IN-DEPTH

Intellectual Property

USA

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EDITION 15

Contributing Editor

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In-Depth: Intellectual Property (formerly The Intellectual Property Review) provides a global overview of the forms of intellectual property coverage available in each jurisdiction, along with an update of the most consequential recent developments. It offers deep insight into the key legal and commercial issues that arise when seeking to obtain and enforce IP rights – including patents, copyright, designs, trademarks and trade secrets.

Generated: March 18, 2026

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Summary

Introduction

A robust system for protecting intellectual property rights is available in the United States. The forms of intellectual property protection available include patent, copyright, trademark and trade secret. Each of these forms of intellectual property has its own strengths and weaknesses, and generally the selection of the type of protection is based on the subject matter at hand and the nature of the protection desired.

Utility patents

Utility patents are generally considered the strongest level of intellectual property protection in the United States. They grant the owner the right to exclude infringers from making, using, offering for sale or selling within the United States, or importing into the United States, the patented invention. To be eligible for a utility patent, the invention must be new, useful and not obvious, and be patentable subject matter. The originally first-to-invent system transitioned to a first-inventor-to-file regime for applications filed on or after 16 March 2013.

The term of a new utility patent is 20 years from filing of the application. Should Patent Office delays cause the examination process to exceed three years, a mechanism called patent term adjustment is used to restore the lost patent term. A patent term extension is also available to restore some of the time lost while awaiting marketing authorisation for one patent covering a pharmaceutical product that was subject to review by the US Food and Drug Administration (FDA). Utility patent applications may be filed directly with the Patent Office, or an applicant may designate the United States for an international application filed pursuant to the Patent Cooperation Treaty.

The United States does not offer utility model protection (or any equivalent protection) as found in many other countries. The United States does, however, allow applicants to file for provisional patent protection to establish a priority date. If one is filed with the Patent Office, it does not undergo substantive patent examination. The applicant has up to one year to file a full utility application that references the provisional application and if that due date is not met, the provisional application is abandoned.

Design patents

Design patents are also available in the United States and cover the ornamental appearance or aesthetic design of tangible articles. A design by itself is not sufficient to be covered by a design patent; the design must be embodied in the tangible article to be claimed. Design patents cover everything from vehicle tyre treads to mobile phones. The design also must be new and not obvious.

Design patents filed before 13 May 2015 have a term of 14 years from grant, whereas those filed on or after that date have a 15-year term pursuant to the United States' implementation of the Hague Agreement for industrial designs. Applicants may also file international design applications with the Patent Office and may designate the United States for design protection based on international applications.

Plant patents

Plant patent protection is available for new plants that have been asexually propagated (even if they are capable of sexual reproduction). It specifically excludes tuber-propagated plants and those found in an uncultivated state. Plant patent protection provides the right to exclude others from using, selling, offering for sale or importing the asexually propagated plants or parts from the plants in the United States for a term of 20 years from filing of the application.

Copyright

Copyrights are available to protect literary and artistic works, and original works by authors or artists in a tangible format. Both published and unpublished works are eligible for copyright protection upon creation. While copyright registration is not necessary to create copyright protection, registration is necessary to enforce those rights and claim statutory damages for infringement. Copyrights are subject to certain fair use defences that allow one to use the copyrighted material without being subject to infringement (eg, news reporting, teaching, research). Copyrights are also subject to First Amendment protection (ie, constitutionally protected free speech). The term of a copyright is generally the author's lifetime plus 70 years.

Works published outside the United States may also be eligible for copyright protection within the United States through a treaty (eg, the Berne Convention) depending upon the country in which the work was first published.

Trademarks

Federal trademark registration is available for products or services used in interstate commerce in the United States. Various state laws also protect trademarks in the United States. While federal trademark registration is not required to use a trademark, there are several advantages to federal registration, including the exclusive right to use the trademark nationwide, the ability to use the symbol within the United States and the ability to bring trademark infringement actions in the federal courts. There is a formal trademark application and examination process, including publication for opposition. Additionally, intent to use applications may also be filed. Trademark applicants may file with the Patent Office or through the Madrid Protocol.

