Patent Law: A Handbook for Congress

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SUMMARY

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Patent Law: A Handbook for Congress

A patent gives its owner the exclusive right to make, use, import, sell, or offer for sale the invention covered by the patent. The patent system has long been viewed as important to encouraging American innovation by providing an incentive for inventors to create. Without a patent system, the reasoning goes, there would be little incentive for invention because anyone could freely copy the inventor's innovation.

Congressional action in recent years has underscored the importance of the patent system, including a major revision to the patent laws in 2011 in the form of the Leahy-Smith America Invents Act. Congress has also demonstrated an interest in patents and pharmaceutical pricing; the types of inventions that may be patented (also referred to as "patentable subject matter"); and the potential impact of patents on a vaccine for COVID-19.

As patent law continues to be an area of congressional interest, this report provides background and descriptions of several key patent law doctrines. The report first describes the various parts of a patent, including the specification (which describes the invention) and the claims (which set out the legal boundaries of the patent owner's exclusive rights). Next, the report provides detail on the basic doctrines governing patentability, enforcement, and patent validity.

For patentability, the report details the various requirements that must be met before a patent is allowed to issue. These requirements include the following:

- **Patentable Subject Matter.** The claimed invention must be directed to one of the statutorily defined categories of patent-eligible subject matter.
- **Definiteness.** The patent claims defining the invention's legal boundaries must be sufficiently clear.
- **Written Description.** The specification must adequately describe the invention.
- **Enablement.** The specification must enable a person in the field of the relevant technology to make and use the invention.
- **Novelty.** The invention cannot be the same as something known in the "prior art" (i.e., public knowledge in the field of relevant technology at the time of invention).
- **Nonobviousness.** The invention cannot be an obvious extension of the prior art.

The report then explains how the rights granted by a patent are enforced, including issues relating to patent infringement (such as direct infringement, infringement under the doctrine of equivalents, induced infringement, and contributory infringement). Also addressed are issues relating to litigation in federal district court and before the International Trade Commission (ITC), including the specialized dispute procedures governed by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

Finally, the report explains how a patent owner may lose their patent. This includes discussions of ex parte reexamination, post-grant review, inter partes review, and covered business method review.

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The patent system has long been viewed as important to encouraging American innovation. Abraham Lincoln, in a speech before he became President, argued that the patent system "added the fuel of interest to the fire of genius, in the discovery and production of new and useful things."[1] In Mark Twain's *A Connecticut Yankee in King Arthur's Court*, the titular Connecticut Yankee related that "the very first official thing I did, in my administration—and it was on the very first day of it, too—was to start a patent office; for I knew that a country without a patent office and good patent laws was just a crab, and couldn't travel any way but sideways or backways."[2] Upon commencing patent infringement litigation against Kodak, Polaroid founder Edwin Land, inventor of the instant camera, explained that "[t]he only thing that keeps us alive is our brilliance. The only way to protect our brilliance is our patents."[3]

Patents and intellectual property (IP) remain important today. In 2019, the U.S. Patent and Trademark Office (PTO) issued 354,507 new patents—the most in its history.[4] In 2016, a joint report from the Economics and Statistics Administration and the PTO estimated that patent-intensive industries added 3.9 million jobs to the U.S. economy.[5] The same report estimated that patent-intensive industries added $881 billion in value to the U.S. gross domestic product (GDP), comprising 5.1% of the U.S. GDP.[6]

Patents also are an important aspect of technology and health care in the United States. It has been estimated that a single smartphone may be protected by as many as 250,000 patents.[7] New pharmaceuticals are often protected by patents;[8] indeed, intellectual property rights, including patent rights, are generally considered to play an essential role in encouraging the research and development necessary to create new pharmaceutical products.[9] For example, one recent study of the top twelve drugs by gross U.S. revenue found that pharmaceutical manufacturers obtained an average of seventy-one patents on each of these drugs.[10] Whether and to what extent any

[1] Abraham Lincoln, *Second Lecture on Discoveries and Inventions* (Feb. 11, 1859) *in* 3 COLLECTED WORKS OF ABRAHAM LINCOLN 356, 363 (Roy P. Basler, ed. 2001).

[2] MARK TWAIN, A CONNECTICUT YANKEE IN KING ARTHUR'S COURT 107 (Charles L. Webster & Co. 1889).

[3] Victor K. McElheny, *Polaroid Is Suing Kodak, Charges Patent Violation*, N.Y. TIMES (Apr. 28, 1976), at https://www.nytimes.com/1976/04/28/archives/polaroid-is-suing-kodak-charges-patent-violation-polaroid-is-suing.html. Polaroid and Kodak eventually settled their dispute in 1991, with Kodak agreeing to pay Polaroid $925 million. Reuters, *Kodak Settles With Polaroid*, N.Y. TIMES (July 16, 1991), at https://www.nytimes.com/1991/07/16/business/kodak-settles-with-polaroid.html. Land had died earlier that year. Eric Pace, *Edwin H. Land Is Dead at 81; Inventor of Polaroid Camera*, N.Y TIMES (March 2, 1991), at https://www.nytimes.com/1991/03/02/obituaries/edwin-h-land-is-dead-at-81-inventor-of-polaroid-camera.html.

[4] Dennis Crouch, *How Many Patents Issued in 2019?*, PATENTLYO (Dec. 31, 2019), at https://patentlyo.com/patent/2019/12/many-patents-issued.html.

[5] Robert Rubinovitz et al., *Intellectual Property & the U.S. Economy: 2016 Update*, at ii, ECONOMICS & STATISTICS ADMINISTRATION and U.S. PATENT & TRADEMARK OFFICE, at https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf.

[6] *Id.* at 22.

[7] Steve Lohr, *Apple-Samsung Patent Battle Shifts to Trial*, N.Y. TIMES, (July 29, 2012), at https://www.nytimes.com/2012/07/30/technology/apple-samsung-trial-highlights-patent-wars.html. Notably, not all of the patents covering aspects of a smartphone are owned by the same entity. *Id.*

[8] *See generally* CRS Report R46221, *Drug Pricing and Pharmaceutical Patenting Practices*, coordinated by Kevin T. Richards, at 9-10, 16-20, 24-28.

[9] Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302, 302 (2015) ("Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals.").

[10] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 6-8 (Aug. 2018), at https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-

countermeasures against COVID-19 should be patented has also been a subject of congressional interest.[11]

As patents and IP remain a subject of congressional interest, this report provides an overview of U.S. patent law. It begins by describing the various parts of a patent to provide context and background for the legal discussion. It then describes the legal requirements that must be met in order to obtain a patent and how the rights granted by a patent may be enforced. Finally, the report closes with a description of how patent rights may be lost, either through litigation or through administrative proceedings before the PTO's Patent Trial and Appeal Board.

What Is a Patent?

The Constitution empowers Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries."[12] Since 1790, Congress has enacted patent laws pursuant to this power, granting inventors certain exclusive rights in their inventions for a period of time.[13] Broadly speaking, those exclusive rights are granted in return for the inventor's public disclosure of the invention.[14] Thus, patents represent a "quid pro quo": in return for the inventor's public disclosure, the inventor receives those time-limited exclusive rights.[15] Many of the specific doctrines underlying patent law can be explained by that rationale.

Parts of a Patent

Before describing the exclusive rights granted by a patent and related issues (such as how to obtain, enforce, and lose a patent), it is helpful to understand the basic parts of a patent.[16] For example, before describing the legal requirements for patent claims,[17] it is important to understand what patent claims *are*. Recently issued U.S. Patent No. 10,000,000 (the '000 patent) provides a good illustration of a patent's format.[18]

Overpriced-Report.pdf.

[11] *See, e.g.*, Press Release, Office of Representative Jan Schakowsky, Congressional Progressive Leaders Announce Principles On COVID-19 Drug Pricing for Next Coronavirus Response Package (Apr. 15, 2020), at https://schakowsky.house.gov/media/press-releases/congressional-progressive-leaders-announce-principles-covid-19-drug-pricing.

[12] U.S. CONST. art. I, § 8, cl. 8.

[13] *See, e.g.*, 35 U.S.C. § 271 (setting forth how patents may be infringed).

[14] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the quid pro quo of the right to exclude.'" (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974))); *see also* Universal Oil Prod. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) ("As a reward for inventions and to encourage their disclosure, the United States offers a ... monopoly to an inventor who refrains from keeping his invention a trade secret. But the quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted.").

