PATENTS ARE GOOD MEDICINE FOR YOUR INNOVATIONS

Medical device development involves some of the most innovative and rewarding work, with direct impact on the lives of patients, doctors, and countless others working in the medical field. Not only are medical device improvements used to save lives, they are also used to improve quality of life, improve quality of care, and decrease costs. Because more often than not, the innovations can translate into lucrative returns, such innovations are ripe for intellectual property protection.

But, what kind of protection? *Intellectual property* is a term used to categorize a number of sometimes overlapping rights that protect different aspects of innovation. Utility patents are used to protect innovations in function or utility. Design patents and design registrations are used to protect innovations in the ornamental aspects of articles (e.g., aspects that are not purely functional).[1] Trade secrets are used to protect undisclosed advantages in processes or business practices. Copyrights are used to protect innovations in expressions (e.g., writings, sound recordings, artwork). Trade dress and trademarks are used to protect attribution as to a source (e.g., manufacturer, seller, innovator). Mask works protect the masks used in the manufacture of semiconductor chips.

Books have been written on each one of these types of intellectual property, and all aspects of even just one of them cannot be adequately covered in a short chapter such as this one. Thus, this chapter only provides an overview of and some comments on aspects of the procurement, distribution, and enforcement of utility patents and design patents/design registrations.[2] Although this article is U.S.-centric, some significant differences in some major foreign countries may be mentioned. The laws of each country of interest should be consulted to truly understand the rights, processes, and obligations associated with that country.

Further, the U.S. Patent Law was significantly changed in 2012 by the Leahy-Smith American Invents Act. [3] This chapter is written from the point of view of patents filed on or after March 15, 2013, as the prior law is not as applicable to current inventions, and is becoming less applicable overall.

What is an Invention?

A patent, albeit a utility patent or a design patent, protects an "invention." The Patent Statute[4] unhelpfully states that the term “invention” means "invention or discovery."[5] Further, the Patent Statute states that term "claimed invention" means the subject matter defined by a claim in a

[1] Examples are provided infra.
[2] The opinions expressed are those of the author and do not necessarily reflect the views of the Dentons US LLP or its clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice.
[3] Public Law 112-29 (Sept. 6, 2011).
[4] 35 U.S.C. Secs. 100, et seq.
[5] 35 U.S.C. Sec. 100(a).

patent or an application for a patent.[6] Perhaps a better way to think about it is the way the term "invention" is used in practice.

The actual subject matter protected by a patent is that which falls within the metes and bounds of the legal description of the invention, as set forth in one or more claims. A claim is a recitation of one or more features that combined are novel, non-obvious, and useful in view of the prior art (prior technological history as of a certain date).[7] To those in the patent world, the terms "invention" and the "claim" or "claimed subject matter" are interchangeable. Utility patents can have many different claims. For design patents, however, only one claim is allowed, and it must be directed to, essentially: "The ornamental design for [an article] as illustrated and described." Design registrations do not include claims. Thus, "invention" is that subject matter which is covered by a patent claim.

The United States uniquely focuses on inventorship as an aspect of patentability. The term "inventor" means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.[8] However, better conceptually is to consider that an inventorship entity consists of each person who contributes to the subject matter of at least one claim in a patent. The contribution involves the sole or joint conception of the inventive subject matter.[9] To complete the invention, it must be reduced to practice at which point it is ready for patenting either actually (e.g., successful experiments or prototypes) or constructively (by filing a patent application). The reduction to practice does not necessarily have to be accomplished by the inventor(s), as the reducer can simply put into effect that which was conceived by the inventors.

The misnaming of those who should be inventors can have critical consequences. There are many notable cases in which an inventor who contributed to the subject matter of one of the claims of a patent was omitted, and enforcement of the patent was derailed by the defendant's ability to procure a license from the unnamed inventor.[10] Thus, care should be taken in making the determination as to who should be named an inventor on a patent. It is better to err on the side of over inclusion than to err on the side of under inclusion.