Trade secrets

Before 2016, trade secret protection was largely governed by individual state law, with the vast majority of states having implemented some form of the Uniform Trade Secrets Act. The Defend Trade Secrets Act enacted in 2016 allows trade secret owners to sue in federal court for misappropriation, supplementing state law causes of action and also includes a civil seizure mechanism. There is also a criminal statute relating to economic espionage and theft of trade secrets that has become more commonly utilised.

Regulatory exclusivities

In the pharmaceutical and biotechnology fields, intellectual property protection is augmented by various types of regulatory exclusivity from the FDA. In the case of pharmaceutical drugs, the FDA grants exclusivity for new chemical entities (five years), new drug products (three years), certain changes to drug products (three years), orphan drugs (seven years), paediatric exclusivity (six months) and exclusivity for the first generic applicant or applicants to challenge patents asserted to cover the drug (six months). In the case of biologic drugs, the FDA grants 12 years of data exclusivity against approval of a generic, or "biosimilar", application, but there is no corresponding exclusivity for the first biosimilar applicant to challenge a patent covering the biologic drug. In the case of new antibiotic drugs that target certain drug-resistant microorganisms, the FDA is authorised to add five years to applicable exclusivities under the Generating Antibiotic Incentives Now (GAIN) Act. GAIN exclusivity allows for up to a decade of marketing exclusivity for certain antibiotic drugs that are eligible for new chemical entity exclusivity.

Year in review

Court opinions

Dewberry Group v Dewberry Engineers (26 February 2025) (Supreme Court)

The Lanham Act's section 1117(a) provides for a prevailing plaintiff to recover the "defendant's profits" from a trademark violation. *Dewberry* addressed whether a named defendant and its non-party corporate affiliates can be treated as a single entity when calculating the "defendant's profits", holding that they may not. Rather, the Supreme Court held, "defendant" in the statute has its usual legal meaning (ie, the named party against which relief or recovery is sought). The court's opinion was limited to statutory interpretation of "defendant's profits" and did not address other potential contexts in which the financial relationship between the defendant and its non-party affiliates might be considered when assessing damages, such as the same statute's "just-sum" provision, under what circumstances a court might "look behind a defendant's tax or accounting records to consider 'the economic realities of a transaction' and identify the defendant's 'true financial gain'", or whether corporate veil-piercing might be appropriate in this case.

Cox Communications v Sony Music Entertainment (argued 1 December 2025) (Supreme Court)

In *Cox*, the Supreme Court is asked to address whether an internet service provider (ISP) can be held liable for materially contributing to copyright infringement, and also for wilful infringement, where it knew its customers were using their accounts to infringe and did not terminate their internet access in response. The Court of Appeals for the Fourth Circuit vacated a US$1 billion judgment against ISP Cox but upheld the contributory infringement verdict and wilfulness finding where Cox had received numerous automated infringement accusations from music rights holders but did not suspend the accounts, which included ones belonging to hotels, hospitals, apartment buildings, universities and regional ISPs serving many individual users. In this case, the trial court had held

that the Digital Millennium Copyright Act (DMCA)'s safe harbour defene could not apply because Cox's repeat infringer policy as implemented was inadequate. Briefing and oral argument in the case also discuss to what extent induced and contributory infringement provisions codified in US patent laws reflect the common-law liability principles applicable to contributory copyright infringement.

Obtaining protection

Patent applications may be filed for utility, design and plant patent protection.