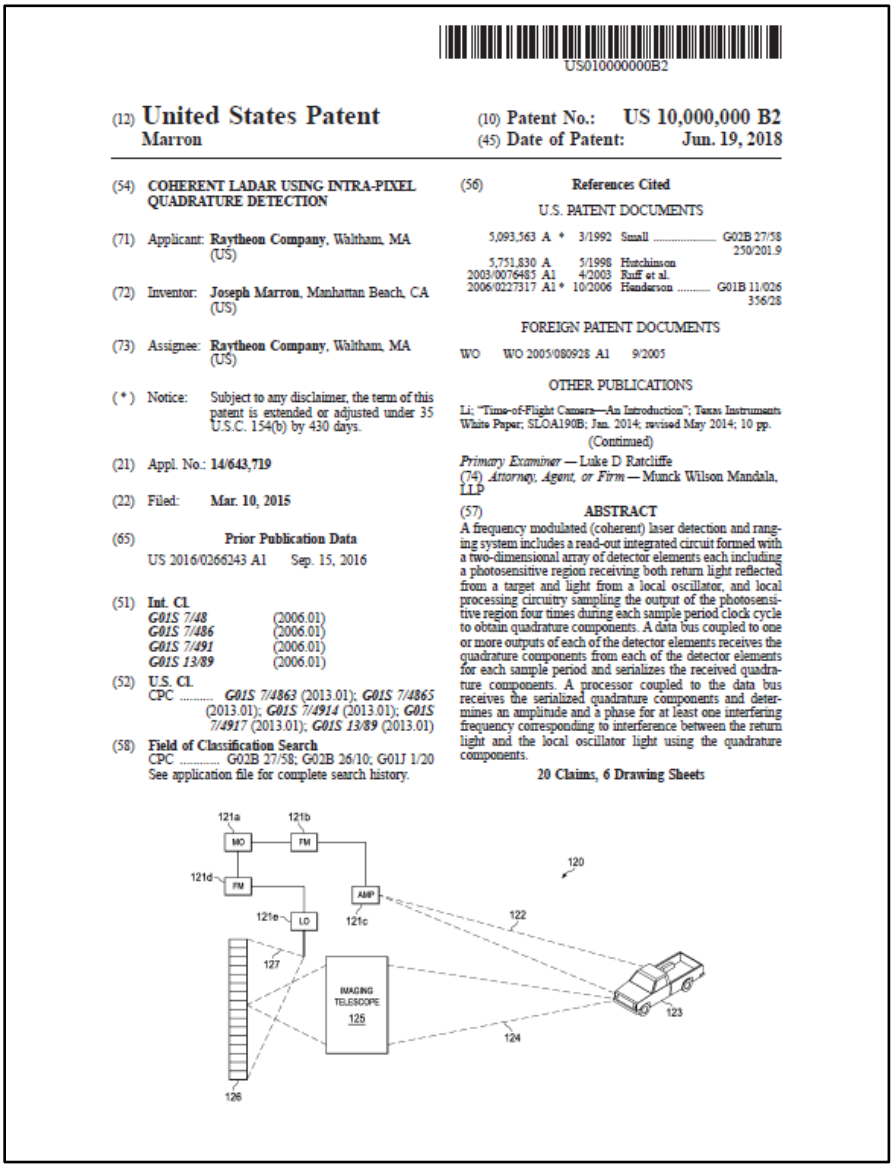
[15] *J.E.M. Ag Supply*, 534 U.S. at 142.

[16] The following description and legal requirements relate only to utility patents. Design patents, which protect a "new, original and ornamental design for an article of manufacture," *see* 35 U.S.C. §§ 171-73, and plant patents, which protect "any distinct and new variety of plant," *see id.* §§ 161-64, are beyond the scope of this report.

[17] *See* discussion *infra* in "Patent Application Requirements."

[18] U.S. Patent 10,000,000 was issued, with much fanfare, on June 19, 2018. U.S. Patent No. 10,000,000; *United States Issues Patent Number 10,000,000*, U.S. PAT. & TRADEMARK OFF. (June 19, 2018), at https://www.uspto.gov/about-

As shown below, a patent's cover page provides basic information about the patent, including the name(s) of the inventor(s), the title of the patent, the date that the patent issued, an abstract briefly summarizing the invention,[19] and a representative drawing:



US010000000B2

(12) **United States Patent**
Marron

(10) **Patent No.: US 10,000,000 B2**
(45) **Date of Patent: Jun. 19, 2018**

(54) **COHERENT LADAR USING INTRA-PIXEL QUADRATURE DETECTION**

(71) Applicant: **Raytheon Company**, Waltham, MA (US)

(72) Inventor: **Joseph Marron**, Manhattan Beach, CA (US)

(73) Assignee: **Raytheon Company**, Waltham, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 430 days.

(21) Appl. No.: **14/643,719**

(22) Filed: **Mar. 10, 2015**

(65) **Prior Publication Data**

US 2016/0266243 A1 Sep. 15, 2016

(51) **Int. Cl.**

G01S 7/48	(2006.01)
G01S 7/486	(2006.01)
G01S 7/491	(2006.01)
G01S 13/89	(2006.01)

(52) **U.S. Cl.**
CPC ***G01S 7/4863*** (2013.01); ***G01S 7/4865*** (2013.01); ***G01S 7/4914*** (2013.01); ***G01S 7/4917*** (2013.01); ***G01S 13/89*** (2013.01)

(58) **Field of Classification Search**
CPC G02B 27/58; G02B 26/10; G01J 1/20
See application file for complete search history.

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2006/0227317	A1 *	10/2006	Henderson	G01B 11/026 356/28

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(Continued)

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(74) *Attorney, Agent, or Firm* — Munck Wilson Mandala, LLP

(57) **ABSTRACT**

A frequency modulated (coherent) laser detection and ranging system includes a read-out integrated circuit formed with a two-dimensional array of detector elements each including a photosensitive region receiving both return light reflected from a target and light from a local oscillator, and local processing circuitry sampling the output of the photosensitive region four times during each sample period clock cycle to obtain quadrature components. A data bus coupled to one or more outputs of each of the detector elements receives the quadrature components from each of the detector elements for each sample period and serializes the received quadrature components. A processor coupled to the data bus receives the serialized quadrature components and determines an amplitude and a phase for at least one interfering frequency corresponding to interference between the return light and the local oscillator light using the quadrature components.

20 Claims, 6 Drawing Sheets

The cover page is followed by drawings illustrating background technology; various aspects of the invention; or different implementations of the invention. For example, Figure 4 of the '000 patent illustrates use of the invention in an exemplary environment:[20]

us/news-updates/united-states-issues-patent-number-10000000; *U.S. Patent 10 Million*, U.S. PAT. & TRADEMARK OFF., at https://10millionpatents.uspto.gov/patent-10-million.html.

[19] Because the purpose of this discussion and description is to familiarize the reader with the various parts of a patent, rather than specifically familiarize the reader with the innovations underlying the '000 patent, description of the relevant technological background and specific advance claimed by the '000 patent are omitted from this report.

[20] '000 patent, col. 6 ll. 7-59.