Distinguishing Utility and Design Patents from Other Intellectual Property

Utility patents cover the functional and utilitarian features of any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. [11] A "process" is an act, or a series of acts or steps, or mode of treatment of certain materials to

[6] 35 U.S.C. Sec. 100(j).
[7] To be more exact, what the claims literally cover what is protected, yet the claims are given some latitude to cover equivalent subject matter under certain conditions. The doctrines and conditions are beyond the scope of this article.
[8] 35 U.S.C. Sec. 100(f).
[9] The manner in which joint conception is determined is beyond the scope of this article.
[10] See, e.g., Ethicon v. U.S. Surgical, 135 F.3D 1456 (Fed. Cir. 1998).
[11] 35 U.S.C. Sec. 101.

produce a given concrete result. It may result in the transformation of a thing from one state to another.[12] A "machine" means any mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.[13] A "manufacture" is an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery.[14] A "composition of matter" includes all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.[15] Utility patents have a term of 20 years from the earliest effective filing date.

Examples of medical device utility inventions include apparatus such as MRI machines, hospital beds, syringes, surgical blankets, surgical devices, to name a few. Machines with innovative programming are also patentable, although programmed general purpose computers typically are not, unless the programming includes innovations resulting in more efficient operation of the computer, or innovative data structures. As of this writing, the eligibility of software-based inventions is highly unresolved in the United States due to a series of Supreme Court decisions,[16] but likely will play out over the next few years either in further court decisions, or new legislation.

Many foreign jurisdictions also have "Utility Models," or "Petite Patents" which typically are not subject to substantive examination, and which have lesser protections and much shorter terms, for e.g., of 5 or 10 years. Utility models can be restricted to certain arts such as mechanical or electrical inventions, or even shapes. Usually they are sought for inventions of lesser importance. These can be in addition to regular patents or in lieu of regular patents. Given the wide variation in laws around the world, they are not further discussed in the his article. However, they should be borne in mind with seeking appropriate protection for an innovation.

Design Patents cover the visual ornamental characteristics embodied in, or applied to, an article of manufacture. Such characteristics are the configuration or shape of an article, the surface ornamentation applied to an article, or a combination of configuration of an article and a surface ornamentation applied to the article. As such, designs may consist of three dimensional features, such as the shape of an article, or two dimensional features, such as patterns or lines, or color. Note that surface ornamentation need be inseparable from the article to which it is applied and cannot exist separately from a surface of an article. Design patents have a term of 15 years from the date of grant.

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[12] 35 U.S.C. Sec. 100(b). See also, Manual of Patent Examination Process Sec. 2106 I. 1.
[13] Manual of Patent Examination Process Sec. 2106 I. 1.
[14] Ibid.
[15] Ibid.
[16] Bilski v. Kappos, 561 U.S. 593 (2010); Alice Corp. v. CLS Bank International, 573 U.S. __, 134 S. Ct. 2347 (2014); and progeny.

A great example of a design patent for a medical device is Zimmer, Inc.'s groove pattern on a femoral hip stem prosthesis.[17]

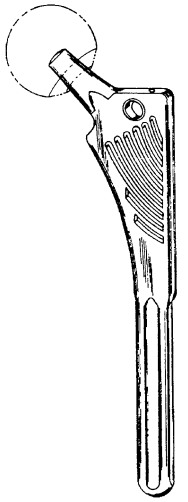


FIG. 1

In the United States, both utility and design patents issue only after a substantive examination process to determine the patentability of the claimed subject matter and compliance with disclosure requirements. This is not true in all other countries, mostly for designs. In many other countries, designs are registered without substantive examination, leaving the question of enforceability and what exactly is protected unresolved until there is a court action. In some, substantive consideration of utility patents are also deferred until the time of enforcement.[18]

Unlike some other forms of intellectual property, patents offer protection even against independent development by third parties. That means that non-awareness of a patent is no defense to infringement, although it might be to a charge of indirect or willful infringement. Thus, patents can pose significant barriers to market entry because it behooves a third party to spend money to research the patent landscape before embarking on a development project, and to design around problematic patents when possible.

What Does a Patent Consist of?

A utility patent consists of three major sections: The specification, the drawings (if any), and the claims. The specification explains in writing the innovation. It usually contains background information to provide context to the innovation and generally must meet three distinct requirements. In the U.S., it must provide (a) a written description of the invention; (b) the manner and process of making and using the invention (the enablement requirement); and (c) the best mode contemplated by the inventor of carrying out the invention at the time the patent

[17] U.S. Patent Des. 364,926.
[18] The Republic of South Africa is a good example of this.

application is filed. Note, however, other countries typically do not have a best mode requirement. Again, the claims define the metes and bounds of the exclusive subject matter protected by the patent. And the drawings, of course, are used to better explain the invention, and support the old saying that "a picture is worth a thousand words," as they can reduce the need for much written explanation.[19] It is best for the specification and the claims to use the same terms as this helps prove that the specification provides the proper written description.