For utility patents, patentable subject matter includes machines, manufactures (ie, articles of manufacture), compositions of matter, methods (including methods of treating human patients) and improvements to any of these four. Some notable exceptions to this broad rule are laws and products of nature, and abstract ideas. Over the past decade, the Supreme Court has considered patentable subject matter on several occasions, finding that exceptions include some business methods,[1] medical diagnostic methods[2] and isolated DNA.[3] The Patent Office has also issued guidance for examining subject matter eligibility in light of the courts' decisions.[4] In July 2019, the Federal Circuit indicated in an *en banc* decision that additional guidance on this issue could be warranted;[5] however, the Supreme Court has so far refused to reconsider its subject matter eligibility jurisprudence.

Prior art is defined in section 102 of the Patent Act, which was modified by the America Invents Act (AIA) for patents subject to that Act's first-inventor-to-file provisions. Generally speaking, the United States provides a one-year grace period in which to file an application following the inventor's own disclosure. Whereas pre-AIA a patentee could disqualify as prior art certain disclosures by others by proving an earlier invention date, disqualification under the AIA requires showing that the disclosure was made by someone who obtained the subject matter from the inventor or that the inventor had previously disclosed the invention. The AIA also expanded prior art to include public uses and sales in foreign countries, and it added a catch-all reference to inventions "otherwise available to the public".

Applicants have a duty to disclose to the Patent Office information known to be material to patentability, namely non-cumulative information that establishes a *prima facie* case of unpatentability or that refutes or is inconsistent with the applicant's positions during prosecution.

Enforcement of rights

Possible venues for enforcement

There are two possible venues for enforcement of patents. First, infringement actions may be brought before the courts of the 94 federal districts that are spread throughout the United States and Puerto Rico. Second, to prevent importation of infringing goods, an investigation can be commenced by, and at the discretion of, the International Trade Commission (ITC), an administrative agency that sits in Washington, DC.

Litigation process

Requirements for jurisdiction and venue

An infringement suit may be brought only in a federal district where the defendant resides or where the defendant has committed acts of infringement and has a regular and established place of business. Domestic businesses are considered to reside in their state of incorporation.[6] Foreign defendants may be sued in any federal district so long as personal jurisdiction can be found in the United States. The ITC, on the other hand, does not depend on personal jurisdiction over the accused infringer but has *in rem* jurisdiction over the accused infringing goods.

Obtaining relevant evidence of infringement and discovery

The US rules allow for significant amounts of pre-trial discovery under a broad concept of relevance. Discovery is available from the opposing party through a variety of vehicles, including mandatory disclosures, requests for documents and things, interrogatories, depositions of witnesses and expert reports. Discovery is also available from non-parties by a subpoena for documents or deposition. In ITC investigations, discovery is also available; however, it is produced more quickly because of the compressed time frame of such investigations.

Preliminary injunctions

A patentee in an infringement action may seek temporarily relief by requesting a preliminary injunction (PI) or, even more urgently and time-limited, a temporary restraining order (TRO). Such temporary relief requires showing:

1. a likelihood of success on the merits;
2. irreparable harm if the relief is not granted;
3. a balance of hardships tipping in the requesting party's favour; and
4. that the public interest does not preclude issuing the relief.

Both PIs and TROs require the requesting party to post a security bond. Complainants in ITC investigations may also seek temporary relief to the same extent as PIs and TROs may be granted in federal court infringement actions.

Trial decision-maker

Patent infringement actions may be tried before either a federal judge or a jury. Jury trials may occur where there is a claim for monetary damages, and not where only equitable relief is sought. There are no specialised district court federal judges and thus many judges have little experience with patent matters. In contrast, ITC investigations are typically decided by an administrative law judge who specialises in patent cases.

Structure of the trial

A patent infringement trial may occur in two phases. The first phase determines infringement, validity and unenforceability, and the second phase, if needed, addresses damages. Evidence is presented through fact and expert witnesses. The Federal Rules of Evidence determine what information can be admitted for consideration by the judge or jury.