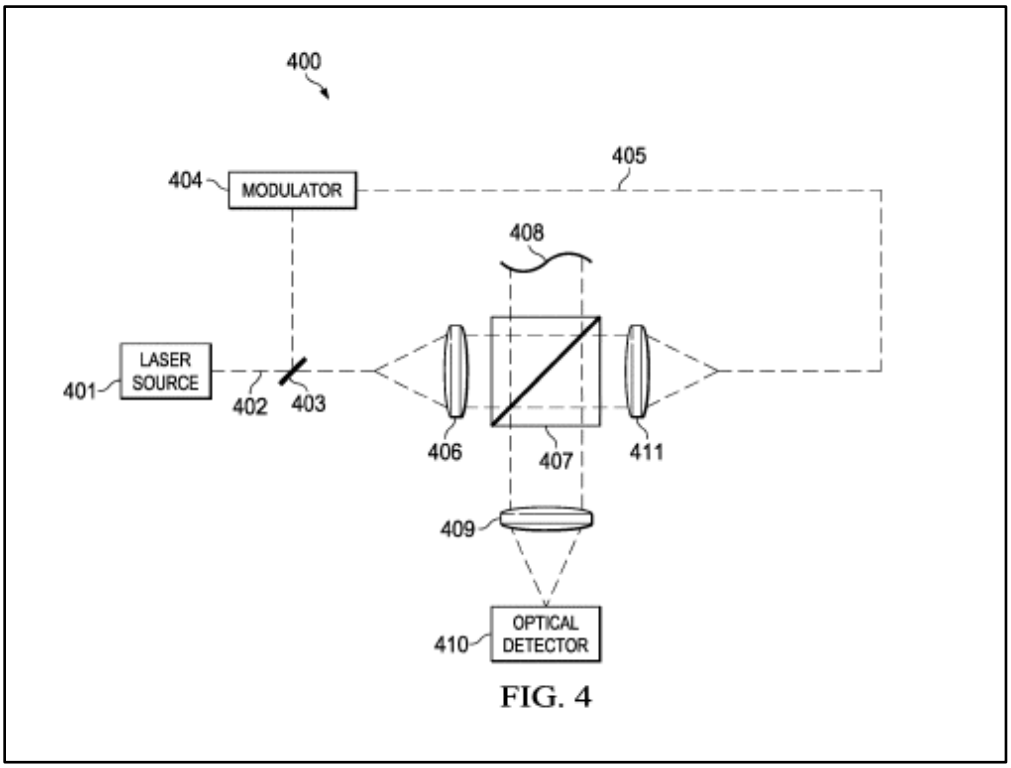
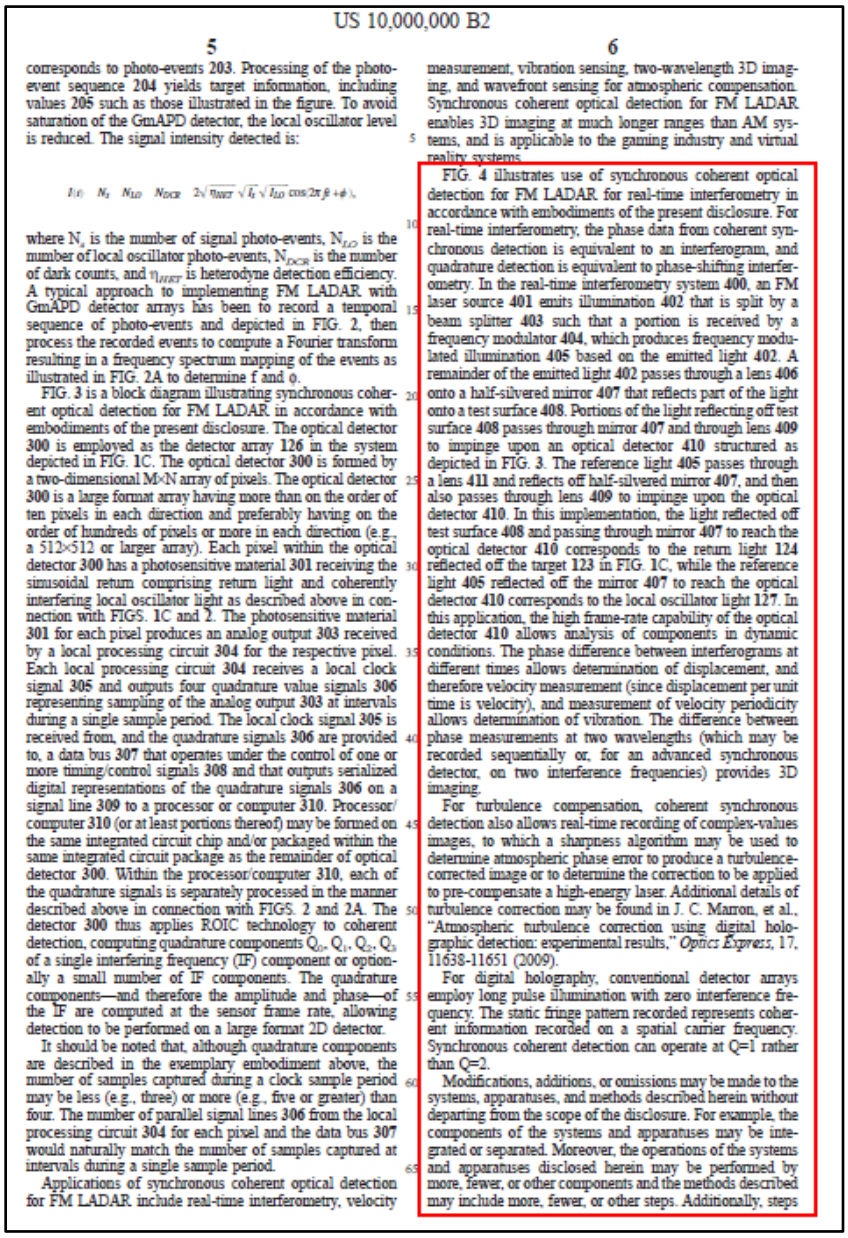


FIG. 4

Following the drawings is the *specification*, a textual description of the invention set out in two-column pages. As shown in the excerpt below, the description relating to Figure 4 appears in column six beginning at line seven (annotated with a red box):



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corresponds to photo-events **203**. Processing of the photo-event sequence **204** yields target information, including values **205** such as those illustrated in the figure. To avoid saturation of the GmAPD detector, the local oscillator level is reduced. The signal intensity detected is:

$$I(t) \quad N_s \quad N_{LO} \quad N_{DCR} \quad 2\sqrt{\eta_{HET}}\sqrt{I_S}\sqrt{I_{LO}}\cos(2\pi\beta+\phi),$$

where N_s is the number of signal photo-events, N_{LO} is the number of local oscillator photo-events, N_{DCR} is the number of dark counts, and η_{HET} is heterodyne detection efficiency. A typical approach to implementing FM LADAR with GmAPD detector arrays has been to record a temporal sequence of photo-events and depicted in FIG. **2**, then process the recorded events to compute a Fourier transform resulting in a frequency spectrum mapping of the events as illustrated in FIG. **2**A to determine f and ϕ.

FIG. **3** is a block diagram illustrating synchronous coherent optical detection for FM LADAR in accordance with embodiments of the present disclosure. The optical detector **300** is employed as the detector array **126** in the system depicted in FIG. **1**C. The optical detector **300** is formed by a two-dimensional M×N array of pixels. The optical detector **300** is a large format array having more than on the order of ten pixels in each direction and preferably having on the order of hundreds of pixels or more in each direction (e.g., a 512×512 or larger array). Each pixel within the optical detector **300** has a photosensitive material **301** receiving the sinusoidal return comprising return light and coherently interfering local oscillator light as described above in connection with FIGS. **1**C and **2**. The photosensitive material **301** for each pixel produces an analog output **303** received by a local processing circuit **304** for the respective pixel. Each local processing circuit **304** receives a local clock signal **305** and outputs four quadrature value signals **306** representing sampling of the analog output **303** at intervals during a single sample period. The local clock signal **305** is received from, and the quadrature signals **306** are provided to, a data bus **307** that operates under the control of one or more timing/control signals **308** and that outputs serialized digital representations of the quadrature signals **306** on a signal line **309** to a processor or computer **310**. Processor/computer **310** (or at least portions thereof) may be formed on the same integrated circuit chip and/or packaged within the same integrated circuit package as the remainder of optical detector **300**. Within the processor/computer **310**, each of the quadrature signals is separately processed in the manner described above in connection with FIGS. **2** and **2**A. The detector **300** thus applies ROIC technology to coherent detection, computing quadrature components Q_0, Q_1, Q_2, Q_3 of a single interfering frequency (IF) component or optionally a small number of IF components. The quadrature components—and therefore the amplitude and phase—of the IF are computed at the sensor frame rate, allowing detection to be performed on a large format 2D detector.

It should be noted that, although quadrature components are described in the exemplary embodiment above, the number of samples captured during a clock sample period may be less (e.g., three) or more (e.g., five or greater) than four. The number of parallel signal lines **306** from the local processing circuit **304** for each pixel and the data bus **307** would naturally match the number of samples captured at intervals during a single sample period.

Applications of synchronous coherent optical detection for FM LADAR include real-time interferometry, velocity measurement, vibration sensing, two-wavelength 3D imaging, and wavefront sensing for atmospheric compensation. Synchronous coherent optical detection for FM LADAR enables 3D imaging at much longer ranges than AM systems, and is applicable to the gaming industry and virtual reality systems.