Design patents and design registrations consist mostly of drawings comporting to the standards of each country. In the U.S., each design patent concludes with solely one claim for the ornamental design as illustrated. Design registrations do not require a claim.

Cost Considerations

As general rule, the cost to obtain a utility patent can run tens of thousands of dollars (U.S.) in one country alone. The cost will depend on the type of invention - those that are extremely simple will cost considerably less than highly complex inventions. Pursuing protection around the world can increase that number to well over a million dollars, especially if a blanket-the-earth approach is taken. Design patents and registrations cost much less, but then also provide very limited protection, as explained below. And, as mentioned above, utility models can provide some limited protection for much less cost. As such, a thorough cost/benefit analysis is appropriate before seeking patent protection for medical devices.

That said, however, besides seeking to protect a market advantage, patents, to an extent, can provide a validation of innovation, and thus serve as a reputation enhancer. This too can be good for marketing. In a similar vein, they can serve for recognition purposes among peers. Yet further, they can serve as a vehicle for determining recognition for inventor compensation purposes, supposing named inventors are compensated more than non-inventors for work on a project, such as a new medical device.

Below are the basic steps which are undertaking to obtain a patent.

Seeking a Patent

Keep It Confidential and Document It

Various actions taken or not taken can affect the ability to secure patent or design rights. Most notably, non-confidential disclosure before filing of an application will be fatal to utility patent protection in most countries around the world. The United States and a handful of countries do provide a public self-disclosure grace period of from 6 months up to one year, i.e., one's own disclosure will not bar the patent, but as a general rule, relying on such a grace period should be a fallback position, rather than a practice. Other countries, such as those in the European Union,

[19] Indeed, in Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991), the Court of Appeals for the Federal Circuit held that circuit diagrams could serve as the written description.

do not recognize such grace periods. It is advisable to keep all inventions confidential at least until an application is on file with a patent office. Interestingly, most countries provide a one year grace period for public self-disclosure for designs.

To keep disclosures non-public, all disclosures prior to filing of a patent application should be the subject of a written and mutually signed non-disclosure agreement (NDA). Although different situations may require different terms, for the most part, NDAs use similar, if not the same, terms. NDAs should be used especially when approaching possible partners.

Public disclosure can take many forms with trade shows, seminars, and publications being the most prevalent and problematic because they tend to involve fuller disclosures. Offers for sale raise additional problems regardless of the amount of disclosure, at least currently.

Gather the Documentation

What is needed to prepare a utility patent application? Whether the application is a provisional or non-provisional application, or their equivalents outside of the U.S., the more robust and complete the disclosure, the better will be the application. Thus, in order to prepare a good patent application, it is advisable to gather together, and, if need be, or useful, generate, as much written material and drawings that can be used to describe the invention and variants thereof. This information then is used to prepare the application.

Consider Searches

A search for relevant prior art is optional, but advisable. A search can help sharpen the focus of the invention and also, possibly, expand the application of the invention, by expanding the background of the invention. At the same time, a search might uncover potential pitfalls such as prior art that could pose an impediment, or force a redesign. Some corporations have in-house departments that conduct such searches, while most outsource such searches to search firms that specialize in these types of searches.

Prepare and File the Application

Individuals can prepare and file patent application in the United States pro se, i.e., on their own. This is not recommended. Regardless of who prepares the application, it must conform to the statutory disclosure requirements. Further, the better applications take into account future litigation concerns and the body of legal precedent that has developed over the last 300 years or so. Thus, it is highly recommended that individuals engage a competent patent practitioner to prepare and file the patent application.

Juristic entities such as corporations, partnerships, etc., must be represented by a registered practitioner such as a registered patent attorney or a registered patent agent.

