

PATENTS OVERVIEW



LEGAL AND REGULATORY AUTHORITY FOR PATENTS

United States patents are regulated by the United States Patent and Trademark Office (the “USPTO”) under the authority of the federal Patent Act, which was enacted in 1952 and significantly amended on September 16, 2011 by the Leahy-Smith America Invents Act (the “AIA”).

The United States Court of Appeals for the Federal Circuit (the “Federal Circuit”) has exclusive jurisdiction to hear appeals: from decisions by the USPTO concerning the patentability of a pending application or issued patent and of patent infringement cases, which may not be brought in state court.



PATENTABLE SUBJECT MATTER

The USPTO grants three types of patents under the Patent Act: utility patents protect "useful" inventions that are "novel" and "non-obvious", including: processes, machines, manufactured goods, chemical, biological, and other compositions of matter, improvements to any of the above; design patents apply to new, original, and ornamental designs of manufactured articles, which can also be subject to copyright and trademark protection (known as registered designs in some other jurisdictions); and, plant patents protect distinct and new varieties of plants (limited to those that can be propagated asexually, by means other than seeds and subject to other specific restrictions). Novelty and non-obviousness are central and complex requirements for valid patents under the Patent Act. The Supreme Court and the Federal Circuit have provided guidelines and standards for these concepts over time by various decisions upholding or invalidating particular patents.

For all patent applications, but not patents issued before September 16, 2011, the Patent Act specifically prevents the issuance of any patent covering tax strategies or human organisms. In addition, the courts have held laws of nature, physical phenomena, and abstract ideas to be unpatentable. However, abstract ideas, such as mathematical algorithms and business methods, may be patentable if the claims contain an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application of the idea.

HOW PATENT RIGHTS ARE SECURED AND MAINTAINED

The USPTO grants patents on successful prosecution of patent applications covering the invention. A patent application can be filed personally by the inventor (or co-inventors). Under the AIA, a patent application may also be more easily filed by the inventor's assignee where the assignee cannot obtain the inventor's signature. A patent application is typically filed and prosecuted by a registered patent attorney or patent agent who is admitted to practice before the USPTO.

The AIA moved to a first-inventor-to-file system effective March 16, 2013. Under this system, a patent to an invention is awarded to the first inventor to file an application on the invention. Before the AIA, the patent would be awarded to the first inventor, generally based on the date of conception, regardless of the filing date of the application.

A proper patent application must:

- Disclose in detail one or more embodiments of the invention.
- Cite any relevant prior art of which the inventor is aware. However, there is no obligation to search for prior art.
- Enumerate specific claims to be granted. Those claims that are ultimately allowed become the basis for enforcement of the patent.

Patent applications are reviewed for patentability by a USPTO patent examiner in relation to:

- Novelty and non-obviousness of the invention, determined in reference to the prior art, whether: cited by the applicant; or discovered by the examiner in an independent search.
- Other statutory requirements for patentability.

HOW PATENT RIGHTS ARE SECURED AND MAINTAINED

A patent application is held by the USPTO in strict confidence unless and until the application is published or a patent is issued. To conform with international standards, the USPTO publishes most utility patent applications, if they are still pending, 18 months after the filing date.

The examiner can: initially reject the application (through formal office actions), to which the applicant can respond or Finally reject or allow the application after continued prosecution of the application.

Appeals from an examiner's final rejection of a patent application can be made to the USPTO's internal Patent Trial and Appeal Board (the "PTAB"), which replaced the Board of Patent Appeals and Interferences as of September 16, 2012, and further to the federal courts.

As of September 16, 2012, the patent applicant may also request that the USPTO conduct a supplemental examination after the patent issues to consider, reconsider, or correct relevant information in the earlier examination. Subject to certain limitations, a successful supplemental examination may prevent the patent from later being held unenforceable based on conduct in the earlier examination relating to that information.

As of March 16, 2013, under the AIA and the first-inventor-to-file system, the USPTO can conduct derivation proceedings to resolve disputes where an applicant of a later filed patent application claims that the applicant of an earlier filed patent application for the same invention derived the invention from the later applicant. Before the AIA, under the first-to-invent system, the USPTO conducted interference proceedings between conflicting applications (or between a pending application and a recently issued patent) to determine who was the first inventor.