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FIG. **4** illustrates use of synchronous coherent optical detection for FM LADAR for real-time interferometry in accordance with embodiments of the present disclosure. For real-time interferometry, the phase data from coherent synchronous detection is equivalent to an interferogram, and quadrature detection is equivalent to phase-shifting interferometry. In the real-time interferometry system **400**, an FM laser source **401** emits illumination **402** that is split by a beam splitter **403** such that a portion is received by a frequency modulator **404**, which produces frequency modulated illumination **405** based on the emitted light **402**. A remainder of the emitted light **402** passes through a lens **406** onto a half-silvered mirror **407** that reflects part of the light onto a test surface **408**. Portions of the light reflecting off test surface **408** passes through mirror **407** and through lens **409** to impinge upon an optical detector **410** structured as depicted in FIG. **3**. The reference light **405** passes through a lens **411** and reflects off half-silvered mirror **407**, and then also passes through lens **409** to impinge upon the optical detector **410**. In this implementation, the light reflected off test surface **408** and passing through mirror **407** to reach the optical detector **410** corresponds to the return light **124** reflected off the target **123** in FIG. **1**C, while the reference light **405** reflected off the mirror **407** to reach the optical detector **410** corresponds to the local oscillator light **127**. In this application, the high frame-rate capability of the optical detector **410** allows analysis of components in dynamic conditions. The phase difference between interferograms at different times allows determination of displacement, and therefore velocity measurement (since displacement per unit time is velocity), and measurement of velocity periodicity allows determination of vibration. The difference between phase measurements at two wavelengths (which may be recorded sequentially or, for an advanced synchronous detector, on two interference frequencies) provides 3D imaging.

For turbulence compensation, coherent synchronous detection also allows real-time recording of complex-values images, to which a sharpness algorithm may be used to determine atmospheric phase error to produce a turbulence-corrected image or to determine the correction to be applied to pre-compensate a high-energy laser. Additional details of turbulence correction may be found in J. C. Marron, et al., "Atmospheric turbulence correction using digital holographic detection: experimental results," *Optics Express*, 17, 11638-11651 (2009).

For digital holography, conventional detector arrays employ long pulse illumination with zero interference frequency. The static fringe pattern recorded represents coherent information recorded on a spatial carrier frequency. Synchronous coherent detection can operate at Q=1 rather than Q=2.

Modifications, additions, or omissions may be made to the systems, apparatuses, and methods described herein without departing from the scope of the disclosure. For example, the components of the systems and apparatuses may be integrated or separated. Moreover, the operations of the systems and apparatuses disclosed herein may be performed by more, fewer, or other components and the methods described may include more, fewer, or other steps. Additionally, steps

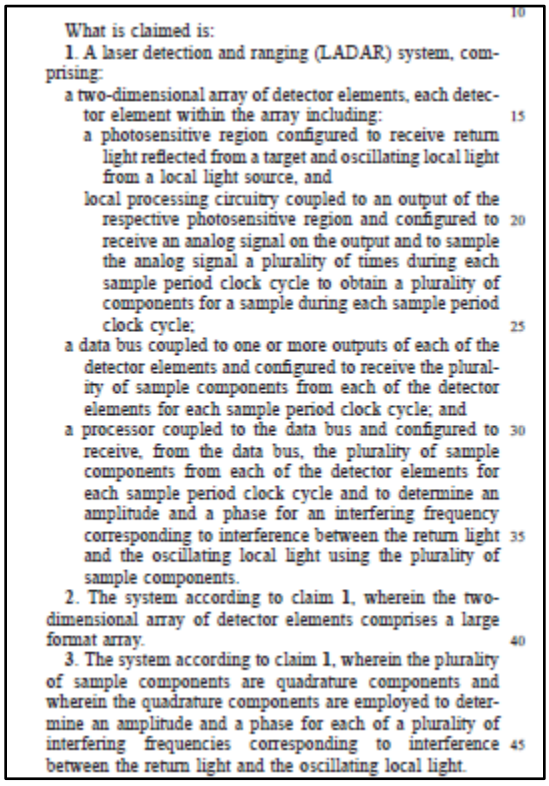
The textual description must meet specific legal requirements in order for the patent to be valid.[21]

Following this textual description (and concluding the patent) are the patent *claims*, a series of numbered paragraphs setting forth what the inventor regards as his invention.[22] These claims form the metes and bounds of the patent right; in other words, the claims define the scope of the

[21] Those requirements are explained in detail *infra*. *See* discussion *infra* in "Patent Application Requirements."

[22] 1 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 1:24 (2020) ("The end of each specification contains a series of numbered paragraphs [where] the patent applicant defines in concise terms the specific invention that the patent applicant particularly claims as his invention. These paragraphs are referred to as patent claims.").

invention, and thus the scope of the legal rights granted by the patent.[23] Some of the '000 patent's claims appear below:



What is claimed is:

1. A laser detection and ranging (LADAR) system, comprising:

a two-dimensional array of detector elements, each detector element within the array including:

a photosensitive region configured to receive return light reflected from a target and oscillating local light from a local light source, and

local processing circuitry coupled to an output of the respective photosensitive region and configured to receive an analog signal on the output and to sample the analog signal a plurality of times during each sample period clock cycle to obtain a plurality of components for a sample during each sample period clock cycle;

a data bus coupled to one or more outputs of each of the detector elements and configured to receive the plurality of sample components from each of the detector elements for each sample period clock cycle; and

a processor coupled to the data bus and configured to receive, from the data bus, the plurality of sample components from each of the detector elements for each sample period clock cycle and to determine an amplitude and a phase for an interfering frequency corresponding to interference between the return light and the oscillating local light using the plurality of sample components.

2. The system according to claim **1**, wherein the two-dimensional array of detector elements comprises a large format array.

3. The system according to claim **1**, wherein the plurality of sample components are quadrature components and wherein the quadrature components are employed to determine an amplitude and a phase for each of a plurality of interfering frequencies corresponding to interference between the return light and the oscillating local light.

The individual clauses within each patent claim are *limitations* that serve to define the invention.[24] Those limitations, taken together, set forth what has been invented. *Independent claims* generally do not reference other claims; for example, claim 1 of the '000 patent is an independent claim. *Dependent claims*, on the other hand, reference and incorporate the limitations of previous claims;[25] for example, claims 2 and 3 of the '000 patent are dependent claims. Patent claims have specific legal requirements, which are explained in more detail later in the report.[26]

Rights Conferred by a Patent

A patent confers certain legal rights on its owner. Specifically, the patent owner may exclude others from making, using, importing, offering for sale, or selling the invention (collectively,

[23] Thorner v. Sony Ent. Am. LLC, 669 F.3d 1362, 1367 (Fed. Cir. 2012) ("It is the claims that define the metes and bounds of the patentee's invention." (citation omitted)).

[24] Hyatt v. Dudas, No. CIV A 04-1138 HHK, 2006 WL 2521242, at *1 (D.D.C. Aug. 30, 2006), *aff'd*, 551 F.3d 1307 (Fed. Cir. 2008) ("[A] single claim can be composed of multiple elements and/or limitations.... Limitations ... usually describe the claim's restrictions, or the interaction between or features of the claim's elements. An application may contain several claims, and each claim usually contains several limitations."); *see also* Bell Commc'ns Rsch., Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 619 (Fed.Cir.1995) ("[T]he language of the claim defines the scope of the protected invention.").

[25] 35 U.S.C. § 112(d) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").

[26] *See* discussion *infra* in "Patent Application Requirements."

"practicing the invention").[27] Notably, the patent includes only *negative* rights to *exclude* others from practicing the invention;[28] the patent grant does not include the positive right for the patent owner to do so.[29] In other words, a patent allows the owner to prevent others from making, using, importing, offering for sale, or selling the invention, but does not give the patent owner the power to perform those acts affirmatively.[30] In some circumstances, a patented invention when practiced in a particular manner may itself infringe another patent.[31] The infringed patent is referred to as a *blocking patent* because it blocks practice of the patented invention.[32] Blocking patents may arise, for example, when a patent's claims are directed to an improvement on another patented invention.[33] In that case, the original patent may "block" practice of the patent on the improvement.[34]

The exclusive rights granted by the patent begin on the date that the patent issues, and generally expire twenty years from the date that the patent application was filed with the PTO.[35] The patent term may be extended under certain circumstances; for example, to compensate for time spent in regulatory review (such as before the Food and Drug Administration (FDA) in the context of pharmaceutical patents)[36] or for delays due to certain PTO procedural failures.[37]

Patents "have the attributes of personal property."[38] Accordingly, although title in an invention initially vests with the inventor, that interest may be transferred or assigned to others.[39] It is common for employment contracts to include provisions under which an employee assigns his interest in any patents developed in the course of employment to the employer.[40] Similarly, patents may be sold from one party to another.[41] A patent owner may also form a contract with

[27] 35 U.S.C. § 271(a). *See also* Bloomer v. McQuewan, 55 U.S. 539, 549 (1852) ("The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.").