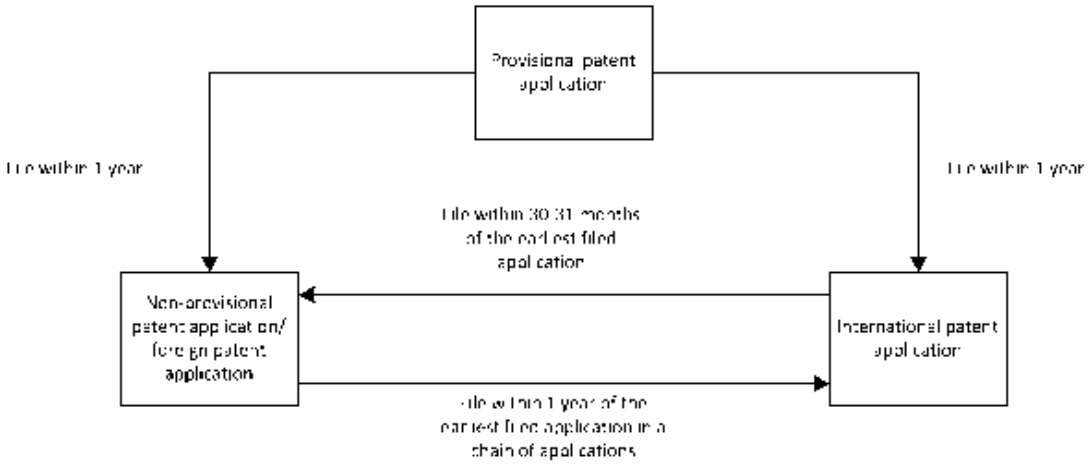
Where to File First?

There are various schools of thought and various different consideration to take into account when deciding where to file the first patent application. First and foremost, if an invention is made in the United States, if the first filing is not made in the United States, all rights to patent protection in the United States are lost. Further, filing outside of the United States is not permitted until granted permission to do so by the United States Patent Office. This permission is provided in the what is called a Foreign Filing License (FFL). FFL's typically are provided very quickly on the filing receipt, but sometimes there can be a delay. While some other countries also have laws requiring first filing in the country where the invention is made, most do not. The purposes of the FFL process is to allow the USPTO (and other agencies such as the Department of Energy and the Department of Defense) the opportunity to prevent the unwanted disclosure of certain types of technologies, such as those relating to nuclear energy or weaponry.

In any event, the first application can be filed in the United States with the USPTO under three scenarios. First, the application can be filed a provisional application. Second the application can be filed as a non-provisional application. Third, the application can be filed as an international application with the United States being the receiving office.

In all three scenarios, it is advisable to have a very robust disclosure that fulfills at least the statutory disclosure requirements. A provisional patent application might be viewed as more informal in nature and is not subject to substantive examination, but, to rely on one later for priority purposes, it is necessary for the provisional application to fully support the claims of the follow-on application. As such, the cost to prepare the application, the largest cost being attorney and draftsman fees, is roughly the same for these different types of applications.

Below is a simple flow chart setting forth the basic times for filing the different applications. Bear in mind that any can be the first filed application.



It should be noted that when filing a non-provisional application, there are options, with added fees and effort, that can speed up the examination process. These fees vary upon the size of the entity (micro (i.e., individual or university inventor with a limited number of other applications), small (a university or business with less than 500 employees), or large (a business with more than 500 employees)). These options are not detailed herein except that they might be worth the cost if speed is of the essence, for example, for a start-up seeking to establish a portfolio quickly to encourage funding.

Duty of Candor

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Patent Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability.[20] While materiality is described in the Patent Office regulations, it basically boils down to a need to disclose information that an examiner would consider important.[21] Thus, with or without a search, all information known to any of those involved in the preparation and examination of the patent application that would be material to the examination of the application should be gathered for submission to the patent office. Such individuals include the inventors, the patent lawyer/agent, and any other person substantively involved in the preparation and protection of the patent application. Intentionally withheld material information such as very good prior art, prior sales, or prior disclosures can give rise to inequitable conduct. The tainting of a patent with inequitable conduct will render the patent unenforceable.

That said, US patent law was recently changed to allow patentees to correct their failure to bring to the attention of the USPTO information material to the examination of their patent. There is now a window of opportunity after the grant of a patent during which a patent can be reexamined with the information considered, if it presents a substantial new question as to the patentability of a claim. This procedure is called a Supplemental Examination.[22] The type of information that can be considered is not defined, and is left open ended.

With all of the above noted materials providing a well-documented and good description of the invention, a patent practitioner, can prepare the specification and drawings suitable for filing. The goal is not only to capture what was conceived, but to also hypothecate the extent to which the invention might be applied. This helps the practitioner, together with the inventors, to

[20] 37 C.F.R. Sec. 1.56.

[21] 37 C.F.R. Sec 1.56(b) provides that " information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability."