At trial, the patentee must prove infringement by meeting the preponderance standard (ie, more likely than not). For an accused infringer to prevail on invalidity or unenforceability, it must meet the more rigorous, clear and convincing standard because of the statutory presumption of patent validity.

Disputes regarding patent claim interpretation are typically decided by the judge prior to trial in a process called a *Markman* hearing. This hearing may, but usually does not, include testimony from fact or expert witnesses. Although the outcome of claim construction may be determinative, the Federal Circuit has consistently refused to review claim construction issues as an interlocutory matter.

Infringement

Infringement may be direct or indirect. For direct infringement, all the claim elements must be present in the accused product or method. For indirect infringement, evidence must show that there is direct infringement and that the indirect infringer is either inducing or contributing to that infringement.

Should a product not literally contain every element, the missing element may be shown by the doctrine of equivalents. This cannot include equivalents that are described in the specification and not claimed or that were distinguished during patent prosecution.

Defences

The most common defences to patent infringement are non-infringement, patent invalidity and inequitable conduct. Accused infringers may also assert more esoteric defences, such as unclean hands, laches[7] and equitable estoppel. All these defences can be brought either as affirmative defences or as counterclaims.

Non-infringement

The non-infringement defence can include the lack of infringement or the existence of an express or implied licence. Accused infringers may also raise patent exhaustion[8] or permissible repair, although those defences are less common.

Patent invalidity

Invalidity defences include anticipation, obviousness and lack of enablement or written description, indefiniteness, subject matter ineligibility and statutory or non-statutory double patenting.

Inequitable conduct

Accused infringers can also assert inequitable conduct to render a patent unenforceable. The standard for inequitable conduct requires clear and convincing evidence that the patent applicant misrepresented or omitted material information during prosecution of the patent with the intent to deceive the Patent Office. Information is material only if the Patent Office would not have allowed a claim had it been aware of the undisclosed prior art or correct information.

Prior commercial use

The prior commercial use defence, which was expanded by the AIA, may apply where the accused infringer shows that it commercially used the invention in the United States at least one year before the patent's effective filing date or a disclosure of the invention as described in section 102(b). The defence may only be asserted by the person engaged in the commercial use, one controlled by or under common control with that person, or one to whom it is transferred as part of the transfer of the entire enterprise or line of business to which it relates. Further limitations include that the defence cannot be asserted against university inventions or if the subject matter was derived from the patentee.

Time to first-level decision

For the federal district courts, the median time to trial for patent infringement actions is about two to two-and-a-half years. For a jury trial, the jury deliberates immediately after closing arguments and renders its verdict very promptly thereafter. For a trial before a judge, typically there are post-trial briefs that will delay the district court's ruling by several months after trial is completed. Because of section 337 and the ITC's rules, ITC investigations are significantly faster, with the time from filing a complaint to a final determination usually taking about a year to a year and a half.

Remedies

Remedies for patent infringement include damages and injunctive relief. The patentee is entitled to actual damages, which may include lost profits and can be no less than a reasonable royalty for the infringement. A court also has discretion to award enhanced (up to treble) damages for egregious infringement; for example, if the conduct was wilful. In 2016, the Supreme Court lessened the standard for enhanced damages,[9] and since then the rates of enhanced damages awards have increased. Even so, enhanced damages still are not typical in patent cases. Additionally, a prevailing party may be awarded attorney fees in an exceptional case, but this type of relief is also discretionary and not frequently granted.

A patentee may also request a preliminary injunction pending trial or, after trial, a permanent injunction against future infringement. Injunctions are not automatic in patent cases and require the court to consider the relative harms to the patentee and the infringer as well as any public interest.

For ITC cases, the principal remedy available is an exclusion order prohibiting importation. The exclusion order may be limited to the articles named in the investigation or, if determined to be appropriate, encompass all infringing articles regardless of source.

Appellate review

The Court of Appeals for the Federal Circuit reviews all trial-level patent decisions as well as appeals from the ITC and Patent Office. Typically, no new evidence is allowed. Three judges hear oral arguments and issue an opinion, usually within six months.