[28] *See Bloomer*, 55 U.S. at 549.

[29] Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 935 (Fed. Cir. 1991) ("It should hardly need saying that the issuance of a patent gives no right to make, use or sell a patented invention ....").

[30] *Id.*

[31] *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 80-82 (1994).

[32] *See id.*

[33] *Id.*

[34] *Id.*

[35] 35 U.S.C. § 154(a)(2). For patents whose application was filed before June 8, 1995, the patent term is seventeen years from the date of issuance; for patents whose application was filed after that date, the patent term is twenty years from the earliest date to which the application claims priority. Novartis Pharm. Corp. v. Breckenridge Pharm. Inc., 909 F.3d 1355, 1358 (Fed. Cir. 2018). Before the change in patent term, patent applications could remain pending for many years (in some cases, decades) before issuing and then disrupting developed industries because the term ran from the date of issuance. *See* Mark A. Lemley & Kimberley A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 79-80 (2004).

[36] *See generally* 35 U.S.C. § 156.

[37] *Id.* § 154(b).

[38] *Id.* § 261.

[39] *See id.*; Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993) ("[T]he patent right initially vests in the inventor who may then, barring any restrictions to the contrary, transfer that right to another, and so forth.").

[40] *See, e.g.*, Daniel F. Spulber, *Intellectual Contract and Intellectual Law*, 23 J. TECH. L. & POL'Y 1, 55 (2018); Robert P. Merges, *The Law and Economics of Employee Inventions*, 13 HARV. J.L. & TECH. 1, 2 (1999).

[41] *See, e.g.*, Steve Lohr, *Microsoft's AOL Deal Intensifies Patent Wars*, N.Y. TIMES (April 9, 2012), at https://www.nytimes.com/2012/04/10/technology/microsoft-to-buy-aol-patents-for-more-than-1-billion.html (describing Microsoft's purchase of more than 800 patents held by America Online for more than $1 billion).

another party permitting the other party to make, use, import, or sell a patented invention in return for compensation (e.g., a lump sum payment or a continuing royalty).[42] Such a contract is referred to as a *license*.[43]

Patent Appeals

Unlike most cases in federal court, appeals involving patent law are heard by a single appellate court—the U.S. Court of Appeals for the Federal Circuit (Federal Circuit).[44] (Appeals from decisions of U.S. district courts in most nonpatent cases are heard by the various U.S. Courts of Appeals for different geographical regions or circuits.) Sitting in Washington, DC, Congress created the Federal Circuit in 1982 in an effort to unify and standardize patent law.[45] Although the Supreme Court left the Federal Circuit's interpretations of patent law essentially undisturbed during the first two decades of the Federal Circuit's existence, in recent years the Supreme Court has taken more interest in patent law cases.[46] In many of those cases, the Supreme Court has reversed the Federal Circuit's interpretation of patent law.[47] Nevertheless, Federal Circuit decisions play a large role in the acquisition and enforcement of patent rights in the United States.

Patent Requirements

The process for receiving a patent begins with the filing of an application with the PTO.[48] A PTO patent examiner then reviews the application for compliance with the substantive requirements

[42] Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 47 LES NOUVELLES 28, 32 (2012) (finding, based on a study of nearly 1,500 licensing agreements filed with the Securities and Exchange Commission between 1994 and 2010, that 83% of licenses used a royalty with a rate based on percentage of sales, number of units sold, percentage of profits, or percentage of costs).

[43] MATTHEWS, *supra* note 22, at 5 § 35:28 ("In essence, a patent license is a permission, backed by a contractual promise not to sue, for a party to perform acts that without the license would be deemed acts of infringement."). *See also* 35 U.S.C. § 261 ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

[44] Daniel Kazhdan, *Beyond Patents: The Supreme Court's Evolving Relationship with the Federal Circuit*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 275, 294 (2012) ("[U]nlike regional courts of appeals, because the Federal Circuit has exclusive jurisdiction over the questions of law that it decides, it can create uniformity.").

[45] MARION T. BENNETT, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT: A HISTORY, 1982-1990 4-8, 10-11 (1991). *See also* Timothy R. Holbrook, *The Federal Circuit's Acquiescence(?)*, 66 AM. U. L. REV. 1061, 1065 (2017) ("When the Federal Circuit was created, it had a monumental task on its hands: creating uniformity from the morass of patent case law developed by the regional circuits."). The Federal Circuit has exclusive jurisdiction in a number of nonpatent areas as well, including appeals from the PTO, the U.S. Court of Appeals for Veterans Claims, the U.S. Court of Federal Claims, the U.S. International Trade Commission, and the U.S. Court of International Trade. 28 U.S.C. § 1295.

[46] Paul R. Gugliuzza, *The Supreme Court Bar at the Bar of Patents*, 95 NOTRE DAME L. REV. 1233, 1234-35 (2020); Peter Lee, *The Supreme Assimilation of Patent Law*, 114 MICH. L. REV. 1413, 1421-22 (2016); Timothy R. Holbrook, *The Return of the Supreme Court to Patent Law*, 1 AKRON INTELL. PROP. J. 1, 2 (2007); John F. Duffy, *The* Festo *Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 274 (2002).

[47] Samuel F. Ernst, *A Patent Reformist Supreme Court and Its Unearthed Precedent*, 29 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1, 5 (2018) ("Since the year 2000, the Supreme Court has reversed or vacated the Federal Circuit in patent law cases in 74% of the opinions it has issued reviewing that court ...."); H.R. Rep. No. 112-98, at 39 (2011) ("[T]he need to modernize our patent laws has found expression in the courts, as well. The Supreme Court has reversed the Federal Circuit in six of the patent-related cases that it has heard since the beginning of the 109th Congress.").

[48] *See generally* 35 U.S.C. § 111.

for receiving a patent.[49] If the examiner determines that the application does not meet one of the requirements, she will reject the application.[50] The applicant may generally then amend the application in an effort to overcome the examiner's rejection.[51] Once the examiner determines that an application meets all of the patentability requirements, she "allows" the application to issue as a patent.[52] *Patent prosecution* is the process of applying for a patent, addressing examiner concerns, and receiving the patent.[53] As PTO examiners are generally not lawyers,[54] but rather are subject specialists in the relevant science and/or technology area, the PTO issues the *Manual of Patent Examining Procedure* (MPEP) as guidance for examiners and practitioners.[55]

The following sections outline the requirements that a patent applicant must satisfy to receive a patent. The discussion begins with two preliminary explanations. First, a discussion of who may receive a patent—an area with some emerging issues in view of the rise of artificial intelligence (AI) in recent years. Second, a discussion of one of the core concepts in analyzing patentability: the "person of ordinary skill." The sections that follow then address the substantive requirements for patentability. Those substantive requirements broadly fall into two groups. First are requirements of the *patent application*; that is, requirements regarding the specification that describes the invention, and the level of clarity required in the patent claims. Second are the requirements of the *invention*; namely, that the claimed invention must be patentable subject matter and not be too similar to what has come before. Examiners may reject patent claims that fail to meet one or more of these requirements while the application is still pending.[56] If a patent claim issues as part of a patent and is later determined to fail one or more of these requirements, then that claim is generally "invalid" and subject to challenge if it is enforced.[57]

[49] *See* JAMES E. HAWES & FREDERIC M. DOUGLAS, PATENT APPLICATION PRACTICE § 2:4 (2020) (providing an overview of the patent application process); *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (Oct. 2015), at https://www.uspto.gov/patents-getting-started/general-information-concerning-patents.

[50] HAWES & DOUGLAS, *supra* note 49, § 14:2.

[51] *Id.* § 15.7-15.19.

[52] *Id.* § 21.1.

[53] Nick Cornor, *Are Changes to the U.S. Patent System Objectively Killing Innovation?*, 24 CURRENTS: J. INT'L ECON. L. 87, 90 (2020) ("Patent prosecution refers to the process of applying for a patent."). Although the foregoing discussion provides a high-level overview of the process, patent prosecution is governed by specific laws and regulations, the detailed discussion of which could fill its own report. *See generally* HAWES & DOUGLAS, *supra* note 49.