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[22] 35 U.S.C. Sec. 257

develop claims that cover not only that which was specifically conceived, but also possibly more general applications.

In the US, the stated disclosure requirements for design patents are the same as for utility patents. However, as a practical matter, there is no elaborate written description, rather the written description is minimized to very terse summary descriptions of the various views. Since the drawings define the invention, it is very important to have good drawings showing all of the views of what is to be protected. It is also important to show what is not protected, and this is accomplished by using broken lines to exclude portions. Some countries, notably China, do not permit shading in the drawings.

The Examination Process

With all of the disclosure materials available, an application can be prepared and filed with the Patent Office. In foreign jurisdictions, design registrations are usually filed in different offices, since they are not subject to substantive examination. China is notable in protecting designs through design patents, but deferring examination until enforcement.

Regardless of country, the first filing is considered the priority application. In the US, for utility patents such an application can be a provisional application or a non-provisional application, the difference being that a provisional application is not subjected to substantive examination of any kind and expires after one year while a non-provisional application is subjected to full examination.

Note, however, the some countries, and the United States in particular, require that a patent application for an invention made in that country, be first filed in that country. Taking the U.S. as an example, foreign counterpart filings are prohibited until permitted by the USPTO. Failure to obtain permission, in the form of a foreign filing license, results in the loss of all U.S. patent rights to the subject matter in the application. Further, if the disclosure contains information subject to technological export restrictions there could be liability for violating those restrictions as well.

Happily, the USPTO generally issues foreign filing licenses within a few days. It is rare for a patent application foreign filing license review to get held up for greater scrutiny, and even rarer that a secrecy order is imposed.

Pursuant to various treaties, such as the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, Substantive Patent Law Treaty, and The Hague System for the International Registration of Industrial Designs, it is possible to file counterpart patent and design applications in other countries and obtain the benefits of the filing date of the first-filed application. This means that counterpart applications can be filed, but prior art published, and any public disclosure occurring after the earliest filing date cannot be used against the counterparts.

To take advantage of these treaties, counterpart utility patent applications must filed within one year from the filing date of the priority application. For design patents and registrations, the rule is stricter. Applicants have only 6 months to file counterpart design patent applications or registrations.

In addition to filing a counterpart application directly in another country, there are several regional offices where is possible to obtain examination of a patent application for countries that have banded together. The notable regional offices are the European Patent Office (EPO) which covers some 40 countries in Europe, including the United Kingdom post Brexit; African Regional Intellectual Property Organization (ARIPO) which covers some 17 countries; the Eurasion Patent Office (EAPO) which covers Russia and former Soviet Socialist Republics; the African Intellectual Property Office (OAIPO) which covers another 17 countries in Africa; and the Gulf Cooperation Council Patent Office (GCCPO) which covers 6 major Arab countries. Indeed, some countries do not provide for direct filings, rather, patents must be sought through their regional patent office.

It should be noted that international applications (PCTs) do not in and of themselves result in patents. Rather they are mainly used to extend the time for filing counterparts in other countries. Secondarily, they can be used to obtain prior art searches in different countries. Pursuant to the Paris Convention, just about all countries afford an applicant one year from the first filing to file a counterpart application. However, using the Patent Cooperation Treaty, it is possible to extend that to, in most cases, 30 months.

The examination of patent applications is usually straight forward. The patent office will search for prior art to see if the claimed innovation was previously disclosed or obvious from what was previously disclosed. The patent office will also consider whether the disclosure requirements are met.

Over the course of the examination process, the patent office will issue actions in which the office raises objections and/or rejections or allows the application. Sometimes the patent office will also require restriction of the application claims to less than all of the inventions that might be set forth in the claims. The applicant is afforded a specific period of time to respond to each such action. The United States is either unique or among very few countries that permit the examination process to go on, essentially indefinitely. In most countries, only two actions may issue, in an up-or-out approach.

Pre Grant Challenges

Generally, in the U.S. Patent system, third parties cannot interfere with the examination of a patent. Challenges to pending applications are not permitted. However, third parties can file a pre-issuance submission that explains the factual relevance of identified prior art printed publications to pending claims. The submission window is limited to a time period following the

publication of the application. Since 2012, the U.S. has provided for post grant challenges, which are discussed below.

Other countries, notably the European Patent Office, provide third parties a period for opposing the grant of a patent, once the office has determined that a patent should be granted.

