PATENT LAW PRINCIPLES & STRATEGIES

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October 2006

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I. The Nature of Intellectual Property

Intellectual property is the intangible product of the mind's work. The United States and other developed nations generally recognize four different routes for protecting intellectual property: copyright, trademark, trade secret and patent. These routes are non-exclusive, and under appropriate circumstances, one may obtain multiple forms of protection for the same "parcel" of intellectual property. Intellectual property has the attributes of personal property. Thus, it may be purchased, assigned, licensed, pledged or transferred in the same manner as other forms of personal property.

A. Overview of Patent Protection

Patents provide a means for protecting the physical embodiments of certain classes of new and useful inventions. Patents are the broadest form of intellectual property protection, encompassing not only the precise machine or process invented, but also variant machines or processes that may employ the underlying concept of the invention.

The United States' patent system provides two kinds of patents: utility patents and design patents. Utility patents are employed to protect functional attributes of an invention. In contrast, design patents serve to protect ornamental aspects of an invention. Design patents are of great importance in inventions relating to consumer products. The criteria for obtaining design and utility patents are the same, as are the available remedies for their infringement.

Like a deed to real property, most governments require a patent to specify the metes and bounds of the property claimed to constitute the invention. This legal description of the invention is found in the patent's claims. Unlike real property whose borders can be measured with precision, the precise boundaries of an invention cannot be precisely determined. Thus, a patent often presents a set of claims of varied scope which extend inward from a broad description of the invention to a narrow description of the patent's core invention. A patent endows its owner with a limited term of years in which the patent owner may exclude others from making, selling, using or importing the invention claimed in the patent. As a general guide, the term of a utility patent expires in most countries (including the United States) on the 20th anniversary of the filing date of the patent (or 17 years from the patent's issue date, if filed before June 8, 1995). The precise duration of a utility patent's term is dependent upon several factors, and may be significantly greater or less than the "20-year" general guide. The term of a design patent is 14 years from the issuance of the patent.

Patents are granted by governmental authorities, such as the United States Patent & Trademark Office. They are territorial in nature, enforceable only in the country that granted them. In the United States and most other nations, the scope and content of the claims is determined through an examination process conducted by a technically trained Patent Examiner. Like a contract, the wording of the claims of the patent are determined through a negotiation process involving the applicant, the Patent Examiner and, typically, patent counsel. Significantly, a patent is granted in reliance upon the representations of the applicant, and can be rendered unenforceable if those representations are later proven to have been false or fraudulently made.

It is important to recognize that a patent provides only a right to exclude others from practicing an invention (i.e., manufacture, use, sale or importation). It does not confer an affirmative right on the patent holder to actually make, use, sell, or import the invention claimed in the patent. The patentee's ability to practice the patented invention may be restricted by the patents of others.

B. Comparison to Other Forms of Protection

1. Copyrights

Copyrights are employed to protect the fixed, tangible expressions of an original artistic idea. They provide the copyright owner with the right to reproduce, publicly display, distribute and perform the work, to prepare derivative works (e.g., a play based upon a copyrighted book).

Copyrights are available for an array of creative expressions including paintings, photographs, songs, instrumental music, writings, furniture, jewelry, slogans, computer software, architectural drawings, sculptures, and dance. In order to obtain a copyright, the expression of the idea must be original (i.e., the work of the applicant) and creative. The expression must be in a fixed and tangible form. Thus, there would be no copyright in an unrecorded performance.

Significantly, the law notes a distinction between the copyrighted material and the physical manifestation of that material. Ownership of a painting (the physical manifestation of a creative idea) does not necessarily convey ownership in the copyright on the painting. Thus, the owner of the painting may not be free to make copies of the painting. Conversely, the owner of a copyright on a building mural may not be able to block the sale or demolition of the building.

There are numerous differences between copyright protection and patent protection. An important tenet of copyright law is that copyrights protect only the expression of an idea and not the idea itself. Thus, a copyright on a painting of a bowl of fruit protects against the copying or public displaying of that painting. It would not, however, provide protection for the idea of painting still-lives, or limit the ability of others to produce similar paintings. Indeed, providing that one did not copy the painting, one would be free to paint an exact duplicate of the copyrighted work. Hence, unlike patents which may be enforced against subsequent independent inventors of a patented invention, a copyright does not protect against independent expressions that may be similar (or even identical) to a copyrighted work.

Copyright protection also differs from patent protection in that functional, non-artistic aspects of an idea are not protectible. A patent on a device prevents others from making the device; a copyright on a device only prevents others from copying the non-functional aspects of that device. Copyright protection lasts considerably longer than patent protection. For example, in the United States, copyrights for most works copyrighted since 1978 last for the life of the creator plus 70 years; and when two or more creators copyright the same work, the copyright extends for the life of the last surviving creator plus 70 years. However, copyright protection may not last as long for anonymous or pseudonymous works or works made for hire. The copyrights on such works extend 95 years from publication or 120 years from creation, whichever is shorter.

Copyrights further differ from patents in the way that they arise. Whereas patents must be applied for, present United States law provides that a copyright arises automatically upon the creation of a work. In the past, United States copyright law presumed that an author of a creative work intended it to be dedicated to the public. Thus, in order to secure a copyright, one was required to mark the work as copyrighted ("©") and to indicate a copyright date prior to its publication. In contrast, the copyright laws of European nations developed a presumption that a work was intended to be copyrighted unless it was expressly dedicated to the public. The United States copyright law was amended in 1989 to adopt the presumption of an author's intent to copyright his/her works; thus, it is no longer necessary to mark and register works as copyrighted in order for them to be protected under United State copyright law. There are, however, several advantages to doing so. These advantages include establishing a public record of the work; attaining the right to sue in United stated federal courts for copyright infringement, and the right to claim statutory damages.

The United States Copyright Office provides a means for registering creative works The Copyright Office does not evaluate the validity of an applicant's representation, but merely reviews the copyright application to ensure that it meets the tests of originality and creativity and that the copyrighted work has been reduced to a fixed medium of expression.

A further distinction between patent and copyright protection is reflected in the treatment of "works for hire." A "work for hire" is a work prepared by an employee within the scope of his/her employment; or a work specially ordered or commissioned. United States copyright law provides that the employer of a work for hire is the owner of the copyright. In contrast, under patent law, an employer of an inventor does not automatically receive title to his employee's invention; such title must be conveyed by an assignment.

2. Trademarks

A trademark (or servicemark) is a word, name, symbol, design, or slogan that functions to distinguish the products (or services) of one company from those of another. As such, a trademark is closely linked to a particular business and/or to a kind of product that it produces. A trademark does not exist alone in the abstract apart from its association with the business and the service or product it represents.

Trademark law permits the owner of a mark to prevent others from taking certain courses of conduct that would disparage the mark, or create the likelihood of confusion in the marketplace. Such conduct includes "palming off" (falsely marketing a product as being the trademarked product, such as be selling phony Rolex® watches), "reverse palming off" (attempting to build one's reputation by falsely marking the products of another as being your products), illegally importations/sales, or actions that "dilute" the value of the mark. The concept of trademark dilution concerns acts that tend to tarnish or blur the value of the mark (e.g., selling Exxon sweaters might tend to dilute the value of the Exxon® mark).

Importantly, whereas the Constitution of the United States delegates control of the patent and copyright laws solely to the Federal Government, trademarks are governed by Federal law, State law and common law. The interactions of these laws complicate the acquisition of trademark rights in the United States. Traditionally, trademark rights are created through the use of a mark in commerce. If the mark has been used only within one state, it may be protected under state or common law. Marks that have been used in interstate commerce may additionally be protected under federal trademark law. Federal Trademark law permits applicants to also obtain trademark protection by expressing a *bona fide* intent to use the mark in commerce in the future.

The United States Patent & Trademark Office grants federal registrations on trademarks. Applicants do not claim the mark in gross, but rather with respect to itemized classes of goods and services. As in the case with copyrights, there is no requirement to register a trademark; however, several important advantages accrue to the owners of a registered mark. These advantages include exclusive use of the mark with respect to the goods or services specified in the registration, public notice of the applicant's claim, and a presumption of entitlement to own the mark nationally).

Trademarks have several similarities and differences from patents and copyrights. Like patents, trademarks are enforceable against subsequent independent creators of the same mark. Trademarks differ from patents and copyrights in being enforceable in state court as well as federal court. Unlike patents and copyrights that have limited durations, a trademark may persist indefinitely. A trademark may be enforceable as long as it continues to serve to distinguish the origin or manufacturer of goods or services. However, if public usage, despite the efforts of the trademark owner, causes the mark to become associated with the product but not the manufacturer or origin, then the mark becomes unenforceable. A large number of trademarks have been lost in this manner (e.g., aspirin, elevator, cellophane, etc.).

3. Trade Secrets

A trade secret is secret or confidential information used to gain a business advantage over others who lack the information. A trade secret may comprise a formula, pattern, device, or indeed any information that may be used to gain such an advantage. Technical information related to product compositions or designs, manufacturing processes, machines, and techniques often qualifies as a trade secret. A trade secret may be enforced indefinitely provided that the subject information does not become publicly available.

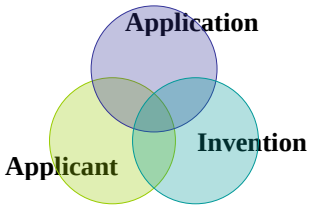
Trade secret protection protects ideas – but only by preserving their secrecy. Whereas a patent grants the patent owner legal rights against all infringers, the owner of a trade secret has rights only against those that have agreed, expressly or implicitly, not to disclose the secret information, or those who obtained the secret information by misappropriation. All others (even if competitors) who innocently gain access to the information can benefit from the trade secret information in any manner they wish. However, those who obtain the information from one who has misappropriated it may be enjoined from

using the information. Significantly, while patents and copyrights are based on federal laws, the protection of trade secrets is grounded in individual state laws.

II. Patent Protection in the United States

Title 35 of the United States Code contains the statutory provisions affecting the grant of a United States patent. The United States' patent system arose in response to the inequities of the English practice of granting royal monopolies. Under that system, patents were granted to known commodities, such as fish or salt, as rewards for service to the Crown. Thus, the United States Constitution and the ensuing patent statutes provide specific criteria that limit what can be patented and who can receive a patent.

The United States' patent system grants patents on inventions in which three classes of requirements have each been met: requirements as to the invention, requirements as to the application, and requirements as to the applicant.



A. Requirements as to the Invention

In order to be patentable, an invention must be useful, novel and non-obvious.