[54] Lital Helman, *Decentralized Patent System*, 20 NEV. L.J. 67, 89 (2019) ("PTO examiners are not lawyers."); Greg Reilly, *Decoupling Patent Law*, 97 B.U. L. REV. 551, 592 (2017) ("Inherently legal tasks—like parsing the wording of documents, analogizing and distinguishing precedent, and applying canons of document interpretation—are better suited for legally trained judges than legally limited patent examiners.").

[55] *See Manual of Patent Examining Procedure*, U.S. PAT. & TRADEMARK OFF. (9th ed. June 2020), at https://www.uspto.gov/web/offices/pac/mpep/index.html.

[56] HAWES & DOUGLAS, *supra* note 49, § 14:2.

[57] Steven Adamson, *Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers*, 30 LOY. CONSUMER L. REV. 241, 267 (2018) ("[A]n invalid patent does not meet the statutory requirements."); Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1552 (Fed. Cir. 1983) ("No claim of a patent declared invalid can be enforced ....").

Inventorship Requirements

Under current law, only natural persons may be listed as an inventor on a patent.[58] However, it is common for inventors to assign their patent rights to their employers.[59] Further, anyone to whom the inventor has assigned or is under an obligation to assign patent rights may apply for a patent in the inventor's name.[60]

An emerging issue is whether an AI device may qualify as a patent's inventor. In a recent decision, the PTO rejected a patent application where the listed inventor was an AI device.[61] In that case, the application named an AI device called "DABUS" as the inventor.[62] The application further stated that "the invention was autonomously generated by artificial intelligence."[63] The PTO ruled that an AI could not be an inventor because, in its view, the relevant statutory provisions permitted only natural persons to be inventors.[64] For example, the PTO reasoned, the patent statutes repeatedly refer to the inventor as an "individual,"[65] and other provisions of the Patent Act state that "[w]hoever" creates a new invention may receive a patent, both of which suggested that the inventor must be a natural person.[66] Finally, the PTO reasoned that the Federal Circuit had indicated in the past under different circumstances that an inventor must be a natural person (although the Federal Circuit has not directly confronted the question whether an AI device may be an inventor).[67] The European Patent Office has similarly rejected patent applications naming DABUS as an inventor.[68]

The question of who invented a particular invention raises the question of what happens when two people claim to have invented the same thing. For applications filed prior to March 16, 2013, the first person to *invent* a particular invention was generally regarded as the inventor and given priority in obtaining a patent.[69] Congress changed that practice, however, when it passed and President Obama signed the Leahy-Smith America Invents Act (AIA).[70] For applications filed on

[58] MBO Labs., Inc. v. Becton, Dickinson & Co., 602 F.3d 1306, 1310 n.1 (Fed. Cir. 2010) ("Individuals, not corporations, create inventions."); *see also* Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993) ("[O]nly natural persons can be 'inventors.'").

[59] *See supra* note 40 and accompanying text.

[60] 35 U.S.C. § 118 ("A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent.").

[61] *In re* Application No. 16/524,350, Decision on Petition, 2020 WL 1970052, at *1 (Apr. 22, 2020).

[62] *Id.* DABUS is an acronym for "Device for the Autonomous Bootstrapping of Unified Sentience." Rebecca Tapscott, *USPTO Shoots Down DABUS' Bid For Inventorship*, IPWATCHDOG (May 4, 2020), at https://www.ipwatchdog.com/2020/05/04/uspto-shoots-dabus-bid-inventorship/.

[63] *Application No. 16/524,350*, 2020 WL 1970052, at *1.

[64] *Id.* at *3.

[65] *Id.* at *3 & n.8 (citing 35 U.S.C. §§ 100(a), 100(g), 115(a)).

[66] *Id.* at *3.

[67] *Id.* at *3-4.

[68] *EPO Refuses DABUS Patent Applications Designating a Machine Inventor*, European Patent Office (Dec. 20, 2019), at https://www.epo.org/news-events/news/2019/20191220.html.

[69] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(n)(2), 125 Stat. 284, 293 (2011); *see also* Sanofi-Aventis v. Pfizer Inc., 733 F.3d 1364, 1366 n.3 (Fed. Cir. 2013).

[70] *See, e.g.*, Biogen MA, Inc. v. Japanese Found. for Cancer Rsch., 785 F.3d 648, 654 (Fed. Cir. 2015) ("The AIA changed the patent system, among other things, from a first-to-invent to a first-inventor-to-file regime for determining patent priority.").

or after March 16, 2013, generally the first person to *file* his application with the PTO is regarded as the inventor.[71]

The Person of Ordinary Skill

Many of the patentability requirements discussed below are analyzed from the perspective of a "person of ordinary skill in the art" ("POSITA," sometimes referred to as "a person having ordinary skill in the art" (PHOSITA), "a person skilled in the art," and the like).[72] For example, the question whether an invention would have been obvious is analyzed by determining what would have been known to a person of ordinary skill at the time of the invention under review.[73] The person of ordinary skill is a hypothetical construct, not a real person.[74] Instead, the person of ordinary skill is assumed to have the level of education and training common in the field of the invention, as well as all of the publicly available knowledge in that field.[75] Thus, for example, the legal question in determining whether an invention would have been obvious (and thus ineligible for patenting) is not whether an invention was *in fact* obvious to the inventor, but instead whether the invention would have been obvious to this hypothetical person of ordinary skill.[76]

Claim Construction

Both a patent's validity and the determination whether a particular patent is infringed upon may turn on the meaning and scope of particular patent claim terms.[77] For example, the Federal Circuit has reversed a jury verdict of infringement, and vacated the associated award of $85 million in damages, based on its conclusion that the trial court applied the incorrect meaning of a single claim term.[78] The process for determining the meaning of a disputed patent claim term is referred to as *claim construction*.[79]

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[71] *Id.*

[72] *See generally* MATTHEWS, *supra* note 22, at 3 § 18:35.

[73] 35 U.S.C. § 103. *See also* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).

[74] *In re* Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. This legal construct is akin to the 'reasonable person' used as a reference in negligence determinations. The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan." (citation omitted)).

[75] Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1363 (Fed. Cir. 2007) (stating that a "person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art") (quoting Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955 (Fed. Cir. 1986)).

[76] *KSR*, 550 U.S. at 420 ("The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.")

[77] MPHJ Tech. Invs., LLC v. Ricoh Ams. Corp., 847 F.3d 1363, 1364 (Fed. Cir. 2017) ("[T]he first step in any validity analysis is to construe the claims of the invention to determine the subject matter for which patent protection is sought." (quoting Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1353 (Fed. Cir. 1999))); Nazomi Commc'ns, Inc. v. Nokia Corp., 739 F.3d 1339, 1343 (Fed. Cir. 2014) ("The first step of the infringement analysis is claim construction ...."). *See also* TVIIM, LLC v. McAfee, Inc., 851 F.3d 1356, 1362 (Fed. Cir. 2017) ("Claim terms must be construed the same way for the purpose of determining invalidity and infringement.").

[78] SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB, 820 F.3d 419, 421 (Fed. Cir. 2016).

[79] Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("'Claim construction' is the judicial statement of what is and is not covered by the technical terms and other words of the claims."). *See also* Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1358 (Fed. Cir. 2008) ("The first step in most infringement suits is the procedure called 'claim construction,' where the scope of the claim is defined by the court."); Pall Corp. v. Hemasure Inc., 181 F.3d 1305, 1308 (Fed. Cir. 1999) ("Analysis of patent infringement starts with 'construction' of the claim, whereby the court establishes the scope and limits of the claim, interprets any technical or other terms whose meaning is at issue, and

There are two standards for determining the proper claim scope. Once a patent has issued, a patent claim term is given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."[80] This meaning is determined by analyzing evidence intrinsic to the patent (i.e., the language of the claims, specification, and history of prosecution before the PTO), as well as extrinsic evidence (e.g., dictionaries or expert testimony) if necessary.[81] Because this standard was clarified by the Federal Circuit sitting en banc in *Phillips v. AWH Corp.*, it is referred to as the "*Phillips* standard."[82]

If the claim being interpreted is part of a patent application still pending before the PTO, however, the claim is given its "broadest reasonable construction."[83] The Federal Circuit has explained that this standard, which is understood to read the patent claims more broadly than under the *Phillips* standard,[84] applies during examination because the patent applicant can amend her claims and therefore "has the opportunity and responsibility to remove any ambiguity in claim term meaning by amending the application."[85]

Patent Application Requirements

Claim Clarity

Under 35 U.S.C. § 112(b), the claims appearing at the end of the patent must "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention."[86] This is sometimes referred to as the *definiteness requirement*.[87] Patent claims meet this requirement by being clear enough to "inform those skilled in the art about the scope of the invention with reasonable certainty."[88] If a claim fails to meet this standard, it is "indefinite" and therefore invalid.[89] The Supreme Court has described this requirement as "essential" to the quid pro quo underlying the patent grant; it "enables efficient investment in innovation" because "[a] patent holder should know what he owns, and the public should know what he does not."[90] The definiteness requirement thus fosters the "delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which

thereby defines the claim with greater precision than had the patentee.").