Issuance

Once an application is found to have allowable claims, the applicant will be notified and given a date certain to pay an issue fee. Patents generally issue about a month or two after the payment of the issue fee. However, applicants will be given a heads up as to the date of issuance so that follow-on applications (e.g., continuation or divisional application) can be filed in time.

Patent Reissue

Should it be determined that a major mistake is present in an issued patent, such as the a claim being too broad (and hence invalid in view of prior art), too narrow (too many limitations, or too ambiguous), a reissue proceeding can be instituted to correct the error. There are other errors than be corrected as well. A reissue application cannot be filed to recapture claim scope specifically surrendered during the examination of the patent, although such scope can be pursued in a follow-on application filed during the pendency of the original patent application.

However, it should be noted that a reissue to broaden a claim must be filed within **two years** of the issuance of the patent. All other reissues can be filed anytime during the life of the patent. Further, it is possible for certain claim changes to give rise to intervening rights that preclude recovery of damages preceding the issuance of the reissued patent, and, in some rare cases, the issuance of an injunction.

Enforcement

Patent rights can be thought of as a bundle of rights. These rights basically include the exclusive rights to make, use, sell, within the United States, and import into the United States a patented invention.[23] Additionally, these rights also include the exclusive right to import into the United States products made by patented processes.[24] There are also some rights specific to pharmaceuticals and the like to accommodate the submission of applications for new and follow on drugs and biologics pursuant to what is commonly known as the Hatch-Waxman Act.[25]

[23] 35 U.S.C. Sec. 271(a).
[24] 35 U.S.C. Sec. 271(f).
[25] The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), the relevant portions of which are at 35 U.S.C. Sec. 271 (e).

Although the U.S. Supreme Court has watered down the right to exclude others from practicing the invention, it still remains the strongest right.[26] The threat of being excluded, especially after the expenditure of much money can lead many a defendant to compromise and take a license rather than fight a lawsuit. Although, by statute, a victorious patent owner is entitled to "no less than a reasonable royalty"[27] as damages, lost profits are available in some situations, e.g., where it is proven that sales were lost. Further, when there is a finding of willful infringement, the law allows the court to increase the amount awarded by up to three times to ensure appropriate compensation.[28] And, increasingly, attorney fees can be awarded.[29] Design patents are afforded the choice of seeking an infringer's total profit as an alternate remedy.[30]

Patent rights are enforced ultimately by threat of court action. In the U.S., patent enforcement actions are exclusive to the federal court system. Some countries have specialized courts that handle such actions. However, only a very low percentage of infringement disputes are actually resolved by a court. Instead, most actions are resolved through negotiation (settlement), mediation, or arbitration.

During the enforcement of a patent, the claims are subjected to a construction or interpretation process in which the parties work to establish the meaning and scope of the claims. As can readily be appreciated, patentees typically seek broad claim constructions so that the claims read on and cover more products and acts, whereas alleged infringers seek the converse. Sometimes, however, in order to avoid prior art, patentees will seek narrower claims constructions while the alleged infringer will seek the opposite.

The doctrines and law under which these positions are argued are not discussed herein. However, the law continues to evolve, and the determinations are context dependent. In essence, claims are given a scope encompassing that which the interpreted words directly read upon (literal infringement), and insubstantial differences as determined by the doctrine of equivalents (equivalents infringement). The doctrine of equivalents analysis is applied to individual claim limitations, not to the invention as a whole. The equivalents encompassed by the doctrine of equivalents is limited by that which was given up (i.e., disavowed) during the examination process.

For design patents, the claim scope is determined by the infringement test. A design patent is infringed if in the eyes of an ordinary observer, the observer would consider the accused design to be substantially the same as the patented design, considering both in view of the relevant prior

[26] In eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006), the Supreme Court held that injunctions are not automatically awarded in patent actions, rather whether to issue an injunction should be based on a four-factor test.
[27] 35 U.S.C. Sec. 284.
[28] Id.
[29] 35 U.S.C. Sec. 285. In Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. ___ (2014) and Highmark Inc. v. Allcare Health Management Systems, Inc., the Supreme Court made fee shifting a bit easier by laying out bases for doing so, such as frivolous positions.
[30] 35 U.S.C. Sec. 289.

art.[31] Thus, a design patent covers exactly what is illustrated in the drawings, as well as that which is visually substantially the same.