1. Utility

The requirement for utility establishes the threshold attribute that must be present in an idea before it can be considered for a patent. The patent statutes provide two independent tests for determining whether an idea possesses utility.

35 U.S.C. § 101 first requires that the idea must be capable of being described as either a process, a machine, a manufacture or composition of matter, or an improvement of such classes of ideas. Inventions that fall outside of these limits (e.g., mathematical expressions, natural laws, etc.) are not patentable. Thus, the requirements of 35 U.S.C. § 101 have been used to preclude the granting of patents on methods of doing business and raw data. One increasingly important exception exists to this preclusion. Since computers are machines, methods of doing business that employ a computer (for example, a method of tracking and selling stock using a computer), or computer systems that permit a user to display or manipulate specialized data (e.g., 3-dimensional coordinates of the atoms of a crystallized protein, etc.) may cross the gateway of 35 U.S.C. § 101 and define patentable subject matter.

35 U.S.C. § 101 further limits the availability of patent protection to only those classes of inventions that are useful. Thus, inventions that lack any use (e.g., such as a method for synthesizing an organic compound that has no known function) and inventions that cannot be used or that are *per se* inoperable (such as a perpetual motion machine) are not patentable. An invention that meets the statutory subject matter threshold will satisfy the statutory utility threshold if the invention has a useful purpose when viewed objectively.

2. Novelty

The patent statutes require the invention to be novel so that the granting of the patent does not deprive the public of any right that it possessed prior to the patent's grant.

The attribute of novelty is defined in 35 U.S.C. § 102 by a series of seven complex definitions. To satisfy the statute, an invention must separately satisfy the requirements of each of these definitions. Virtually every word in each definition has been litigated, and a large body of case law exists to govern the interpretation and applicability of the provisions of 35 U.S.C. § 102.

35 U.S.C. § 102 defines novelty both with respect to the *date of invention* and to the *date of filing* the patent application to protect the invention. Under United States law, invention requires two steps: first, the mental step of

conception and, second, the physical act of reducing the conception to practice. The act of conception is achieved when the inventor has such a definite understanding of the invention that he/she is able to describe it in a manner that is sufficiently detailed to permit others to carry it out. The act of reduction to practice involves either the actual practice of the invention or the act of filing a patent application that is sufficiently detailed to permit others to carry it out (a "constructive" reduction to practice).

In cases involving the elucidation of a new gene, the Court of Appeals for the Federal Circuit has concluded that the sequence of the new gene cannot have been conceived until the gene was physically isolated. For such cases, the conception and reduction to practice are said to be simultaneous.

Three sections of 35 U.S.C. § 102 (§§ 102(a), 102(e), 102(g)) define novelty with respect to the inventor's date of invention. For example, 35 U.S.C. § 102(a) precludes patentability if the invention "was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. § 102(e) precludes patentability in situations in which the invention sought to be patented by an inventor had been disclosed in a patent of another that had been filed before the inventor's date of invention. 35 U.S.C. § 102(g) bars one from receiving a patent if the invention being claimed was made before one's date of invention and claimed in a patent by another inventor.

United States law favors the first to invent an invention over the first to file an application on it. Thus, an applicant can surmount the effects of 35 U.S.C. §§ 102(a), (e) or (g) by establishing that he/she had invented the invention prior to the knowledge or use by others (§ 102(a)), filing of a third party patent (§ 102(e) or § 102(g)).

Two sections of 35 U.S.C. § 102 (§§ 102(b) and 102(d)) define novelty with reference to the date upon which the applicant filed for patent protection. Thus, for example, 35 U.S.C. § 102(b) precludes patentability if the invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(d) bars the granting of a patent if the applicant patented the invention in a foreign country more than 12 months before filing for a patent in the United States.

The interplay of 35 U.S.C. §§ 102(a) and 102(b) provides a so-called one year "grace period" in which inventors who have published, publicly used or sold their work can nevertheless file for patent protection. This interplay is of central importance, since a public use of the invention, an offer for its sale, or publication of an article describing an invention, even if authored by the inventors, will be an absolute bar to obtaining patent protection unless a patent application is filed before the end of the one year grace period. Due to the interplay of §§ 102(a) and 102(b) an inventor is able to submit declarations or other evidence to establish that he/she invented the invention prior to the occurrence of what would otherwise be a patent barring event.

Critically, however, if the inventors lack adequate records with which to prove prior invention, or if they did not in fact invent the invention before the publication date of an earlier published reference, then they will be unable to avail themselves of the grace period.

Ethical, political, and evidentiary issues are raised by such proofs of prior invention. Significantly, prosecution before the PTO is conducted *ex parte*, without any opportunity for others to refute the proofs offered by the inventors. However, in litigation, the validity of the ensuing patent is often challenged on such grounds.

3. Non-Obviousness

A central tenet of 35 U.S.C. § 102 is that a conclusion of non-novelty requires a showing of conduct (i.e., a publication, sale, use, etc.) that embraces and includes each and every element of the invention being claimed. If the prior art fails to describe even one aspect of an invention being claimed, the assertion of non-novelty is refuted. The patent laws also however, prevent the patenting of inventions that are obvious in light of the prior art.

35 U.S.C. § 103(a) provides that even if an invention is novel, it may nevertheless be

unpatentable 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, at the time the invention was made, have been obvious to a person having ordinary skill in the art to which the invention pertains. The analysis is conducted in three steps. First one determines the scope and content of the prior art, one next determines the level of skill of the hypothetical person of ordinary skill, and then one determines whether the differences between the subject matter sought to be patented and the prior art would have been obvious to such a person.

It is impermissible to employ hindsight to reconstruct the invention. A determination of obviousness requires a reasonable expectation that a particular combination of teachings (i.e., the teachings need to achieve the invention) would lead to a successful result, and a suggestion in the art that would have motivated a person of ordinary skill to actually combine the teachings. Factors such as the simultaneous development of the invention by different inventors may be cited as supporting an assertion of obviousness.

A conclusion of obviousness may be refuted by showing secondary considerations such as unexpected results or benefits, commercial success, long felt need, the failure of others to achieve the invention, etc., provided that such a showing is commensurate with the level of alleged obviousness.

Assertions of obviousness may also be refuted by showing that the prior art taught away from producing the invention. Evidence of objective acclaim by disinterested parties may also be effective in establishing that an invention is non-obvious.

B. Requirements as to the Application

A central purpose of the patent system is to promote the development and exploitation of technology. In order to accomplish this goal, the invention must be disseminated to the public in a manner that will allow its appreciation and exploitation.

Whereas the requirements of utility, novelty and non-obviousness are directed to the essence of an invention, the statutory requirements of written description and enablement (35 U.S.C. § 112, first paragraph) are directed to the sufficiency with which an invention is described.

35 U.S.C. § 112, 1st paragraph, requires that the patent application describe the invention, in writing, and that it do so in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Written Description

The written description requirement reflects a desire to ensure that the invention can be readily disseminated to the public, and that the description of the invention be reduced to a permanent form. Provided that the description is enabling, it serves the ancillary purpose of providing a means for proving that an inventor was, in fact, in possession of the invention being claimed. In some instances, an invention may not be amenable to written description. One significant example concerns biological materials whose isolation cannot be described in an enabling way using text. In response to this problem, U.S. and foreign laws have developed to permit the deposition of such materials in certified depositories. The written description requirement for such biological materials can be satisfied by referring to an accession number that would be sufficient to permit one to obtain the materials.

2. Enablement

The enablement requirement reflects the essential contract of the patent: a limited property right in the invention in exchange for a full disclosure to the public of a useable invention. The enablement requirement serves the further purpose of ensuring that only inventors who have actually developed a useable invention will receive a patent. It is an objective standard directed to whether the application enables those of ordinary skill in the art to carry out the claimed invention.

C. Requirements as to the Applicant

1. Inventorship

The United States patent system flows from the Constitutional directive that Congress "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." Thus, 35 U.S.C. § 102(f) requires that patents be awarded only to an applicant who is, in fact, the inventor of the subject matter being claimed. This requirement distinguishes the U.S. system from other patent systems which permit corporations and other business entities to be the "applicant" for the patents of their employee inventors.

Inventorship is determined by identifying the individual(s) who contributed to the conception of the invention being claimed in the patent application. As discussed above, conception is the mental step of contemplating a new means for achieving the useful result that defines the invention. It involves the formation in the inventor's mind of a definite and permanent idea of a complete and operable invention. Assistance that involves only reducing an invention to practice is insufficient to create inventorship. Those whose role in the invention involves merely assisting in the invention's reduction to practice are not inventors under U.S. law.

Under past law, in order for two or more individuals to be named as co-inventors of a patent, each was required to have contributed to the conception of each claim of the patent. That requirement has been eliminated from present law. Under present law, every individual who has contributed to the conception of at least one claim is an inventor/co-inventor, and must be named as an inventor or co-inventor of the patent.

Each inventor possesses an undivided interest in all of the claims of the patent, irrespective of the number of claims that he/she invented. Thus, in the absence of any agreement to the contrary, each owner/inventor may exploit the invention without any need for the consent the other owner/inventors, and without any obligation to account to the other owner/ inventors

The fact that patent ownership follows inventorship is another factor that can complicate determinations of inventorship. In situations in which multiple inventors of different companies or institutions collaborate with one another to achieve the invention, the resolution as to who invented the invention necessarily decides which company or institution will own the patent, or whether it will be jointly owned. The perceived potential value of the patent may lead companies or institutions involved in such joint collaborations to resist accurate determinations of inventorship. While such ownership issues may be readily resolved by establishing a contractual obligation to assign rights in the invention, such an obligation must be in place prior to the invention's conception and reduction to practice; a retroactive assignment is not permitted.

In light of the complexity surrounding inventorship, simple errors in determining the identity of all of the inventors can be readily corrected, and do not comprise inequitable conduct. In contrast, a willful decision not to include a true inventor on the application (or to add a false inventor) does comprise inequitable conduct, and cannot be corrected. Such decisions may arise with respect to improper inclusion of non-inventor senior management, faculty, colleagues, etc. or the exclusion of *bona fide* inventors who are junior researchers, technicians, etc. It is important to ensure that all relevant information is provided to patent counsel and to the United States Patent & Trademark Office.

2. Disclosure of the Best Mode

United States law requires not only that the application disclose how the invention might be practiced but also the best mode known to the inventors for practicing the invention. This requirement advances the *quid pro quo* nature of the patent: ensuring that the public receives the inventor's most preferred understanding of the invention in exchange for granting the patent.

