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IN FOCUS

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Patent Law: An Introduction and Issues for Congress

Patents, a form of intellectual property, give their owners certain exclusive rights in new and useful inventions. To encourage innovation, the Constitution gives Congress the power to grant patents to inventors for a limited time. Patents have been a part of federal law ever since Congress enacted the first Patent Act in 1790.

Patents play a critical role in many industries, such as pharmaceuticals and computer technologies. The U.S. Patent and Trademark Office (USPTO) estimated in a 2022 study that utility patent-intensive industries contributed $4.4 trillion to the U.S. GDP and directly employed 18.2 million people in 2019. In light of patents' effect on innovation and technological competitiveness, Congress often considers amendments to patent law. This In Focus provides an overview of patent law and highlights potential areas of congressional interest. (For more detail, see CRS Report R46525, *Patent Law: A Handbook for Congress*.)

Patent Prosecution

To obtain a patent, an inventor must file a patent application with USPTO. The patent applicant must describe the claimed invention in detail through words and drawings in a written *specification*. The application must also propose written *patent claims*, which define the legal scope of the claimed invention.

The patent application process is called *patent examination* or *patent prosecution*. During prosecution, a USPTO patent examiner determines whether the application and claimed invention meet the legal requirements for patentability discussed below. If so, USPTO issues (i.e., grants) the patent. In FY2025, USPTO received over 600,000 utility patent applications and issued nearly 350,000 patents.

Patentability Requirements

Patent-Eligible Subject Matter and Utility

Section 101 of the Patent Act allows patents on any "process, machine, manufacture, or composition of matter." Congress thus sought to ensure that almost anything made by humans may be patented if it meets the other patentability requirements. For example, new inventions in fields ranging from chemistry and computers to agriculture and manufacturing are all potentially patent-eligible.

Section 101 also requires an invention to be *useful* to be patented. The standard for the utility requirement is low, requiring only that the claimed invention have some benefit to the public that is not so vague as to be meaningless.

Novelty and Nonobviousness

Perhaps the most fundamental patentability requirement is that the claimed invention must be *novel* (i.e., new). Under 35 U.S.C. § 102, USPTO will not issue a patent if it finds that the claimed invention was *anticipated by* (i.e., disclosed in) any earlier invention already known in the "prior art" (e.g., an earlier patent, product, or publication). USPTO therefore denies a patent if the claimed invention had already been patented, publicly described, publicly used, or on sale before the patent application was filed.

Even if a claimed invention is novel because it is not identically disclosed in the prior art, the invention must also be *nonobvious* to be patentable under 35 U.S.C. § 103. USPTO and courts consider many factors in determining whether an invention is obvious from the perspective of a person with ordinary skill in the relevant field. For example, an invention may be obvious if it merely combines already known elements in a predictable way.

Disclosure-Related Patentability Requirements

The Patent Act also contains several requirements relating to the disclosures in the patent application. For example, under 35 U.S.C. § 112, the application must *enable* the invention by describing it with enough detail to teach a person of ordinary skill in the field how to make and use it. The enablement requirement ensures that the public can use the patented technology after the patent expires. In addition, a patent's claims, which define the patent holder's legal rights, must be sufficiently *definite* (i.e., clear and well-defined) to inform others in the field what is covered by the patent, and what is not.

Patent Term and Rights

A valid U.S. patent gives the patent holder a temporary monopoly on the invention in the United States, in exchange for disclosing it to the public. (USPTO publishes both granted patents and patent applications.) This means that the patent holder has the exclusive right to practice the invention in the United States until the patent expires. Any other person who makes, uses, sells, or imports the invention without permission from the patent holder is said to *infringe* the patent and may be liable for various legal remedies if the patent holder sues them in court.

A patent's term begins on the date that the patent application is granted and ends 20 years after the date that the underlying patent application was filed with USPTO. Because patent examination typically takes a little more than 2 years, an average effective patent term is about 17 or 18 years. The Patent Act allows for extensions of a patent's term based on delays in patent examination or in obtaining regulatory approval for patented drugs and medical devices.

Ownership of a patent initially vests with the inventor or inventors, as a general rule. Like other personal property, patents may be transferred or assigned to others. For example, employment contracts may require employees to assign patent rights in inventions created while on the job to

their employer. Patent owners may also permit others to practice the invention through a contract called a *license*. In return, the licensee may have to pay a lump sum of money or a continuing *royalty* to the patent holder.

Patent Enforcement

Patents are not self-enforcing. To obtain relief from infringement, the patent holder must generally sue alleged infringers in court. Federal courts have exclusive jurisdiction over patent lawsuits. In addition, the U.S. International Trade Commission (ITC) conducts administrative proceedings that may bar infringing goods from being imported into the United States. A single specialized court, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), hears all patent appeals from the ITC and federal district courts across the country.

