LLP

Fenwick & West LLP attorneys provide a full range of patent-related services to the firm's clients. More than 75 of the firm's attorneys practice in the areas of patent prosecution, licensing and litigation, obtaining and enforcing patents for clients' inventions ranging from computer architectures, Internet commerce systems and encryption software to new types of semiconductors and biotechnology processes and products. Many of these attorneys have advanced degrees in electrical engineering, computer science, software engineering, life sciences, physics and other disciplines.

The patent practice of Fenwick & West is fully integrated with the other practice areas of the firm, most notably those involving licensing, litigation, antitrust and general corporate matters. The firm is continuously involved in creatively structuring patent-based business transactions, as well as resolving patent disputes through litigation or alternative dispute resolution (ADR) techniques.

Because Fenwick & West is a full-service law firm, its attorneys have a somewhat broader perspective than attorneys from firms with more limited practices. For instance, the firm might counsel against patent protection for an invention if the obtainable claims would be narrow and existing trade secret protection is strong.

Fenwick & West also performs audits of companies' intellectual property. Such audits may range from a limited review of an existing patent portfolio to a comprehensive investigation of all forms of intellectual property available for the client's technology. Clients who are considering investments in, or acquisitions of, other companies often request Fenwick & West to perform an intellectual property audit of a target company to help assess the true ownership and worth of the target company's intangible assets. Other clients periodically request audits of their own intellectual property, especially where they have not had a well-defined, established policy of seeking such protection.

Conclusion

Patents can provide one of the strongest legal protections available for intellectual innovations. This booklet addresses many of the key business and legal issues that should be considered in determining whether to seek patent protection for an invention. Fenwick & West has many years of experience in working with high technology companies and in helping them protect their intellectual property. We would like to assist you in evaluating what forms of legal protection are most appropriate for your innovations, and in implementing a cost-effective intellectual property protection program.

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