THIRD-PARTY ADMINISTRATIVE PATENT CHALLENGES

Any person may use numerous mechanisms to challenge the validity of an issued patent in the USPTO, such as:

- Ex parte reexamination, which is based on prior art patents and printed publications. Any person at any time may request that the USPTO conduct a reexamination of a patent. The patent owner may also request reexamination to verify the validity of the patent.
- Post-grant review, which can be based on any ground allowed under patent law. Any person, except the patent owner, may file a petition to institute a post-grant review. A petition for post-grant review must be filed within nine months after the patent issue or reissue date.
- Inter partes review, which may be based solely on the ground that the challenged patent is not novel or is non-obvious in view of prior art patents or printed publications. Any person, except the patent owner, may file a petition to institute an inter partes review. The petition for inter partes review must be filed after the later of: nine months after the patent issue or reissue date; or the termination of any post-grant review of the relevant patent.
- Transitional business method patent post-grant review, which may only be instituted where a patent infringement claim has been asserted against the petitioner.
- Submission of information to the USPTO, which may be made by any person at any time and can include: prior art; and statements by the patent owner in federal court or the USPTO.

MAINTENANCE OF PATENT RIGHTS

Once issued, patents are subject to maintenance fees that must be paid to the USPTO in three installments at specified intervals over the term of the patent. Unlike trademark rights, maintaining patent rights generally does not depend on the patent holder exercising its rights or enforcing the patent against infringers.

Articles made or sold under a patent must be marked with the word patent or the abbreviation pat. and the assigned number or numbers. Otherwise, in an infringement action, damages are not awarded for any period of time before the infringer has actual notice of the infringement. This marking requirement may be satisfied by providing the patent number and product information on a publicly accessible website.

TRANSFER OF PATENT OWNERSHIP

Ownership of a pending patent application and any patent that issues from it originally vests with the inventor or inventors. However, the owner of a patent or patent application can transfer title or grant a security interest for value, and documents evidencing transfers and grants can be recorded in the USPTO.

SCOPE OF PATENT RIGHTS

A patent holder has the right to exclude others from: making the patented invention within the United States; using the patented invention within the United States; offering to sell or selling the patented invention within the United States; and, importing the patented invention into the United States.

For utility patent applications filed on or after June 8, 1995, a patent has a maximum duration of 20 years from the filing date of the earliest application to which priority is claimed, subject to any terminal disclaimers or patent term adjustments for delays, which may be caused by the USPTO during prosecution. Before a 1995 amendment of the Patent Act to conform with international patent standards, the maximum term of patents had been 17 years from the issue date of the patent.

A patent owner can license any of its rights to others on an exclusive or non-exclusive basis, subject to various terms and conditions agreed on by the parties, for example: license fees or royalties and restrictions based on time, territory or markets.

PATENT ENFORCEMENT

A patent owner can bring an infringement action in federal district court or, where the importation of infringing goods is involved, before the International Trade Commission (the “ITC”). The grounds of the action can be any of the following alleged activities by the defendant:

- Making, using, offering to sell, or selling within the United States, or importing into the United States, any invention covered by the patent claims (literally or under the doctrine of equivalents).
- Importing into the United States a product made by a process patented in the United States.
- Inducing another entity to engage in direct infringement.
- Contributory infringement, defined as offering to sell, selling or importing a component of a patented product or a material or apparatus for practicing a patented process, where: the contributory infringer had knowledge that the component, material, or apparatus was either used or designed for infringement of the patented product; and the component, material, or apparatus does not have a substantial non-infringing use.
- Supplying in or from the United States components of a patented invention intending that the components be combined outside of the United States in a manner that would be inducement of infringement or contributory infringement if the combination occurred in the United States.

A defendant typically defends a patent infringement action by showing the patent is any one or more of the following: not infringed, invalid, or unenforceable due to inequitable conduct by the patent applicant.

PATENT ENFORCEMENT

A potential defendant to a patent infringement suit may also seek a declaratory judgment on any of the foregoing grounds. In addition, the following defenses may be available to a defendant in a patent infringement action:

The allegedly infringing use of a drug or medical device was solely for purposes reasonably related to developing and submitting information under a federal law to a federal regulatory agency.

The challenged business method was already in use before the effective filing date of the patent. This defense also includes certain manufacturing processes in connection with patents issued on or after September 16, 2011.

The patent rights are exhausted for a later disposition of a patented article that was lawfully acquired from the patent owner or an authorized licensee.

The alleged infringer is a physician or related healthcare entity practicing a medical activity.

- Equitable defenses, including laches and estoppel, may also be available.

The following remedies are available in patent infringement actions: preliminary and permanent injunctions; direct damages, including lost profits or reasonable royalties; and enhanced (treble) damages and attorneys' fees for willful infringement.