In addition to direct infringement, patents can be indirectly infringed by those how contribute to or induce direct infringement. The determinations of liability for such infringement are complicated, and fact dependent. But suffice it to say that the law does accommodate liability for various participants in an infringement.

Outside of the United States, the tests are similar, but usually narrower, especially for designs. Usually, nearly identical designs are needed for infringement. Some, systems, such as countries in Europe, will hew more closely to the disclosure when looking at infringement, making infringement by equivalents less likely to be found.

Since 1982, all patent litigation appeals are heard by a single court, the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). This is to provide country-wide uniformity to patent law. While many countries in Europe continue to develop a unified patent that can be enforced across those countries and a court system for enforcing such patents, as of this writing, it still is not implemented.

Post-Grant Review

Post-grant review is a proceeding that allows a party to challenge a patent within nine months of issue on a broad undefined basis. A challenger may attack a patent on virtually any basis that is available in an invalidity case at trial. Post-grant review is available only if the challenger has not already initiated a civil action in district court to challenge the patent. (Such a limitation does not apply to counterclaims.) To initiate post-grant review, the challenger must show that at least one claim is more likely than not to be deemed unpatentable. The merits are decided by the Patent Trial and Appeal Board ("PTAB"), and both parties may appeal final decisions to the Federal Circuit.

***Inter partes* Review**

Inter partes review is a process under which the USPTO allows third parties to challenged issued patents. An IPR may be requested at any time during the life of a patent beginning nine months from issuance, provided that the requesting party has not previously challenged the validity of the patent in a civil action and was not sued for infringement more than a year prior to the request. The scope of review is more limited than under post-grant review. Only patents and printed publications may be used to challenge the target patent. To initiate *inter partes* review, the challenger must establish a reasonable likelihood that he or she will prevail on at least one claim. The merits are decided by the PTAB, and both parties may appeal final decisions to the Federal Circuit.

[31] Gorham v. White, 81 U.S. 511, 528 (1871) and Egyptian Goddess, Inc. v. Swisa, Inc., 5543 F.3d 665 (Fed. Cir. 2008).

Ex Parte Reexamination

Ex parte reexamination may be initiated anonymously and requires the patent challenger to introduce patents or printed publications that raise a substantial new question of patentability. The challenger's participation is limited to the filing of a petition to request institution of the reexamination, and reply should the patent owner file a response to the petition. The patentee may appeal adverse decisions to the Eastern District of Virginia or the Federal Circuit, but the challenger may not.

Distribution of Rights

In the United States, patent rights vest first in the inventors. Absent any assignment, an inventor remains a full owner of an undivided interest in the entire patent, no matter how small their contribution. Outside of the U.S., ownership often vests in an employer, with possible residual rights in the inventor should the employer decide not to assume the invention. The distinction is important, because, as mentioned previously, if someone who is an inventor, is omitted as an inventor on the application, it is possible for an infringer to derail a lawsuit or otherwise acquire rights from the unnamed inventor, after proving that the person should have been named in an inventor. The same result can occur if an assignment of rights is not obtained from all inventors.

Patent rights can be thought of as a bundle of rights that can be transferred or share as the bundle, or individually. In the most straight forward case, patents are assigned and all rights are transferred. However, it is possible to assign a patent and hold back some rights.

In any event, in nearly all situations, a patent owner is free to divvy up the patent rights in most any manner, e.g., by field of use, quantities, specific use, to list a few. This means there is great leeway to devise different licenses for different situations and licensees. Of course, the converse is that licensees are not entitled do similar licenses in most situations.

Patents that cover industry standards (also referred to Standard Essential Patents) are different. Standards organization typically require participants to agree to license their patents on what is known as FRAND requirements. This means that the patents must be licensed on a fair, reasonable, and non-discriminatory (in the market sense) basis. The determination of what factors constitute FRAND has been the subject of much debate, although recently some court decision have thoroughly explored the factors and provide much guidance in this area.

The same is true for licenses. Some or all of the rights can be shared with others.

Monitoring

There are two basic perspectives for monitoring of patent rights. One is monitoring of patents by potential infringers/defendants. The other is monitoring by the patent owner. These have different considerations.