The losing party can petition for a panel rehearing or for the entire Federal Circuit Court to hear the case. Such petitions are almost never granted. The losing party may also petition the Supreme Court through a writ of *certiorari*, but those are granted even less frequently than *en banc* petitions and generally are only granted to decide a very significant legal issue.

Alternatives to litigation

Mediation and arbitration are available to resolve patent disputes if both parties agree to the procedure. These procedures may be less costly than litigation.

The Patent Office also has independent procedures for reviewing patent applications and issued patents, including the following.

Pre-issuance submissions

Third parties may file patents, published applications or other printed publications, along with a concise statement of their relevance (limited to factual descriptions, not unpatentability arguments), for consideration by the examiner and inclusion in the prosecution record. The submitter must be identified, but the real party in interest need not be disclosed. Pre-issuance submissions must be made before a notice of allowance. Additionally, they must be made before the first rejection or six months from publication, whichever is later.

Supplemental examination

A patent owner may request supplemental examination to have the Patent Office consider, reconsider or correct relevant information. If such a request is found to raise a substantial new question of patentability, the matter proceeds to *ex parte* re-examination. Supplemental examination can insulate a patent from being held unenforceable for inequitable conduct, but only if it was requested before inequitable conduct is alleged with particularity. In addition, such insulation will not occur in an infringement suit filed before the Patent Office proceedings conclude. Thus, a patent owner seeking to avail itself of supplemental examination procedures should consider doing so well in advance of potential litigation.

Post-grant review

For patents subject to the AIA (generally, those with an effective filing date on or after 16 March 2013), a third party may file a post-grant review (PGR) petition asking the Patent Trial and Appeal Board (PTAB) to consider challenges based on any statutory requirement for patentability other than best mode. PGR petitions must be filed within nine months of the date of grant. The Patent Office may institute a PGR if it finds that it is more likely than not that at least one challenged claim is unpatentable or if the petition raises a novel or unsettled legal question that is important. The determination of whether to institute a PGR is not appealable to a court.[10]

If a PGR is instituted, the petitioner must prove unpatentability by a preponderance of the evidence. The PTAB's final written decision can give rise to estoppel before the Patent Office and in civil actions and ITC proceedings.[11] The PTAB's final written decision may be appealed to the Federal Circuit. Whereas constitutional standing is not required to petition for a PGR or *inter partes* review (IPR), the Federal Circuit has held that it is required to appeal from post-grant proceedings.[12]

Inter partes review

A third party may also file an IPR petition asking the PTAB to consider anticipation or obviousness challenges based on patents or printed publications. For patents subject to the AIA, IPR petitions may be filed the later of nine months after the patent issues or termination of a PGR. For pre-AIA patents not eligible for a PGR, IPR petitions may be filed following grant. If the party seeking an IPR has been sued for infringement, it must file the petition within one year of being served with the infringement complaint. The Patent Office may institute an IPR if it finds there is a reasonable likelihood that the petitioner will prevail in showing that at least one challenged claim is unpatentable. The determination of whether to institute an IPR is not appealable to a court.[13]

If an IPR is instituted, the petitioner must prove unpatentability by a preponderance of the evidence. As with a PGR, the PTAB's final written decision can give rise to estoppel, including in civil actions, and is appealable to the Federal Circuit.[14]

The PTAB's claim construction decision is likely to precede the district court's *Markman* ruling in concurrent litigation, and thus may potentially influence the court's claim construction decision.[15]

In both IPRs and PGRs, a patent owner may hedge against potential unpatentability by submitting a reasonable number of substitute (amended) claims. The petitioner bears the burden of showing that any proposed substitute claims are unpatentable.[16] Although the grant rate for motions to amend was reported to have increased following the Federal Circuit's *Aqua Products* decision, most such motions are still denied.[17]