While this requirement obviously relates in part to the content of the patent application, it is considered a requirement of the applicant since it relates to a requirement that is personal to the applicant. The disclosed "best mode" need not be objectively better than other modes. What is required is the disclosure of the best mode subjectively contemplated by the inventor(s) as of the filing date of the application. The statute does not require "highlighting" the best mode; it requires merely that the best mode be set forth in the application.

3. The Duty of Candor

U.S. law imposes upon patent applicants a duty of candor and good faith. Thus, despite the patentability of an invention, the grant of a patent may be denied if the applicant pursues a course of inequitable conduct before the Patent & Trademark Office. Such inequitable conduct involves making a material misrepresentation with the intent to deceive the Patent Examiner. The penalty for committing inequitable conduct is severe; a holding of inequitable conduct will render all of the claims of a patent unenforceable, and may affect the enforceability of related patents of the same inventor.

U.S. law has exhibited significant movement in the interpretation of what constitutes inequitable conduct. Decisions in the late 1980's held that if the materiality of the misrepresentation were great, a finding of intent could be inferred. Indeed, cases held that inequitable conduct could occur despite the patentee's good faith efforts. Present case law has clarified that intent to deceive is an element of inequitable conduct, and that in the absence of a finding of intent, there can be no finding of inequitable conduct.

The most frequent inequitable conduct issue raised in litigation involves an alleged failure to inform the Patent Examiner of information known to the applicant, the assignee, or others having an interest in the patent that, viewed objectively, would be of interest to a reasonable Examiner (for example, by creating a *prima facie* inference of unpatentability). In view of the severity of the sanctions associated with inequitable conduct, it is important to ensure that all individuals understand their respective duties to the Patent & Trademark Office, and that all information of potential relevance is brought to the attention of the Patent Examiner.

4. Diligent Pursuit

The patent statutes require inventors to diligently pursue the patenting of their inventions. 35 U.S.C. § 102(c) provides that an inventor's right to a patent may be lost if he/she abandons the invention. Thus, irrespective of the merits of the invention or the quality of an applicants' application, an applicant may lose the right to obtain a patent if the same invention is later achieved by other inventors who pursue patent protection with greater diligence.

III. The Patenting Process

Patents are granted through a protracted interaction with the Patent & Trademark Office ("PTO"). An understanding of the patenting process can expedite the granting of a patent, decrease legal costs, and increase the commercial value of the invention to potential licensees.

A. The Preparation of the Invention Disclosure

The invention disclosure marks the initial step in the patenting process. The disclosure should be prepared by the inventors, and include information relating to the funding of the project, the names of all participants, and the existence of any contractual obligations to assign the invention. The disclosure should be forwarded to patent counsel (and, for companies and institutions, to the relevant patent administrators). For most inventions, the date of invention and the initial details of the respective contributions of the inventors do not become relevant. In some cases, however, circumstances may arise in which the inventors may need to prove that their conception of the invention occurred prior to the publication date of a reference. Likewise, the inventors may need to establish that they were indeed the first to invent the invention being claimed. Thus, the conception and initial work of the invention should be documented with contemporaneous memoranda, lab notes, films, gels, photographs,

etc. These documents should be dated and witnessed (especially if the documents are authored by the inventor). It is important that such information be obtained as early in the process as possible in order to ensure that it is neither lost nor destroyed.

B. The Drafting of the Application

A patent application is a complex instrument. It must be sufficiently technical in its description of the invention to enable other researchers to reproduce it. However, it must also be sufficiently non-technical so that judges, jurors, business people, licensees, etc. will be able to understand the invention and appreciate why it is a patentable advance over the art, and why it has economic value.

If an invention is only in a preliminary stage at the time of filing, its commercial embodiments may not yet have been defined. In such circumstances it is important for the patent application to provide room for the invention to grow and to change to fit future perceptions. Such a practice is particularly important to the commercial success of institutional inventions since the ultimate commercial embodiment will be determined not by the institution, but by licensees who may not yet have been identified.

Recent changes to United States law relating to the written description requirement mandate that great care be exerted in drafting the application. Earlier statements of the law had suggested that the written description requirement could be satisfied by the mere mention of an embodiment. The evolution of the law in this area has, however, clarified that an embodiment's description should be of a quality sufficient to enable its practice by others. Thus, while present law provides little advantage to mere listings of potential embodiments, it continues to provide great advantage to applicants willing to carefully describe potential uses and embodiments of their invention.

In the area of biotechnology patenting, the law has evolved to emphasize structure over function. Early chemical patent law focused on compounds that lacked inherent function (acetone, for example, can be used in a myriad of different chemical processes). Such compounds are analogous to a piece of lumber; one doesn't know what it is until one has measured its physical dimensions. As a consequence, the law evolved to require that claims to chemical compounds be supported by a description of the compound's *structure*.

In contrast to such structural molecules, biotechnology molecules (particularly functional proteins and nucleic acid molecules) possess an ascertainable *inherent* function, and are *informational* in character, like a book. One seeking to possess a desired book does not read the entire book in order to know what it is. Rather, one analyzes just enough of the book (title, preface, etc.) to distinguish it from other books. Early biotechnology inventors envisioned that their biological molecules could be defined by their informational attribute, i.e., by *function*.

The distinction between structural and informational chemicals has, however, not yet been recognized by United States law. Thus, under present U.S. law, the informational nature of biological molecules is essentially irrelevant and biological molecules, like all chemicals, must be defined and described by their structures. As a consequence, one seeking to obtain a claim to a protein or nucleic acid molecule must either include the sequence of the molecule in the patent application or deposit the biological molecule (or a vector or cell producing it) in a depository (such as the American Type Culture Collection) under the terms of the Budapest Treaty On The International Recognition Of The Deposit Of Microorganisms For The Purposes Of A Patent Procedure.

The evolution of the law affects the scope of allowable claims. It is a fact that knowledge of the amino acid sequence of a protein permits one of ordinary skill to deduce the nucleotide sequences of enormous numbers of nucleic acid molecules that could be used to produce the proteins using recombinant DNA technology. Although these different nucleic acid molecules are functionally equivalent, they have different structures. Thus, due to the evolved emphasis of structure in chemical patent law, in order to secure claims to these functionally equivalent (but structurally diverse) molecules, a patent application must contain a recitation of each equivalent nucleic acid sequence. The

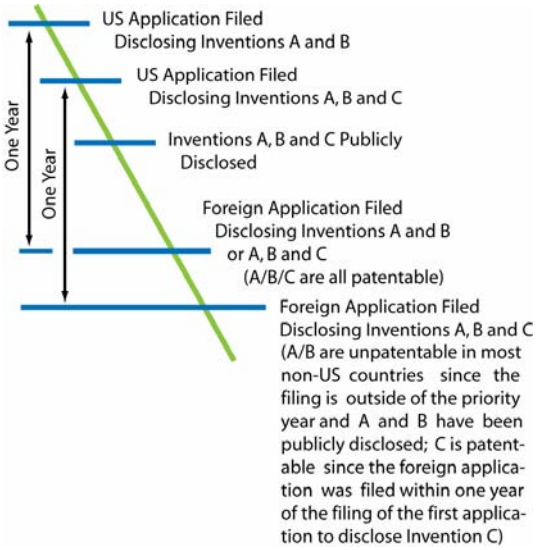
magnitude of this burden is so great as to often make it effectively impossible to obtain protection for equivalent nucleic acid species. Consistent with the evolved emphasis of structure over function, it is common to obtain claims directed to an organic compound having a substituent groups "R_1" and "R_2", in which "R_1" and "R_2" are independently aromatic, aliphatic, etc. Such claims read upon functionally diverse (and even inoperative) species, but remain patentable because of the structural commonality.

It is desirable to file the patent application as quickly as possible. Although U.S. law provides a one year grace period, foreign rights are largely lost by any prior publication. Moreover, it is important to recognize that a publication of the invention whose authors differ from those named as inventors on the patent application qualifies as prior art irrespective of the 1-year grace period. Thus, newspaper reports, announcements of meetings, etc. may all be considered as prior art. Despite the belief of many academic researchers, abstracts of meetings are references, and are frequently cited against patent applications.

C. Filing Strategies

Present applicants for patents have numerous options with respect to the manner and timing of securing a patent. Patent protection may be pursued through the filing of a "Provisional" patent application, an International ("PCT") application, or a regular "Utility" application. Each strategy has advantages and drawbacks.

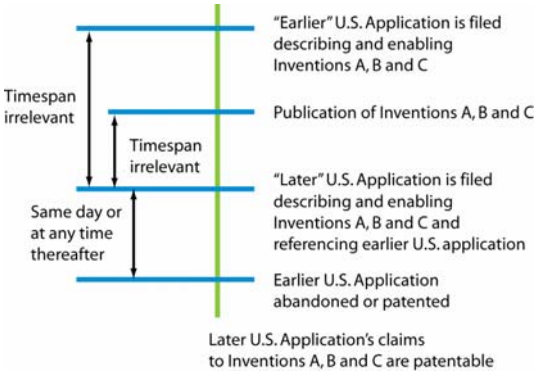
Central to all patent filing strategies is the right of priority accorded by the Paris Convention for the Protection of Industrial Property, signed in Paris, France, on March 20, 1883. Prior to the advent of the Paris Convention, applicants seeking to obtain patent protection in multiple countries were required to file application in each country on the same date. This resulted in significant logistical problems and led to a demand for the right of priority created by the Paris Convention. This right of priority permits an applicant, who has filed an enabling patent application in one country, to defer filing in other countries for up to one year. A filing occurring in another country within the "priority year" relates back to the filing date of the initial application ("priority date"). Thus, if the invention is published or disclosed after the filing date of the initial application, it may not be used as prior art against later filed applications that are filed within the "priority year." The right of priority is very strictly construed. An application filed even one day late is entitled to *no* right of priority. Also, the priority year extends only from the *first* filed application of the applicants describing the claimed invention. Design patent applications are not entitled to the above-described right of priority.



The Paris Convention right of priority described above, which is limited to a single year and concerns applications filed in the US *and foreign countries*, is distinct from, and in addition to, a domestic right of priority accorded to applicants of multiple related U.S. applications. U.S. law provides that a second (or later) U.S. patent application relating to an invention disclosed in a prior U.S. application is entitled to the benefit of the filing date of a first (or earlier) application. To receive this benefit, the later application must have been filed before the patenting or abandonment of the earlier patent application, and must contain a specific reference to the earlier application. Additionally, *and critically*, the earlier application must disclose the invention being claimed in the later application, and do so in such a way as to enable those of ordinary skill to carry out the invention being claimed in the later application.