[80] Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

[81] *Id.* at 1313-19.

[82] *See, e.g.*, Hamilton Beach Brands, Inc. v. f'real Foods, LLC, 908 F.3d 1328, 1339 n.3 (Fed. Cir. 2018).

[83] *Phillips*, 415 F.3d at 1316 ("The Patent and Trademark Office ... determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" (quoting In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004))).

[84] Celgene Corp. v. Peter, 931 F.3d 1342, 1362 (Fed. Cir. 2019) ("And [inter parte reviews], at the time of these proceedings, used the broadest reasonable interpretation for claim construction rather than the narrower standard from *Phillips v. AWH Corp.*, ... used in district court.").

[85] *In re* Bigio, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

[86] 35 U.S.C. § 112(b).

[87] HZNP Meds. LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 694 (Fed. Cir. 2019) (describing one of the purposes of "the definiteness requirement" as "to afford clear notice of what is being claimed so as to apprise the public of what is still open to them").

[88] Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 910 (2014).

[89] *See, e.g.*, Intellectual Ventures I LLC v. T-Mobile USA, Inc., 902 F.3d 1372, 1381 (Fed. Cir. 2018).

[90] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002).

should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights."[91]

Specification Contents

The specification must also meet certain requirements. The specification must provide "a written description of the invention, and of the manner and process of making and using it,"[92] which is referred to as the *written description requirement*.[93] The written description requirement is met when the specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" of the patent.[94] Because "the invention" is defined by the patent claims, the practical analysis is whether the specification conveys possession of the subject matter of a particular claim or claims.[95] The Federal Circuit has explained that whether an inventor had possession of the invention "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" and requires the specification to "describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."[96] If a patent claim is not adequately described in the specification, then that claim is invalid.[97]

The specification must also provide sufficient detail to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" the invention,[98] referred to as the *enablement requirement*.[99] Because, again, the "invention" is defined by the patent claims, the practical analysis is whether the specification enables a person skilled in the art to make and use the full scope of a particular claim.[100] Thus, the enablement requirement is met when the specification teaches "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"[101] If the full scope of a claim is not enabled, then that claim is invalid.[102]

The specification must also specify the "the best mode contemplated by the inventor or joint inventor of carrying out the invention."[103] The *best mode requirement* means that if inventors possess a best mode for practicing the invention, they must disclose in the specification "sufficient information such that one reasonably skilled in the art could practice the best

[91] *Id.*

[92] 35 U.S.C. § 112(a).

[93] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc).

[94] Rivera v. Int'l Trade Comm'n, 857 F.3d 1315, 1319 (Fed. Cir. 2017) (quoting *Ariad*, 598 F.3d at 1351).

[95] *See id.*

[96] *Ariad*, 598 F.3d at 1351.

[97] *See, e.g.*, Idenix Pharm. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1164 (Fed. Cir. 2019).

[98] 35 U.S.C. § 112(a).

[99] *Ariad*, 598 F.3d at 1340.

[100] Trustees of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1361-65 (Fed. Cir. 2018).

[101] Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1360 (Fed. Cir. 2007) (quoting *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

[102] *Everlight*, 896 F.3d at 1361-65.

[103] 35 U.S.C. § 112(a).

mode."[104] Unlike the written description and enablement requirements, however, claims may not be held invalid for a failure to disclose the best mode.[105]

Patentability

The preceding requirements control the form and content of the disclosure supporting the patent. The following requirements relate to the claimed invention itself.

Patentable Subject Matter

Section 101 of the Patent Act (Section 101) states that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is patentable if the invention meets other requirements.[106] Despite the seemingly broad scope of this provision, however, the Supreme Court "has long held that this provision contains implicit exceptions. Specifically, "'laws of nature, natural phenomena, and abstract ideas' are not patentable."[107]

To determine whether a patent claim encompasses one of these "judicial exceptions" to patentability, courts use a two-step test.[108] First, the court determines whether the claim is directed to one of the exceptions.[109] If it is, then the court determines whether the claim includes an "inventive concept" such that the claim is more than just a patent on the abstract idea, law of nature, or natural phenomena itself.[110]

The law of patentable subject matter received less attention than the other patent requirements until about a decade ago, when the Supreme Court began to show renewed interest in the doctrine.[111] Since then, some stakeholders (including a former Chief Judge of the Federal Circuit) have criticized the Supreme Court and the Federal Circuit for failing to apply the two-step test in a predictable way, and applying it broadly to inventions that should be eligible for patent protection.[112] The Federal Circuit itself has suggested that Supreme Court revision or congressional intervention is needed to prevent inventions on important innovations from being held invalid.[113] Last summer, the Senate Committee on the Judiciary's Subcommittee on Intellectual Property held three days of hearings on possible legislative revisions to Section 101.[114] Petitioners have also asked the Supreme Court to reconsider its patentable subject matter

[104] *In re* Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1085 (Fed. Cir. 2012).

[105] 35 U.S.C. § 282(b)(3)(A).

[106] *Id.* § 101.

[107] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012).

[108] *See* ChargePoint, Inc. v. SemaConnect, Inc., 920 F.3d 759, 765 (Fed. Cir. 2019).

[109] Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).

[110] *Id.*

[111] For the history of the law of patentable subject matter and its development, see CRS Report R45918, *Patent-Eligible Subject Matter Reform in the 116th Congress*, by Kevin J. Hickey.

[112] *See, e.g.*, Paul R. Michel, *Reviving and Repairing the American Patent System*, 27 FED. CIR. B.J. 263, 277-80 (2018). Paul R. Michel is a former chief judge of the Federal Circuit. *Id.* at 263 n.a1.

[113] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019) (denying en banc rehearing of the Section 101 issue, with opinions by eight judges); CRS Legal Sidebar LSB10344, *Judges Urge Congress to Revise What Can Be Patented*, by Kevin T. Richards (discussing the *Athena* en banc denial in more detail).

[114] *See* Sen. Chris Coons & Sen. Thom Tillis, *What Coons and Tillis Learned at Patent Reform Hearings*, LAW360 (June 21, 2019), at https://www.law360.com/articles/1171672/. Video of the hearings and the written testimony are available online. *See* The State of Patent Eligibility in America: Part I: Hearing Before the S. Judiciary Comm.,

jurisprudence in a number of high-profile cases.[115] To date, neither the Supreme Court nor Congress has revised its approach to Section 101.

Novelty

An applicant also may not receive a patent on something that is not new.[116] Thus, if the claimed invention was, among other things, in public use, on sale, or described in a publication prior to the filing date of the patent application, then it is ineligible for a patent.[117] The requirement that the invention be different from what came before is referred to as the *novelty requirement*.[118] To establish a lack of novelty, the PTO examiner (or, in post-issuance proceedings, another party challenging the patent) relies on the "prior art"—references, such as publications and other patents, that establish what was known in the art at the time of the applicant's alleged invention.[119] To demonstrate a lack of novelty (or, in other words, to demonstrate that a patent claim is "anticipated"), a single reference (usually, a patent or publication) must disclose all of the limitations in a patent claim.[120] Notably, the statutory provision governing novelty states that an applicant "shall be entitled to a patent unless" the invention is not novel.[121] Thus, the statute places the burden on the PTO to demonstrate that the invention is not novel.[122]

Under the statute, certain references do not qualify as prior art that would serve to prevent patenting.[123] For example, disclosures by the inventor or a joint inventor made one year or less before the filing date of the patent application do not qualify as prior art.[124] This establishes a one-year "grace period" for inventors to disclose information regarding the invention without losing the opportunity to receive a patent.[125]

Subcomm. on Intellectual Property, 116th Cong. (2019), at https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i; The State of Patent Eligibility in America: Part II: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property, 116th Cong. (2019), at https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-ii; The State of Patent Eligibility in America: Part III: Hearing Before the S. Judiciary Comm., Subcomm. on Intellectual Property, 116th Cong. (2019), at https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-iii.