Persons accused of patent infringement may defend on several grounds. First, the accused infringer may claim *noninfringement*: that is, that their activities fall outside the scope of the patent claims. Second, the accused infringer may argue that the patent is *invalid*: that is, that USPTO should not have issued the patent because the invention does not actually meet one or more of the legal requirements for patentability. Third, the accused infringer may argue that the patent is *unenforceable* based on inequitable or illegal activities of the patent holder, such as obtaining the patent through fraud on USPTO.

Issues for Congress

Patent-Eligible Subject Matter

As explained above, the statutory scope of patent-eligible subject matter (i.e., the types of inventions that may be patented) is broad. Yet federal courts have long held that three general types of discoveries may *not* be patented: laws of nature, natural phenomena, and abstract ideas. These judicially created exceptions preclude patenting basic tools of scientific work, such as a mathematical equation or scientific law, even if newly discovered.

A series of Supreme Court decisions in the 2010s narrowed patent-eligible subject matter by broadening the scope of these judicially created exceptions. The Court's decisions established a new judicial test for patent eligibility called the *Alice/Mayo* framework. As a result, fewer inventions are now patentable, particularly in computer software, business methods, and biotechnology. Some stakeholders contend that the Court's decisions have increased uncertainty as to what is patentable and undercut innovation and investment. Others argue that the decisions foster innovation by preventing monopolies on basic research tools and fundamental concepts. For more detail, see CRS Report R45918, *Patent-Eligible Subject Matter Reform: Background and Issues for Congress*.

The Patent Trial and Appeal Board

In 2011, Congress created the Patent Trial and Appeal Board (PTAB), a USPTO tribunal that hears challenges to already-issued patents through administrative procedures such as inter partes review (IPR). Through an IPR, any person other than the patent holder can petition PTAB to review the validity of an already-issued patent based on a lack of novelty or nonobviousness. If PTAB hears the IPR and agrees with the petitioner, USPTO cancels the invalid patent claims. In effect, IPR makes it easier, faster, and less expensive to challenge a patent's validity, compared with making the same arguments in court. For more detail, see CRS Report R48016, *The Patent Trial and Appeal Board and Inter Partes Review*.

While some stakeholders argue that PTAB offers an efficient means to invalidate low-quality patents, others contend that its proceedings are unfair to patent holders and undermine certainty in patent rights. Some Members of Congress have proposed reforms to PTAB (see, e.g., S. 1553 or H.R. 5811), while the USPTO has made various regulatory changes in recent years that restricted or expanded access to IPR. For example, beginning in March 2025, USPTO leadership has taken several actions that have restricted the availability of IPR by expanding the circumstances in which USPTO will exercise its discretion to decline to institute (i.e., hear) an IPR proceeding.

Federally Funded Inventions and "March-in" Rights

Special rules apply to patented inventions made using federal funding. In 1980, Congress established a uniform federal patent policy to promote the commercialization of inventions made with federal support through the Bayh-Dole Act (P.L. 96-517). Under Bayh-Dole, federal contractors or grantees generally retain the patent rights on inventions made with federal support. In exchange, the contractor or grantee provides the federal funding agency with a license to use the patented invention for government purposes without paying a royalty. The agency also retains the authority to grant compulsory licenses to third parties in some cases, known as *march-in rights*.

No federal agency has ever exercised march-in rights. Some stakeholders argue that agencies should use march-in rights to lower prices on patented inventions such as prescription drugs made with federal support. Others argue that using march-in to lower prices conflicts with the statute and would harm innovation. Various proposed regulatory changes in 2021 and 2023 that would have clarified the role (if any) that pricing should play in march-in determinations were abandoned after generating controversy. For more detail, see CRS In Focus IF12582, *Pricing and March-In Rights Under the Bayh-Dole Act*.

Patents and Artificial Intelligence

Recent developments in artificial intelligence (AI) raise novel patent law questions. Limitations on patent-eligible subject matter may prevent certain AI innovations from being patented, if USPTO or a court finds that they seek to claim an abstract idea. Another emerging issue concerns inventorship for inventions created by or with AI. The Federal Circuit has held that an invention made "autonomously" by AI alone is not patentable because it lacks any human inventor. For AI-assisted inventions, 2025 guidance from the USPTO emphasizes that the ordinary legal rules for inventorship apply when a human inventor uses AI as a tool in the inventive process. For more detail, see CRS Legal Sidebar LSB11251, *Artificial Intelligence and Patent Law*.

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