This domestic right of priority, which concerns only U.S. applications, is *not* limited to a single year. A second U.S. application filed many

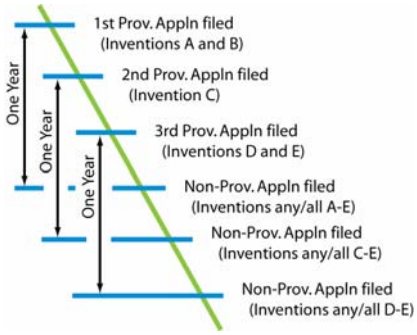
years after the filing of the initial U.S. application may be entitled to claim priority to it as long as the above requirements have been met.



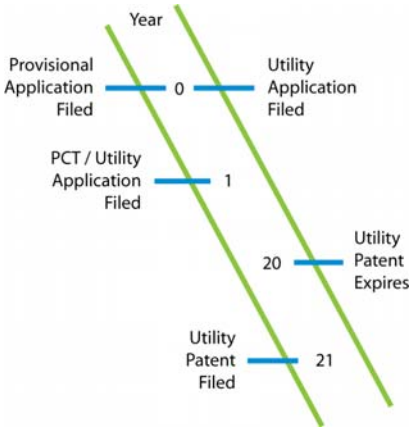
The domestic right of priority is of great significance in formulating an effective patent strategy. .

1. The Provisional Application

Provisional patent applications are placeholder applications. They are not examined, and do not issue as patents. Apart from the requirement of a specific cover page, there are no requirements as to the application's form or content. Importantly, provisional applications lapse irrevocably on the 1-year anniversary of their filing. During their pendency, provisional applications may be relied upon for the right of priority provided by the Paris Convention. Indeed, they are designed to be superseded by the filing of a utility application or a PCT application at the close of the one year pendency. One can file multiple provisional applications during the one year pendency; however, the superseding application must be filed within one year of the first application in order to be able to claim the subject matter of the first application.



The use of provisional applications provides two major advantages. First, since the filing requirements are minimal, provisional applications can be filed rapidly and relatively inexpensively. Second, because provisional applications are not examined, but are able to serve as basis for a claim of priority, they serve to "shift" the term of the ensuing patent – delaying grant by a year (the period of the pendency of the provisional application) and extending term by a year until the expiration of the utility patent. By filing a request, a provisional application may be converted to a non-provisional utility application. However, the term of the utility application will then run from the filing date of the provisional application. In order to avoid this disadvantage, a non-provisional utility application is generally filed to supersede the provisional application.



Provisional applications have two serious drawbacks. First, since they irrevocably lapse on their one-year anniversaries, it is critical to mark this deadline and ensure that it is not inadvertently missed. Second, although provisional applications are not examined during their pendency, they may well be scrutinized during the prosecution of the superseding utility application, in the course of licensing negotiations, and during the course of enforcement actions. As indicated above, in order to be effective in establishing a right of priority, the first filed application must be enabling – it must describe the invention so that those of ordinary skill in the art can practice it. If the provisional application is not carefully drafted, and does not describe the later-claimed invention in an enabling manner, it may fail to achieve its objective, and cause the Patent Examiner to conclude that the invention claimed

in the superseding utility application is unpatentable in light of intervening prior art. Likewise, if a patent's claim of priority fails due to a non-enabled provisional application, reviewing courts may conclude that the patent is invalid.

One approach that may be taken to address this issue is to file multiple provisional applications – filing an initial application to address an urgent need (e.g., an imminent disclosure), and a superseding complete provisional application as soon as practical thereafter to minimize the risk of any loss of a right of priority. It may likewise be desirable to file a provisional application prior to meeting with potential licensees, partners, etc. as a way to document the scope of invention that was in one's possession prior to such a meeting.

Unlike PCT and utility applications, provisional applications are not published. Thus, the use of provisional applications provides applicants with one year to elect whether to pursue patent protection for an invention or keep it a trade secret.

2. The PCT Application

The Patent Cooperation Treaty (PCT) provides a streamlined mechanism to efficiently accomplish the filing of an application in multiple countries. The United States and virtually all developed and developing countries are signatories to the PCT (Taiwan being a notable exception).

Whereas the Paris Convention permits applicants to avoid the logistics of filing an application in multiple countries (and in multiple languages) all on the same date, the PCT extends this flexibility by permitting applicants to file a single patent application that has the legal effect of a patent application in every PCT signatory country. Like the provisional application, the PCT application does not issue as a patent; it serves only as a placeholder application, preserving an applicant's right to file superseding national utility applications in every country in which patent protection is desired. The basic attribute of the PCT system is the ability to foreign file an application by merely filling out a request form and filing that form (and a copy of the application) in a PCT Receiving Office (such as the United States Patent & Trademark Office). The filing of such a request is the legal equivalent of filing the application in the patent office of each PCT signatory country. Significantly, for U.S. citizens, because the application is filed with the PTO, it is not necessary to secure a foreign filing license from the PTO in order to foreign file the application.

Once the request has been filed, the applicant has a certain period of time to translate the application into the foreign language of those signatory countries in which a patent is actually desired and to effect the actual filing of the application in such countries. The period of time varies depending upon the country involved. Most countries provide 30 month periods; some provide only 20 month periods. The periods are calculated from the filing date of the first application for which a claim of priority is made under the Paris Convention (the "priority date"). The application is published approximately 18 months after its priority date.

The PCT system includes provisions for the conducting of a preliminary search and examination of the application, and to amend the application in light of the results of the search and/or examination. If an applicant designates the United States Patent & Trademark Office as the searching authority, the examination will be conducted by a U.S. Patent Examiner, and will resemble an initial action. In some cases, the information obtained in the examination may aid the applicant in predicting the difficulty that may be encountered during the national phase prosecution of the application.

The PCT system provides a crucial advantage to foreign institutions or corporations. As discussed above, 35 U.S.C. § 102 provides a one year "grace period." This period runs from the filing date of a U.S. national application. Thus, a foreign institution that files first outside of the United State, and then (in accordance with the Paris Convention) files in the United States one year later loses the complete benefit of the 35 U.S.C. § 102 grace period. In contrast, if the foreign institution had filed its application as a PCT application (with a local PCT Receiving Office), the grace period would relate back one year from the PCT filing date. This is particularly important since the full state of the prior art can never be known in advance with certainty.

The PCT system also provides significant advantages for institutional applicants. First, at modest cost, it preserves the institution's options regarding foreign filing. Second, because the PCT provides a substantial gap from the date of filing to the commencement of national examination, it provides the institution with more time in which to secure a licensee. Thirdly, because PCT applications are published they are available on databases and thus can reach a large number of possible licensees.

In sum, PCT applications have the disadvantage of being merely placeholder applications. However, their worldwide publication, significant deferral of translation and filing fees, and the capacity to use them to assess the patentability of an invention provide significant advantages.

3. The Non-Provisional Utility Patent Application

The non-provisional utility patent application is the only U.S. patent application that is examined and is capable of issuing as a utility patent. The requirements of the application are described in Section II above. Additionally, applicants must submit a Declaration (to the United States Patent & Trademark Office) averring that they are the original/joint inventors of the subject matter claimed in the application. This Declaration may need to be supplemented if changes to the nature of the claimed invention (made during prosecution of the application) alter the composition of the inventive entity. Where a duty of assignment exists, applicants should also submit an assignment to the United States Patent & Trademark Office for recordation.

The utility application presents several strategic opportunities. A threshold decision is whether to seek patent protection only in the United States, or to potentially pursue protection in foreign countries. U.S. law provides that utility applications are to be published prior to their issuance (at approximately 18 months from their earliest priority date). This publication is automatic unless the applicant notifies the United States Patent & Trademark Office that the invention *disclosed* in the application will not be the subject of a patent application filed in a foreign country. Critically, this notification must be prominently made *at the time of the filing of the U.S. application*. The publication provisions thus provide U.S. applicants seeking only domestic patent protection with an initial option of keeping their invention a trade secret in the event that it is found to be unpatentable. The notification may be rescinded at any time, and thus an applicant's decision to forego foreign patent protection may be reconsidered after the U.S. filing date. An application that has been foreign filed despite notification to the contrary will be considered abandoned unless remedial action is take before the United States Patent & Trademark Office within 45 days of the filing date of the foreign application.

Because the application will be examined, it is highly desirable to submit an information disclosure statement bringing to the Examiner's attention all prior art known to the applicants, those working with the applicants, and their respective attorneys, that might reasonably affect the Examiner's determination of the patentability of the invention.

The U.S. patent system is a claim based system and the central concern of the non-provisional utility patent application is the claims of the application. Every aspect of the invention can be potentially claimed: methods of manufacture, compositions, methods of use, etc. The claims of the application will define the scope of the Examiner's search, the boundaries of the prosecution negotiation, the timing and difficulty of prosecution, the scope of patent protection, and ultimately the value of the entire endeavor. Accordingly, great care should be given to the precise formulation of the wording of the claims, preferably at the time of filing, or at least in response to the initial response ("Office Action") of the Patent Examiner.

D. Strategic Patenting

Patents can serve multiple purposes beyond offensively blocking competitors from practicing a technology. Since patents comprise prior art, they may be used defensively to prevent competitors from blocking one's ability to practice one's its core technology. Patents may be used to obtain facilitate capital acquisition (e.g., through the out-licensing of non-core

technology, from venture capital, banks, etc.). Patents are often used simply to motivate researchers and enhance morale. In sum, obtaining a patent should not be pursued as a goal; it is a means to obtain a goal.

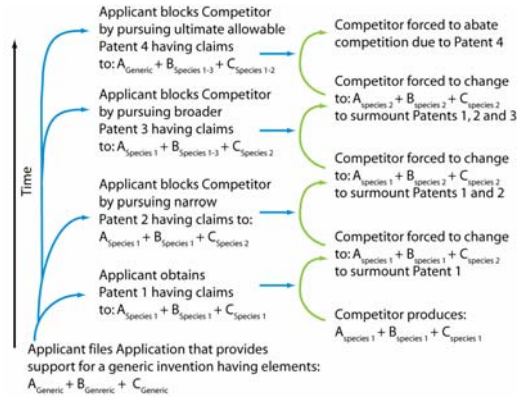
The term "strategic patenting" may be employed to describe the use of patents to secure market control of a technology. Rather than securing a single patent of great scope, it may be preferable to construct one's patent protection using an array of patents of differing scope.

Provided that one's application supports claims of differing scope, one can use multiple filings (applications claiming priority on earlier pending applications) to claim additional aspects of an invention. By analogy to chess, strategic patenting involves the coordinated use of pawn, bishop, knight, rook and queen patents.