In 2025, the Patent Office made several changes to IPR practice, particularly the process for assessing and potential reasons available for discretionary denials of institution.[18] It has also proposed further rules that would limit the availability of IPR in situations where the same patent has been or is involved in other patentability or validity challenges, and require an IPR petitioner to stipulate that it will not challenge validity for lack of novelty or obviousness in other forums.[19]

Derivation actions

The AIA replaced interference practice under the previous first-to-invent system with derivation proceedings, in which a patent applicant may challenge an earlier-filed application on the basis that its named inventor derived the claimed invention from an inventor on the petitioner's application, and the earlier application was filed without authorisation. Derivation petitions must be filed within one year of the first publication of an allegedly derived claim. The effective date for the AIA's derivation provision is 16 March 2013. Earlier applications are still eligible for interference proceedings.

Outlook and conclusions

As in other areas of legal practice, the interplay between artificial intelligence (AI) and intellectual property law will continue to evolve. Meanwhile the use of generative AI in many aspects of industry, legal practice and everyday life continues to become more ubiquitous.

Endnotes

1 *Alice Corp Pty Ltd v CLS Bank Intl* (decided 19 June 2014) (Supreme Court) and *Bilski v Kappos* (decided 28 June 2010) (Supreme Court). ^ Back to section

2 *Mayo Collaborative Servs v Prometheus Labs* (decided 20 March 2012) (Supreme Court). ^ Back to section

3 *The Association for Molecular Pathology v Myriad Genetics, Inc* (decided 13 June 2013) (Supreme Court). ^ Back to section

4 See October 2019 Update: Subject Matter Eligibility, www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf (last visited 22 February 2021); 2019 Revised Patent Subject Matter Eligibility Guidance, www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf (last visited 22 February 2021); Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals-* , www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF (last visited 21 February 2021). ^ Back to section

5 *Athena Diagnostics, Inc v Mayo Collaborative Servs, LLC* (decided 3 July 2019) (Federal Circuit) (*en banc*). ^ Back to section

6 *TC Heartland LLC v Kraft Foods Group Brands LLC* (decided 22 May 2017) (Supreme Court). ^ Back to section

7 Laches cannot bar damages claims for patent or copyright infringement during the respective statutory look-back limitations periods. *SCA Hygiene Products Aktiebolag v First Quality Baby Products, LLC* (decided 21 March 2017) (Supreme Court); *Petrella v Metro-Goldwyn-Mayer, Inc* (decided 19 May 2014) (Supreme Court). ^ Back to section

8 See *Impression Products, Inc v Lexmark International, Inc* (decided 30 May 2017) (Supreme Court). ^ Back to section

9 *Halo Electronics, Inc v Pulse Electronics, Inc* (decided 13 June 2016) (Supreme Court). ^ Back to section

10 35 USC Section 324(e). ^ Back to section

11 See 35 UCC Section 325(e). ^ Back to section

12 e.g., *Phigenix, Inc v Immunogen, Inc* (decided 9 January 2017) (Federal Circuit). ^ Back to section

13 35 USC Section 314(d). ^ Back to section

14 See 35 UCC Section 315(e). ^ Back to section

15 In IPR proceedings, the PTAB now applies the same claim construction standard as courts, instead of its previous "broadest reasonable interpretation" standard. ^ Back to section

16 37 CFR 42.121; www.govinfo.gov/content/pkg/FR-2024-09-18/pdf/2024-21134.pdf (last visited 22 January 2025). ^ Back to section

17 See *In Re: Aqua Products, Inc* (decided 4 October 2017) (Federal Circuit) (*en banc*). ^ Back to section

18 See www.uspto.gov/patents/ptab/interim-director-discretionary-process (last visited 21 January 2026). ^ Back to section

19 www.govinfo.gov/content/pkg/FR-2025-10-17/pdf/FR-2025-10-17.pdf (last visited 21 January 2026). ^ Back to section

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