Monitoring by patent owners

It is not necessary that patent owners monitor the market for potential infringers. However, it can help them improve the chance of identifying potential infringers earlier rather than later. The Patent Statute allows recovery of damages for up to 6 years in some circumstances prior to a proper notice of infringement. Unfortunately, once a patent owner become sufficiently aware of a potential infringer, they need to take some action else potentially lose the ability to do anything about it. Sleeping on one's patent rights can give rise to laches, an equitable doctrine which prevents recovery of damages. Also, a patent owner needs to be careful what they say or imply as giving the wrong impression regarding enforcement can prevent enforcement altogether under a legal doctrine of estoppel.

Monitoring by Potential Infringers or Competitors

Monitoring by a potential infringer or competitor can be a different type of two-edged sword. On the one hand, one can learn of a potential problematic patent early and possibly avoid it with a design-around, especially before much is expended on the development and marketing of a new product. On the other-hand, discovery of such a patent can give rise to a finding of willful infringement, which can lead to treble damages and more, if there is no good design around or invalidation.

Also, monitoring can be useful if one is aware of a pending application and wishes to file a third party preissuance submission in the US , or file an opposition elsewhere. Given the limited time frames when such actions can be taken, it is helpful to learn about the opening of the time periods so as to have ample time to prepare and file the required documents.

Many companies employ outside providers who can monitor patents as they issue and/or the existing patent landscape, using key word searching and the like to provide some degree of monitoring. Others may have in house staff who are capable of performing this function.

Are patents worth all this hassle?

Prior to 1982, patent litigation was not as prevalent as it is today, and the appeals were heard in the different United States Courts of Appeal. This resulted in splits in the law among the different courts with some exhibiting a pro-patent bent, and others exhibiting either an anti-patent bent, or at a non-supportive bent. However, that changed in 1982 with the creation of the Federal Circuit which was given exclusive jurisdiction over appeals of patent matters.

The Federal Circuit developed a body of case law including rules and doctrine under which crucial determinations of claim interpretation/construction, burdens of proof, burdens of providing and relying on opinions of counsel, and non-literal infringement, to name a few. This strengthened patents, and, naturally, increased the value of patents. The increase in the value

garnered the interest of investors and plaintiff's attorneys who then greatly increase the amount of patent litigation, and market for patents.

However, this increase in patent litigation and assertion of patents produced a backlash that took many forms. The Patent Statue has twice been amended in substantive form to address perceived problems. Notably, most patent applications are published and made public after 18 months from filing and expire 20 years after filing, thus addressing the alleged inequity of patents coming out of secrecy many years after the adoption of critical and/or widely adopted technology. Further, the United States transitioned from a first to invent regime to a first inventor to file regime, thereby addressing an perceived concern with the definition of the body of prior art, and related expense with ambiguities in the prior definition.

Increasingly the United States Supreme Court has weighed in and accepted appeals in patent appeals. The Supreme Court has reversed some important decisions by the Federal Circuit. The result has been a weakening in all patents due to the increase in power handed to defendants. Notably, victorious patentees are not automatically entitled to injunctions, instead each must prove that the circumstances of the case favors an injunction.[32] Further, the Supreme Court has issued decisions that deemed various types of patents, such as those directed to business methods, notably financially related products, many diagnostic methods, and many computer software related patents unpatentable as directed to judicially created exceptions such as abstract ideas or naturally occurring phenomenon.[33] Thus, the pendulum of patent power has swung backward considerably.

Coupled with the foregoing, the America Invents Act made the keeping secret of some technology attractive. This usually concerns in-house processes and non-publically discoverable software applications. The result is that one seeking to protect medical device technology, including designs, should consider a myriad of factors before embarking on the patenting path.

That said, if the technology is being made public, or is easily reverse engineered or discoverable, and concerns a sufficiently lucrative product, it typically will make sense to obtain one or more patents covering aspects of the technology. This will provide at least a fighting chance to stave off others from exploiting the technology for their own advantage, and to protect one's market.

[32] ebay, Inc. v. MercExchange, LLC, 547 U.S. 388 (2006).

[33] See, e.g., Alice Corp. v. CLS Bank International, 573 U.S. __, 134 S. Ct. 2347 (2014) (claims for computer-implemented escrow services deemed abstract); Bilski v. Kappos, 561 U.S. 593 (2010) (claims for a method of hedging losses deemed abstract) ; and Mayo v. Prometheus, 132 S. Ct. 1289 (2012)(claims for a method of giving a drug to a patient, measuring metabolites of that drug, and with a known threshold for efficacy in mind, deciding whether to increase or decrease the dosage of the drug deemed drawn to a naturally occurring phenomenon).