Particularly when there is no initial infringement of an invention, it is often desirable to erect an initial defensive position that would block others from establishing a conflicting intellectual property position in the field. This may be done using applications having claims of narrow scope ("pawns" and "knights") that, due to their narrow scope, may encounter rapid and favorable prosecution and thus issue quickly. The patents issuing from such applications (and the publications of the applications themselves), can create prior art barriers to competitors, and may provoke one's competitors into making design changes or patent filings that would reveal their respective competitive technologies. Such competitor actions create targets for one's offensive patent applications (the "bishops" and "rooks"). Such patents are longer term solutions to the competitor's activities. These applications have claims of a scope that is closely directed to the activities of one's competitors. The prosecution of such claims complicates competitor activities and helps to elucidate the scope and content of the prior art.

Once the scope of the prior art has been fully ascertained, "queen" applications having more dominant claims may be pursued. However, it is important to recognize that a patent need be no broader than that necessary to block one's competitors. Indeed, patents of greater breadth present a broader target for attack and may be counterproductive.

The strategic approach to patenting is illustrated below with respect to a hypothetical disclosure of a combination product. The initial patent discloses a product comprising one species of each of the three generic elements A, B, and C. The quality and completeness of the initial disclosure is central to the success of the approach. A narrow pawn patent is obtained on embodiment $A_1B_1C_1$, prompting the emergence of an $A_1B_1C_2$ competitor product. This creates a target for an offensive bishop patent directed to the $A_1B_1C_2$ embodiment. Additional patenting rounds may be pursued ultimately resulting in a blocking (queen) patent directed to all that may be allowable: a product having $A_{1-\infty}B_{1-3}C_{1-2}$.



One advantage to employing such a process is to provide the patentee time to assess the true state of the prior art, the weaknesses in any claim drafting stratagem, and the full dimensions of its invention.

In this regard, it is an unfortunate observation that one cannot predictably rely upon the claims of a single patent to provide full protection. Competitors may thwart the limitations of the claims, or courts may construe the claims or their recitations in ways that could not have been fairly predicted during the prosecution of the patent. In many instances, the technology may move past the claims, so that they no longer provide useful protection either for one's own products or against the products of one's competitors.

Additionally, despite the greatest care, latent errors may be present in the claims that will diminish their value when discovered. New prior art may be found that might impact upon the scope or validity of the claims. If only a single patent application has been filed, it may be

impossible to surmount such problems because the issued patent becomes prior art after one year, and procedures such as Reissue and Reexamination (discussed below) may give rise to intervening rights (enabling competitors who relied on the patent's weaknesses the right to continue to practice the claimed invention). One approach to surmounting these problems is to refile the application prior to issuance, so that at least one patent application is always pending. The claims of the refiled application can be amended as needed to address emerging problems. Optimally, this approach should be pursued until the technology at issue no longer has commercial significance or the first issued patent describing the technology has expired.

In designing the claims of one's offensive patents, it is important to identify the class of entities that would comprise one's likely competitors and to ensure that one's claims define an invention that could actually be practiced by such entities. This is particularly of concern in "method" claims. For example, a claim to a method of treating cancer comprising the steps of screening for compounds having anti-cancer activity and then administering successful anti-cancer compound to cancer patients is unlikely to be capable of infringement (i.e., those conducting the screening step are unlikely to be the same as those who would administer the identified compound to patients).

E. The Prosecution Process

The prosecution process begins with the submission of the application, inventor's declaration to the United States Patent & Trademark Office. Assignment documents, information disclosure statements (citing relevant prior art to the Patent Examiner), and Sequence Listings (in the case of biotechnology inventions) should be filed with or soon after the filing of the application.

Typically several months elapse before the application is acted upon by a Patent Examiner. After reviewing the application, the Examiner will provide a written "Office Action" that will attempt to explain the factual and legal basis for any perceived insufficiency in the application. The Office Action will "reject" claims that fail to meet the statutory requirements.

The present examination system is run as a quota system with examiners having to review and "dispose" of a number of applications each year, depending upon their seniority and the complexity of the technology that they examine. The quota system often means that the Examiner has very limited time to read and consider each invention. Thus, the Examiner's comments may not be accurate, or may fail to consider contradictory evidence. It is the job of the applicant (or the attorney or agent prosecuting the application) to explain the invention to the Examiner and to resolve any misunderstandings. Although U.S. law permits applicants to represent themselves before the Patent Examiner, it is highly recommended that one employ a registered patent attorney or agent. Lists of registered patent attorneys and agents can be found at www.uspto.gov.

The Office Action and the applicants' response define a negotiation process in which the claims may be revised or limited in scope in order to address concerns raised by the Examiner. The process is highly individualized, both as to the invention and the examiner. Examiners have great discretion in determining patentability.

In responding to Office Actions it is important to ensure that the Examiner is aware of and considers the most pertinent art. Significantly, highly technical (as opposed to legal) arguments may be profitably advanced to address the Examiner's rejections. As discussed above, there is an ethical component of responding to the Office Actions, and it is important to proceed in full candor, assisting the Examiner in finding and considering relevant art, and correcting any misconceptions. Failing to correct inaccurate descriptions of the art, or not providing the Patent Examiner with fully accurate arguments can weaken (or eliminate) the licensing value of a patent, and can undermine the Examiner's confidence in the patentability of other, unrelated, applications of the applicant. The application should be prosecuted as though it will be litigated.

The Patent Examiner will review and consider the rebuttal arguments submitted in response to the initial Office Action. In some cases, the Examiner will withdraw the rejections, and allow the application to proceed to issuance. In a majority of cases, however, the applicants' response will not place the application in

condition for allowance, and a second, often final rejection will be issued. An assertion of finality in an Office Action limits the scope of possible responses and issues that may be raised during subsequent prosecution.

F. Refiling, RCE or Appeal

An applicant responds to the "final" rejection by submitting new or clarified arguments to support patentability, or by further amending and limiting the application's claims. Often, such arguments will be successful, and the case will be passed to issuance.

In other instances, however, the Patent Examiner will indicate that the second response fails to resolve all of the outstanding issues and that the rejections will be maintained. Applicants, in such instances, have three options: (1) filing a new application containing an augmented disclosure, (2) filing a Request for Continued Examination ("RCE"), or (3) appealing the Patent Examiner's rejection to the PTO's Board of Patent Appeals and Interferences.

The U.S. patent system provides applicants with the right to refile their applications in order to continue to address an Examiner's rejections. A refiled application that contains exactly the content of the earlier filed application is known as a "continuation" application; a refiled application that contains more or less than the content of the earlier filed application is referred to as a "continuation-in-part" application. 35 U.S.C. § 120 provides that continuation and continuation-in-part applications can be accorded the benefit of the filing date of their earlier filed applications. The filing a continuation-in-part application may well surmount concerns raised by an Examiner, however, it is a problematic option to pursue since the new material of the application would not relate back to the original filing date of the parent application. Thus, the filing of a continuation-in-part application may complicate efforts to surmount the prior art.

The ability to file such applications is a substantial and somewhat controversial right. It has the effect of permitting applicants to address and resolve problems raised in prosecution, and thus limits the impact of any errors that might be committed by the PTO or the applicant. Unfortunately, it also has the effect of permitting "submarine" patents (i.e., patents that issue many years after their filing date and which thereby surprise businesses that had concluded that a certain course of conduct had not been the subject of a patent application

Filing an RCE is often the option of choice where the outstanding issues are technical, pertaining either to informalities or to the technical interpretation of cited documents, or in cases in which the Examiner has decided not to consider any amendments made in the second response (the RCE serves to withdraw the finality of the rejection and force the Examiner to consider any previously provided amendments). An RCE should be filed if the claims can be amended to define patentable and commercially significant subject matter. Similarly, an RCE should be filed to correct any inadvertent errors or misstatements that may have been made during initial prosecution.

In some cases, however, an Appeal to the PTO's Board of Patent Appeals and Interferences may be warranted. This approach is particularly desirable to resolve legal issues pertaining to the Patent Examiner's application of the patent statutes and case law, to challenge PTO policies, or to secure claim scope that is supported by the application, but denied by the Examiner. The Appeal process involves submitting an Appeal Brief, and optionally, presenting oral arguments before the members of the PTO's Board of Patent Appeals and Interferences. A significant "backlog" of Appeals currently exists, and thus in many instances, it may be more advantageous to refile a case that is otherwise ripe for Appeal and re-pursue allowance of the application with the Patent Examiner.

G. Appeal to the Court of Appeals for the Federal Circuit

An application whose "final" rejection is affirmed by the PTO's Board of Patent Appeals and Interferences may appeal that decision to the Court of Appeals for the Federal Circuit, or to U.S. District Court for the District of Columbia. Appeal to the Federal Circuit is generally preferred. The Appeal uses the application

papers and arguments made before the Patent Examiner and the Board of Patent Appeals & Interferences as its evidentiary record. The appellate process involves briefing the issues to the court, and defending the asserted position in oral argument.

Appeals to the U.S. District Court for the District of Columbia are valuable where one wishes to supplement the evidentiary record. Such appeals comprise *de novo* reviews, and can be both more expensive and more time consuming than an appeal to the Federal Circuit.

H. Post-Allowance Prosecution

In the vast majority of all patent applications, allowance of the application terminates all further prosecution in the Patent & Trademark Office. In some instances, however, issues pertaining to conflicting claims of invention, uncited prior art, or errors in defining the invention and errors identified in the patent will warrant further prosecution.

1. Interference Proceeding

An Interference Proceeding is an *inter partes* administrative trial, conducted by an administrative law judge to resolve conflicting claims of inventorship and patentability asserted by a third party. U.S. law provides that only the first to invent an invention is entitled to the patent. Thus, a party who filed second may obtain a patent over the party who was first to file if the second party can demonstrate an earlier date of invention, or can demonstrate an earlier date of conception coupled with diligence in reducing the invention to practice. The Interference Proceeding is thus a contest to determine priority of invention. Ancillary issues, such as patentability can also be determined. The Interference arises by bringing to the PTO's attention the existence of two or more patent applications, generally filed within one year of another, that claim the same patentable invention.

The Interference Proceeding is an action that is characterized by discreet stages. The preliminary stage commences with an indication to the parties that an Interference Proceeding might be declared, and ends when the Interference has actually been declared. The stage provides an opportunity for each party to assemble the proofs that will document its conception and reduction to practice of the invention. During the preliminary stage, the client's objectives must be determined, and a strategy for responding to the potential Interference devised. Such action is needed because the Interference Proceedings quickly lock the parties into positions that cannot be subsequently changed. Moreover, the rules provide very short, non-extendible deadlines (1-2 months) for action once the Interference has been declared.

The motions stage is the most important stage of the Interference. Most Interference Proceedings are effectively won or lost due to actions taken in this stage. The strategy that was developed during the preliminary strategy stage is implemented during the motions stage of the Interference. This stage thus entails carefully determining compliance with Interference rules and attempting to convince the Interference Examiner to take certain actions in accordance with the party's strategy. During the motions stage, a party must consider and respond to any efforts that its opponent(s) may make that might direct the Interference into a less desirable direction.

Relatively few Interference Proceedings encounter a discovery stage in which document productions and depositions may be required. After discovery, most Interference Proceedings enter a settlement stage in which the parties negotiate a resolution to their priority claims.

In the event that the Interference Proceeding does not resolve or terminate, a trial stage commences, and an administrative law trial is conducted. The trial judge's decision may be appealed to the Court of Appeals for the Federal Circuit or to U.S. District Court for the District of Columbia.

2. Reexamination

A Reexamination is a Proceeding that is instituted in order to resolve a substantial new question of patentability raised by prior art

patents or printed publications. In the past, such Proceedings were ex parte. Present law permits either *ex parte* or *inter partes* Reexamination.

Ex parte Reexamination can be instituted at the request of any person (including the patentee). However, once instituted, parties other than the patentee have little or no opportunity to comment on their course. In contrast, the patentee is permitted to file rebuttal arguments, and may submit declarations, etc. to support its contentions. An *Ex parte* Reexamination Proceeding is quite limited in scope. Issues involving public use, sales, prior invention, inequitable conduct, etc. cannot be raised. The Reexamination Proceeding either reaffirms the patentability of the patent's claims, or results in the revocation of affected claims.

Inter partes Reexaminations are permitted on patents arising from applications filed after November 29, 1999. The third party requesting the Reexamination may appeal to the Board of Patent Appeals and Interferences any decision favorable to the patentee. The decision of the Board of Patent Appeals and Interferences is however not appealable by the third party requestor. One drawback of the *Inter partes* Reexamination procedure is that a third party requestor that fails to establish the invalidity of a claim is estopped from later challenging any fact determined in the Reexamination or asserting that any reexamined claim was invalid on any basis that was (or could have been) raised in the Reexamination.

3. Reissue

A Reissue Proceeding may be brought pursuant to 35 U.S.C. § 251 when a patent is, through error without deceptive intent, wholly or partly inoperative or invalid because the specification was defective, or because the inventors claimed either more or less than they were entitled to claim. It is important to recognize that an allegation of error is needed to support a Reissue Proceeding. A Reissue Proceeding is not proper where the patentee has merely failed to claim a particular aspect of the disclosed invention.

A broadening Reissue Proceeding (in which the patentee has through error claimed less than it was entitled to, and now seeks broader claims than those that originally issued) can be pursued only if requested within two years of the issue date of the patent. In contrast, a narrowing Reissue Proceeding can be pursued at any time. 35 U.S.C. § 252 provides that third parties who practiced an embodiment covered by a claim of the Reissued patent that did not appear in the originally issued patent have intervening rights and can continue to practice the invention even if such practice would infringe one of the Reissued claims. The Reissue procedure may be used to correct or perfect claims of foreign priority or claims of priority to an earlier filed utility application. For applications filed after November 29, 2000, Reissue cannot be used to perfect or correct claims of priority to a provisional application. The public may request access to Reissue applications.

4. Certificates of Correction

A request for a certificate of correction is the appropriate remedy to correct minor errors in the issued patent. 35 U.S.C. § 254 provides a means for correcting any error committed by the PTO in printing the application as a patent. 35 U.S.C. § 255 provides a substantially more limited ability to correct errors that arose through the fault of the applicant. The only classes of errors that are correctable are those that are clerical or typographical in nature, or errors of minor character. The test is not whether the patent would support the desired correction (i.e., not enablement or written description criteria), but rather whether the existence and correction of the error would have been obvious on its face in view of the patent and its patent office file history. The correction cannot result in the introduction of new matter, or change the scope of the issued claims.

5. Correction by Federal Courts

Where a patent's claims contain errors that would be correctable by a certificate of correction, a Federal Court can direct that the claim be interpreted as though it had been corrected by a certificate of correction. Courts can also direct the Patent & Trademark Office to correct inventorship.

IV. Patent Litigation

A. Infringement

Under U.S. law, a patent is infringed by a third party only if that party's conduct encompasses actions that meet each and every limitation (such as a method step, a component of a composition, etc.) of at least one patent claim. Such infringement can be either literal or by equivalency.

Three types of infringement conduct can be described. One "directly" infringes a patent by making, using, selling, offering to sell, or importing an article or process covered by at least one claim of the patent. One "induces" infringement by encouraging direct infringement. One "contributes" to infringement by selling, offering to sell, or importing a material part of a patented product knowing it to be specially adapted for infringement.

Conduct that fails to include even one limitation of a claim does not infringe that claim, and is not actionable. The converse is untrue. Conduct that adds a limitation not present in the claim does not avoid infringement.

To prove infringement, a patentee must show by a mere preponderance of the evidence that the accused infringer's action infringes the patent. In contrast, in order to prove a patent is invalid, an accused infringer must show such invalidity by clear and convincing evidence.

To establish infringement, one must thus first determine the proper construction of the claim, by defining the terms used in the claim with relation to the patent specification, the prior art, and the file history of the application. After the proper scope and meaning of the claims has been determined, the infringing conduct is analyzed to determine whether it exactly embodies the claimed invention. This determination is known as a *Markman* determination. The *Markman* determination is a question of law (as opposed to a question of fact) and is conducted by the trial judge and not jurors.[1] Because the *Markman* determination is a question of law, it is freely reviewable upon appeal (by the Court of Appeals for the Federal Circuit, which has exclusive jurisdiction over patent infringement appeals). In many instances, the *Markman* determination is dispositive of infringement. In light of the significance of the *Markman* determination, it might seem useful to appeal an adverse determination to the Court of Appeals for the Federal Circuit prior to a full trial on the merits. The Federal Circuit has, however, declined to accept such interlocutory appeals. Thus, litigants may need to conduct a full trial before they can learn whether the trial judge's interpretation of the claims in suit was correct. In the event that trial judge's *Markman* determination was incorrect, a second trial may be required.

1. Literal Infringement

Literal infringement occurs when the exact language of a claim can be read on the conduct of a third party. Thus, a claim to a round, striped, metal widget would not be literally infringed by the sale of widgets that were solid-colored, or made of mirrored plastic, or cube-shaped. The absence of a single element negates literal infringement.

2. Infringement under the Doctrine of Equivalents

The severity of the literal infringement test, and the possibility that an infringer may escape liability for infringement by making *de minimis* changes to the patented invention have led to the development of a judicially created equitable doctrine (the Doctrine of Equivalents) under which a party that does not infringe a claim literally may nevertheless be liable for infringement if its product/process is insubstantially different from the patented product/process.[2] Application of the Doctrine is limited by the scope and content of the prior art, and by the prosecution history of the patent. Thus, for example, a claim to a round, striped,

[1] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir.) (en banc), *affirmed*, 517 U.S. 370 (1996)

[2] *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

metal widget would likely be infringed by equivalency by the sale of striped, round widgets made of mirrored *plastic* unless (1) the prior art taught mirrored plastic widgets, (2) during prosecution, the patentee had made statements that disclaimed mirrored plastic widgets or distinguished the claimed invention from widgets made of mirrored plastic, or (3) the plastic widgets are *not* insubstantially different from the patented widget.

The proper application of the equivalency standard is quite difficult, and pits the public's right to rely upon the language of a claim with the patentee's right to have its invention protected from *de minimis* variation. The role of prosecution history in limiting the application of the Doctrine of Equivalents has been particularly problematic. In many cases, amendments are made in patent claims without adequate (or any) explanation, creating an ambiguity as to whether the amendment was made to surmount prior art (thereby creating a prosecution history estoppel that would limit the application of the Doctrine of Equivalents), or for reasons unrelated to patentability (an action that would not create prosecution history estoppel). Such circumstances engender unpredictability as to claim scope, and encumber true efforts at innovation.

The Court of Appeals for the Federal Circuit attempted to resolve this problem by holding that *any* amendment narrowing the scope of a claim completely bars the availability of the Doctrine of Equivalents to the amended claim element. While such a position holds have held certain advantages of clarity as to the application of the Doctrine of Equivalents, it also would have worked significant injustice to patentees who made narrowing amendments for purposes unrelated to patentability.[3] The United States Supreme Court rejected the breadth of the Federal Circuit's approach.[4] It held that any amendment could potentially create an estoppel that would limit the application of the Doctrine of Equivalents, but that the extent of the limitation on the doctrine should be determined on a case by case basis. The Supreme Court advises that a patentee's silence as to the purpose of an amendment creates a presumption that the amendment was made for purposes of patentability. If the patentee is unable to explain the reason for the amendment, a prosecution history estoppel would apply to bar application of the Doctrine of Equivalents as to amended element.

B. Remedies

1. Injunction

A patent is a property right, and the essence of property rights is exclusive use. Thus, the patent statutes provide the equitable remedy of injunction as the preferred remedy for patent infringement. A patent injunction is a court order that compels an infringer to cease its infringement of the patent. It is a prospective remedy designed to prevent future harm to the patentee by restoring the patentee's exclusive use of the patented invention. Injunctions can be awarded before ("Preliminary Injunction") or after ("Permanent Injunction") the determination of infringement. Although Permanent Injunctions are the preferred patent remedy, they may be unavailable in cases involving public welfare. The test of whether an injunction should be granted requires a plaintiff to demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity[5] is warranted; and (4) that the public interest would not be disserved by a permanent injunction. The decision to grant or deny such relief is an act of equitable discretion by the district court.[6]

Thus, for example, a court may elect not to enjoin a party marketing an infringing blood test if the well-being of recipient patients might be affected. Likewise, a court has the discretion not

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[3] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (*en banc*), *cert. granted*, 121 S.Ct. 2519 (2001); *vacated and remanded*, 535 US 722 (2002).

[4] *Id.*

[5] U.S. courts can grant remedies in law or in equity. Remedies in law are limited to a requirement that a party pay money "damages" in response to a finding of liability. Remedies in equity are broader, and can include requirements that a party modify its future behavior. Courts prefer granting remedies in law whenever possible.

[6] *eBay Inc v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

to enjoin a party that has elected to commercialize a patented invention that the patentee has not commercialized or has been unable to commercialize. While the public policy behind ensuring that patients receive critically needed tests, or that technology actually be made available to the public is laudable, the policy does have the effect of permitting larger or better financed companies to infringe technology of smaller companies or universities with significant impunity. Thus, it may have an adverse long-term impact on innovation.

2. Damages

The remedy of "damages" (money paid to compensate the patent holder for the infringement) is also available in cases of patent infringement. Damages are typically retrospective (compensating the patent holder for past infringement), however, where an injunction has not been sought, damages may be prospective. Importantly, infringement is not a crime, and damages are not intended as a penalty. Typically, damages are assessable from the commencement date of infringement or from the issue date of the patent, whichever is later. However, U.S. law now provides patent holders with "Provisional Rights" entitling them to receive a reasonable royalty from infringers during the period between the publication date of the non-provisional utility application (or the PCT application) and the issue date of the ensuing patent provided that (a) the claims of the patent are substantially identical to the claims of the published application, and (b) the infringer had actual notice of the published application.

The standard measure of damages is that the awarded amount be at least as high as the "Reasonable Royalty" that the Patentee and the infringer would have negotiated in a hypothetical negotiation. The reasonable royalty is not set so high as to consume all of the infringer's profit. The factors used to determine what constitutes a reasonable royalty are often referred to as the "*Georgia-Pacific*" factors[7], after the patent case in which they were most clearly articulated. These factors include: (1) the royalties paid by others who have licensed the patent ("the established royalty rate"); (2) the royalties paid by the infringer to license other patents comparable to the patent-in-suit; (3) the nature and scope of the proposed license (exclusivity, geographic restrictions, etc.); (4) the licensor's established policy to license or not license his patent; (5) the commercial relationship between the parties (competitors, non-competitors, etc.); (6) the effect that the licensee's sales would have on sales of derivative or convoyed products / services; (7) the duration of the patent and the term of the license; (8) the established commercial success and profitability of the patented product; (9) the advantages of the patent over other prior products or processes used for similar purposes; (10) the nature of the patented invention and the benefits accruing to those who have used it; (11) the extent to which the infringer has used the patented invention, and the value of that use; (12) the portion of the profit or selling price that is customary in the industry for use of inventions; (13) the portion of the profit that is credited to the invention (and not to unpatented aspects, etc.); (14) the opinion testimony of qualified experts; and (15) the royalty that the parties *would have* reached had they conducted a voluntary negotiation aimed at obtaining a license.

If a patentee can prove that an infringer had no reasonable basis for believing that it could freely practice the patented invention (i.e., had not obtained any objective and reasoned advice (even if ultimately incorrect) of counsel that the patent was invalid or that the infringer's product did not infringe), it may be entitled to receive trebled damages for "Willful Infringement." For this reason, it is highly desirable to obtain advice of counsel (preferably written) articulating the arguments of non-infringement, invalidity and unenforceability.

In certain circumstances, a lost sale can involve the additional loss of ancillary revenue, such as revenue for future maintenance, parts, consumables, etc. If a patentee can prove that it lost not only a sale of a patented item, but also sales of derivative or associated items or services, it may obtain damages for such "convoyed sales." Likewise, in certain circumstances, each sale of the infringer comes at the expense of a lost sale by the patentee. If the patentee can prove that it lost a sale due to sales made by the infringer, it may be entitled to recover its "Lost Profits" as damages.

[7] *Georgia-Pacific Corp. v. United States Plywood Corp*., 318 F. Supp 1116 (SD NY 1970).

Significantly, the patentee's lost profits can exceed the total amount of money made by the infringer. To become entitled to a lost profits award, a patentee must prove that *but for* the infringers' actions, it would have made the lost sales.

C. Defenses to Infringement: Invalidity and Unenforceability

It is common in patent infringement suits for the accused infringer to assert that the patent in suit is invalid or unenforceable, and thus that its infringement should not incur liability to the patentee. Invalidity, which is proven claim by claim, is established by showing that one of the statutory requirements for a patent was not satisfied. Unenforceability, which affects every claim of a patent (and under certain scenarios, every claim of a family of related patents) is established by showing that the applicant's conduct before the United States Patent & Trademark Office was inequitable (such as by contravening the duty of candor). Inequitable conduct is established by proving that a material misrepresentation or omission occurred (such as a failing to cite known prior art affecting the patentability of the claims, misrepresentation of data, advancing fallacious arguments, etc.) and that the misrepresentation or omission was made with an intent to deceive.

Assertions of invalidity or unenforceability are affirmative defenses. In light of a patent's presumption of validity, such assertions must be proven by clear and convincing evidence.

1. Anticipation

The term "anticipation" denotes that a claim lacks novelty and is thus invalid. A patent claim is "anticipated," and thus invalid, if a single prior art reference discloses each of its limitations.[8] A challenger asserting that a prior art product anticipates a claim must prove that the prior art product possesses the specific limitations of the relevant claim.[9] Importantly, in order to be an anticipatory reference, the prior art document must enable one of ordinary skill in the art how to make and use what is described.[10]

An anticipatory reference, however, need not duplicate word for word what is in the claims. Instead, anticipation can occur when a claimed limitation is "inherent" or otherwise implicit in the relevant reference. Under this doctrine, a claim is anticipated if a compound, process, or apparatus of the prior art necessarily possessed the structure, function or characteristics of the claimed invention – even if such attributes had not previously been recognized.[11] Thus, if a prior art reference discloses certain elements of a claimed invention, but the remaining elements are inherent features of a compound, process, or apparatus disclosed in the reference, the claim is anticipated.[12]

2. Obviousness

A patent claim may be found to be invalid even though each and every one of its limitations is *not* disclosed in a single reference if the

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[8] 35 U.S.C. § 102; *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002); *Elmer v. ICC Fabricating Inc.*, 67 F.3d 1571 (Fed. Cir. 1995); *Lewmar Marine, Inc. v. Barient, Inc*., 827 F.2d 744, 747 (Fed. Cir. 1987).

[9] *See Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1188 (Fed. Cir. 2002); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434 (Fed. Cir.), *cert. denied*, 488 U.S. 986 (1988).

[10] *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001); *Scripps Clinic & Research Foundation, Inc. v. Genentech, Inc.*, 927 F.2d 1565, 1568 (Fed. Cir. 1991) (*citing Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986).

[11] *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1109 (2002); *Continental Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268 (Fed. Cir. 1991); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002), *cert. denied*, 538 U.S. 907 (2003); *In re King*, 801 F.2d 1324 (Fed. Cir. 1986); *Harris Corp. v. IXYS Corp.*, 114 F.3d 1149, 1153 (Fed. Cir. 1997); *Verdegaal Brothers, Inc. v. Union Oil Co.*, 814 F.2d 628 (Fed. Cir.), *cert. denied*, 484 U.S. 827 (1987); *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

[12] 35 U.S.C. § 103(a); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *Tyler Refrigeration Corp. v. Kysor Industrial Corp*., 777 F.2d 687 (Fed. Cir. 1985).

differences between the claimed invention and the combined 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."[13] In line with this statutory standard, case law provides that test for determining the obviousness of a claim is: (1) a showing of a suggestion, teaching, or motivation – to one of ordinary skill in the art and found within the prior art – to have combined the teachings of the prior art references, and (2) a reasonable expectation of success.[14]

A patent's validity may be challenged using art considered by the patent examiner, but the burden of establishing invalidity is stated to be less easily carried.[15] Nevertheless, the extent of deference to be accorded the determination of the patent examiner is related to the evidence that it had before it.[16] A court, being the final arbiter of a patent's validity, may thus decide this question without deference to the conclusions of the patent examiner.[17]

3. Lack of Enablement

A patent claim is invalid if the patent fails to enable those of ordinary skill in the art to make and use the invention that it claims.[18] The enablement requirement is met if the description of the invention provided in the patent enables *any* mode of making and using the invention.[19] Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the level of skill on the date that the patent application was filed.

Importantly, a claim must be enabling for its full scope.[20] Thus, the specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.[21] A patentee may satisfy the enablement requirement even if some experimentation is required to practice the claimed invention, however, if a patentee has obtained claims that are not reasonably commensurate with the scope of the patent's disclosure, such that *undue* experimentation would be required to practice a claimed invention, the affected claims are properly declared invalid for lack of enablement.[22]

Whether the practice of a claimed invention would require undue experimentation requires the weighing of the ***Wands*** factors: (1) the nature of the invention; (2) the relative skill of the art; (3) the state of the art; (4) the breadth of the claims; (5) the amount of direction or guidance provided by the patentee; (6) the presence or absence of working examples; (7) the quantity of experimentation necessary; and (8) the

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[13] 35 U.S.C. § 103(a); see also *Graham v. John Deere Co.*, 383 U.S. 1, 13 (1966); *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999).

[14] *In re Dow Chem.*, 837 F.2d 469, 473 (Fed. Cir. 1988). *See also Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000); *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996); *In re O'Farrell*, 853 F.2d 894, 903-904 (Fed. Cir. 1988); *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

[15] *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1353, 1356 (Fed. Cir. 2001); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760 (Fed. Cir. 1983).

[16] *Mendenhall v. Cedarapids, Inc.* 5 F.2d 1557 (Fed. Cir. 1993); *see also Ultra-Tex Surfaces Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000).

[17] 35 U.S.C. § 112, first paragraph; *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991).

[18] *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999); *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970), *In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[19] *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003); *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991).

[20] *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993); *AK Steel Corp. v. Sollac*, 344 F.3d 1234 (Fed. Cir. 2003).

[21] *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[22] *Enzo Biochem.*, 188 F.3d at 1371; *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

predictability of the art and the breadth of the claims.[23]

4. Inadequate Written Description

In order to be valid, a patent must provide a written description of the claimed invention.[24] The "written description" requirement serves a teaching function, as a quid pro quo in which the public is given a meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time. The requirement has two prongs. First, the patent must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation.[25] Second, it must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is being claimed.[26] The written description requirement is independent of the requirements that a patent enable one skilled in the art to make and use the invention.[27] Thus, it is possible for an invention to be fully enabled, and yet fail to comply with the written description requirement.[28] Compliance with the written description requirement is predicated upon the factual determination that the patent specification discloses to those of ordinary skill in the art a complete conception of the invention being claimed. Although complete conception is preferably demonstrated by the presence of working examples and by an actual reduction to practice of the full scope of the claimed invention, such demonstrations are not essential.[29] The descriptive text needed to meet the written description requirement varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.[30] Although satisfaction of the written description requirement is a question of fact, a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification.[31]

D. Special Defenses to Infringement

1. The "Research Purposes" Exception

United States law has long recognized a doctrine of experimental purposes as a defense to an assertion of infringement. Unfortunately, the doctrine has been commonly misinterpreted to suggest a blanket freedom to pursue research involving a patented process or machine free from the threat of liability.

Under the actual doctrine, a party who practices a patented will not be liable for infringement if the infringement is performed solely for intellectual purposes, and without any intent or effort to commercialize the invention. Thus, research that is conducted with an eye toward patenting, licensing or exploiting the products of the research may indeed create liability under the patent laws.

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[23] *Enzo Biochem.*, 188 F.3d at 1371-72; *In re Wands*, 858 F.2d at 736-37.

[24] 35 U.S.C. 112, first paragraph; *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002), *cert. denied*, 537 U.S. 1232 (2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

[25] *See Tyler v. City of Boston*, 74 U.S. 327, 330 (1868); *AK Steel*, 344 F.3d at 1244.

[26] *See O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320-21 (Fed. Cir. 2003); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005), *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004).

[27] *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *Rochester*, 358 F.3d at 920; *Hoechst*, 314 F.3d at 1330; *Gen-Probe*, 323 F.3d at 963; *Lilly*, 119 F.3d at 1559; *In re Ruschig*, 379 F.3d 990 (C.C.P.A. 1967).

[28] See, e.g., *Fiers*, 984 F.2d at 1164, *In re Di Leone*, 436 F.2d 1404, 1405 (CCPA 1971).

[29] *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006).

[30] *Capon*, 418 F.3d at 1357-58.

[31] *Rochester*, 358 F.3d at 927.

2. The 35 U.S.C. § 271(e)(1) Exception

35 U.S.C. § 271(e)(1) provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention "solely for uses reasonably related" to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The purpose of the statute is to address an anomaly resulting from the extensive review of pharmaceutical safety and efficacy conducted by the U.S. Food & Drug Administration ("FDA"). For a typical patented product, a third party seeking to compete with a patentee would be able to enter the market with its competing product immediately upon the expiration of the relevant patent. Although the third party would not be able to stockpile an inventory for sale until after the patent had expired, the time of manufacture for a typical product is relatively short. In contrast, prior to the enactment of 35 U.S.C. § 271(e)(1), a third party seeking to compete with the patentee of a pharmaceutical product/process would first need to obtain approval from the FDA before it could commence its sales. As such approval might take years to obtain, the interplay of patent and FDA statutes provided the patentee with a significant *de facto* extension of its market exclusivity. 35 U.S.C. § 271(e)(1) addresses this issue by providing that a third party can apply for pharmaceutical product approval during the term of a patentee's patent. Thus, the statute provides a third party with the opportunity to obtain such approval in time for it to commence its sales immediately upon the expiration of the patentee's patent.[32]

The elliptical language employed in the statute ("solely for uses reasonably related") has engendered substantial litigation. Of particular interest is the impact of this language on the value of "toolkit" patents. Such patents relate to methods or biologicals that facilitate the discovery and identification of new pharmaceuticals. As an example, the recognition that a virus infects a cell by binding to a particular cellular receptor suggests that an agent capable of blocking such binding might have anti-viral activity. As such, an improved process for purifying the receptor may facilitate the identification of an antiviral agent. Although for most inventions, the value received by the infringer in infringing the patent ends when the infringement ends, such a conclusion is not necessarily valid for "toolkit" patents. Returning to the above example, once a researcher has used the receptor to identify an anti-viral agent, it need never again prepare the receptor, and thus need never again infringe the patent. The infringer's value in infringing the patent continues and is reflected in the profits that it may derive from the sale of the identified anti-viral agent.

Since most biotechnology inventions have the ultimate goal of facilitating the development of improved diagnostics and therapies, it has been argued that infringement of "toolkit" patents would not be actionable as long as the resulting data were submitted to the FDA in the context of an application for a new therapy. The U.S. Court of Appeals for the Federal Circuit rejected this argument in *Integra*, holding that 35 U.S.C. § 271(e)(1) protected acts performed only after a new drug had been identified and did not protect the search for a new drug.[33] The U.S. Supreme Court, however, reversed the Federal Circuit's decision, concluding that 35 U.S.C. § 271(e)(1)'s exemption from infringement extended to all uses of patented inventions that were reasonably related to the development and submission of any information to the FDA.[34] Thus, under present U.S. law, the use of "toolkit" patents to search for a new drug is not an act of infringement if the information is used in the development and submission of information to the FDA. The value of toolkit patents has been significantly impaired by the Supreme Court's action.

[32] The FDA's review also serves to delay the launch of the patentee's product. 35 U.S.C. § 156 provides that the term of the patent may be extended to compensate the patentee for such loss.

[33] *Integra LifeSciences I, Ltd. v. Merck KGaA,* 331 F.3d 860 (Fed. Cir. 2003).

[34] *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193 (2005).

3. The "*De Minimis*" Use Exception

For accidental, occasional or *de minimis* use of a typical patented invention, Patent Law has developed a *de minimis* use exception which provides that use is not actionable. This result is consistent with the application of the *Georgia-Pacific* factors. Little or no royalty might be reasonable under circumstances of such accidental, occasional or *de minimis* use.

For *de minimis* activities that involve "toolkit" patents but which do not relate to the development and submission of information to the FDA, the holding of *Integra* would not appear to apply and significant royalty obligations may be incurred regardless of the brevity of any period of infringement. An actual negotiated royalty rate would depend on the probability that the screening assay would actually succeed in identifying the new therapeutic, on the therapeutic's value, on the availability and expediency of substitute approaches, etc. In sum, application of the *Georgia-Pacific* factors suggests that the reasonable royalty for the *de minimis* infringement of a screening assay claim could be substantial. Importantly, once infringement has been found, any convenient metric may be employed as a measure of the damages. Thus, the sale of the unpatented therapeutic could be used as a measure of the damages upon which the reasonable royalty would be based.

V. Patent Protection outside the United States

The laws affecting patent protection differ from country to country, and reflect diverse cultural, societal, and technological views regarding the protection of intellectual property. In a global economy, obtaining patent protection in foreign jurisdictions is often critical to commercial success.

Europe and Japan comprise the two most common regions in which foreign patent protection is sought. The patent systems of Europe and Japan differ from that of the United States in several salient characteristics. Both award patents to the first-to apply rather than the first-to-invent. Thus, in Europe and Japan, patenting is essentially a race to the patent office. A party that is even one day later than another party may lose all rights. Indeed, the application of the first party will be used as prior art to the second for all that it discloses. Thus, the second application will be patentable only if it describes some aspect of the invention that is not disclosed in the first application. A consequence of the first-to-file system is the absence of Interference Proceedings.

A second difference between the European/ Japanese systems and the United State's system is the application of strict novelty. In contrast to the one-year grace period provided under U.S. law, a patent in Europe or Japan will be barred if the invention was disclosed even one day prior to the application's filing date (or priority date).

The third salient difference in the systems concerns the inability to file continuation and continuation-in-part applications under the European or Japanese patent systems. One has only one chance to secure a patent on each invention.

A. The European Patent Convention

The acquisition of a patent in Europe has been simplified by the establishment of the European Patent Community ("EPC") in 1973. The present member states of the EPC are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hellenic Republic, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Monaco, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom. Albania, Bosnia and Herzegovina, Croatia, the Former Yugoslav Republic of Macedonia, Serbia and Montenegro (formerly known as the Federal Republic of Yugoslavia) recognize European patents and are expected to eventually join the EPC.

Under the terms of the convention, one files a single patent application with the European Patent Office. That application is searched and examined by a single searching/examining

authority that has the power to grant the application. Examination is for completeness of description, novelty, non-obviousness ("mental step"), and utility ("industrial applicability").

The application is published approximately 18 months after its priority date. Parties that oppose the grant of the patent may initiate *inter partes* opposition Proceedings to argue against the grant of the patent. Such Proceedings may be quite extensive and very costly, since there is no limit to the number of potential challengers.

If an application survives opposition or is not opposed, it is granted. The EPC does not provide for a "European patent," rather, it provides a unified examination and processing system. After grant, an applicant must translate the application into the language of each country of the EPC in which patent protection is desired, and file the application in the respective patent offices of such countries.

The granted patents are enforceable for 20 years from the initial EPC filing date. Significantly, after grant, each patent is enforced under the laws of the particular country that issued it. Thus, in contrast to U.S. practice, there is no unified law in Europe relating to enforcement and infringement of patents.

B. The Japanese Patent System

The Japanese patent system has several unique attributes. It permits applicants to defer examination for up to seven years, and examination must be specifically requested. As in the European system, applications are published ("kokai") approximately 18 months after their priority dates. The examination process is similar to that of the U.S. system. Examination is for completeness of description, novelty, non-obviousness, and utility.

If the Patent Examiner finds no reason to deny grant of the patent, a post examination publication of the application occurs ("kokoku"). As in the European system, any person may lodge an opposition to the application. The Proceedings, however, are *ex parte* and thus differ from EPO Opposition Proceedings. Adverse decisions are ultimately appealable to the Tokyo High Court.

C. The Canadian Patent System

The Canadian patent system is similar to the European patent system. Patents are examined for the completeness of their disclosure, as well as the novelty, utility and non-obviousness ("ingenuity") of the claimed invention. Unlike the European system, Canada provides a one-year grace period in which one can still file an application even though the invention may have been publicly disclosed. Business methods and natural laws are unpatentable. Canadian patent applications are not automatically examined. Examination must be requested within five years of the Canadian filing date. Compulsory licenses may be granted in extraordinary situations (e.g., failure to meet demand, blocking trade, failure to grant reasonable licenses, etc.)

D. The Australian Patent System

The Australian patent system enjoys several similarities with the U.S. system. Provisional applications are permitted, as are continuation and continuation-in-part applications ("patents of addition"). As in the U.S. system, provisional applications never issue and automatically lapse after 12 months. Australia grants two kinds of patents: standard patents (having a 20 year term), and innovation patents having a more streamlined prosecution and an 8 year term. Applications are published 18 months after their priority date.

Examination is not automatic, and must be requested. Additionally, unlike the other patent systems discussed herein, the Australian system provides a final deadline date. All matters relating to patentability must be resolved by that deadline or the application will be deemed withdrawn. For standard patents, the deadline falls twenty-one months from the date of the initial Examiner's report. For patents of innovation, applicants have only a six month period.