[115] *See, e.g.*, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 855 (2020); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

[116] *See generally* 35 U.S.C. § 102.

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] Acoustic Tech., Inc. v. Itron Networked Sols., Inc., 949 F.3d 1366, 1373 (Fed. Cir. 2020) ("In an anticipation analysis, the dispositive question is whether a skilled artisan would 'reasonably understand or infer' from a prior art reference that every claim limitation is disclosed in that single reference." (quoting Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003))).

[121] 35 U.S.C. § 102.

[122] *See id.*

[123] *See generally id.* § 102(b).

[124] *Id.* § 102(b)(1).

[125] Peter Lee, *Patents and the University*, 63 DUKE L.J. 1, 69 (2013).

Nonobviousness

An applicant also may not receive a patent on an invention that is an obvious extension of the prior art.[126] Thus, "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention," then the applicant may not receive a patent.[127] The Supreme Court has directed that four factors must be considered when determining whether the prior art renders a claimed invention obvious:

1. the scope and content of the prior art;
2. the differences between the prior art and the claimed invention;
3. the level of ordinary skill of the art; and
4. any secondary considerations (also referred to as *objective indicia*) of nonobviousness.[128]

Secondary considerations/objective indicia that may be considered in evaluating obviousness include commercial success, long-felt but unsolved needs, and failure of others, which might provide evidence regarding whether the invention would have been obvious at the time of invention.[129]

While a single prior art reference is generally used to demonstrate lack of novelty, multiple references may also be used to establish that a claim would have been obvious.[130] Simply demonstrating that all of the limitations in a claim were disclosed across several references, however, is insufficient to establish that an invention would have been obvious.[131] Instead, the party challenging the patent must further prove that a person of ordinary skill would have had some reason to combine the different references.[132] For example, a party may argue that a person of ordinary skill would have had a reason to modify the system disclosed in one reference by incorporating a part disclosed in another reference.[133]

[126] *See* 35 U.S.C. § 103.

[127] *Id.*

[128] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966) ("Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.").

[129] Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) ("[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." (quoting Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1349 (Fed. Cir. 2012))).

[130] *See, e.g.*, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 422-26 (2007) (determining that claims would have been obvious in view of two references).

[131] *Id.* at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

[132] *Id.* at 417-18.

[133] *Id.* at 422-26.

Maintenance Fees

Although not a prerequisite to receiving a patent, patentees must also pay periodic maintenance fees (due at 3.5, 7.5, and 11.5 years after issuance) in order to keep their patent in force once it issues.[134] Those fees begin at $1,600 at 3.5 years after issuance, and climb to $7,400 at 11.5 years after issuance.[135] These fees change periodically.[136] If a patentee fails to pay the maintenance fees, then the patent is no longer enforceable.[137]

Patent Infringement and Enforcement

Although patent rights are granted by the government, the government does not actively protect those rights once granted; for example, there is no criminal penalty for infringing another's patent.[138] Instead, the patent owner is responsible for enforcing the patent.[139] Often, a patent owner will sue a party she believes is violating her exclusive rights in federal court.[140] Violating the exclusive rights granted by a patent is referred to as "infringing" a patent.[141] This section will describe patent infringement and related doctrines, before turning to how a patent owner may attempt to enforce a patent that she believes is being infringed.

Proving Patent Infringement

Patent infringement primarily takes two forms: *direct infringement*, where a party itself makes, uses, imports, sells, or offers to sell a patented invention without authorization; and *indirect infringement*, where a party in some culpable way causes direct infringement by another.[142]

Direct Infringement

A party directly infringes a patent by itself making, using, importing, selling, or offering for sale the claimed invention.[143] To determine whether a party infringes, the patent claims are construed

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[134] HAWES & DOUGLAS, *supra* note 49, § 24:2.

[135] *USPTO Fee Schedule*, U.S. PAT. & TRADEMARK OFF. (accessed July 9, 2020), at https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Maintenance%20Fee.

[136] HAWES & DOUGLAS, *supra* note 49, § 24:2.

[137] *Id.*

[138] Dowling v. United States, 473 U.S. 207, 227 (1985) ("Despite its undoubted power to do so, ... Congress has not provided criminal penalties for distribution of goods infringing valid patents."); Noel Mendez, *Patent Infringers, Come Out with Your Hands Up!: Should the United States Criminalize Patent Infringement?*, 6 BUFF. INTELL. PROP. L.J. 34, 34-35 (2008) ("In the United States, however, there are no criminal penalties for patent infringement.").

[139] *See* 35 U.S.C. § 281 ("A patentee shall have remedy by civil action for infringement of his patent.").

[140] *Id.*

[141] *Id.*

[142] A third type of infringement, "artificial infringement," arises in the context of the specific patent dispute procedure that Congress developed for resolution of disputes between brand-name and generic pharmaceutical manufacturers. See discussion *infra* in "Specialized Dispute Procedures"; *see also* Richards, *supra* note 8, at 10-12. Infringement is "artificial" in those situations because the patent statute defines certain acts as infringing, even though no party has yet practiced the invention, in order to encourage early resolution of those disputes.

[143] 35 U.S.C. § 271(a). *See also* Lifetime Indus., Inc. v. Trim-Lok, Inc., 869 F.3d 1372, 1378 (Fed. Cir. 2017) (explaining that a party can "make" an invention by assembling separate parts into an infringing combination, as well as through commercial manufacture); Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc., 631 F.3d 1279, 1284 (Fed. Cir. 2011) ("We hold that to 'use' a system for purposes of infringement, a party must put the invention into service, i.e., control the system as a whole and obtain benefit from it."); Transocean Offshore Deepwater Drilling, Inc.

and then compared to the product or method accused of infringement.[144] There are two ways a patentee can prove that an element of an accused product or method meets a patent claim limitation. First, an element of an accused product or method may exactly match (or "meet") the claim limitation. This is referred to as an element "literally" meeting the claim limitation.[145] For example, if the limitation at issue requires a wooden doorknob and the accused product includes a wooden doorknob, the accused product literally meets the limitation.

An element may also meet a claim limitation under the *doctrine of equivalents*; in other words, even if the accused product or method does not literally meet a claim limitation, that limitation may be met if the accused product or method includes an element that is equivalent to the claim limitation.[146] Under the doctrine of equivalents, an element is equivalent to a claim limitation if it performs the same function, in the same way, to reach the same result.[147] For example, if the limitation at issue requires a wooden doorknob and the accused product includes a steel doorknob, the accused product would not *literally* meet that claim limitation, but might meet the limitation under the doctrine of equivalents.

Indirect Infringement

Indirect infringement refers to conduct where a party does not itself directly infringe a patent, but causes another party to infringe directly.[148] There are two main types of indirect infringement: *induced infringement* and *contributory infringement*.[149]

Induced Infringement

Under the patent statute, "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[150] To induce infringement, a party must take an affirmative action to encourage another to perform direct infringement of a patent, knowing that those actions would constitute

v. Maersk Contractors USA, Inc., 617 F.3d 1296, 1311 (Fed. Cir. 2010) ("A 'sale' is not limited to the transfer of tangible property; a sale may also be the agreement by which such a transfer takes place."); 3D Sys., Inc. v. Aarotech Labs., Inc., 160 F.3d 1373, 1379 (Fed. Cir. 1998) (holding that "price quotation letters" were an offer to sell).

[144] Cordis Corp. v. Bos. Sci. Corp., 658 F.3d 1347, 1354 (Fed. Cir. 2011) ("The infringement analysis is a two step inquiry. 'First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device.'" (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (internal citations omitted))).

[145] E.I. du Pont De Nemours & Co. v. Unifrax I LLC, 921 F.3d 1060, 1073 (Fed. Cir. 2019) ("For literal infringement, the patentee must prove that the accused product meets all the limitations of the asserted claims; if even one limitation is not met, there is no literal infringement.").

[146] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (explaining that under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention").

[147] Plastic Omnium Advanced Innovation & Rsch. v. Donghee Am., Inc., 943 F.3d 929, 938 (Fed. Cir. 2019) ("A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." (quoting AquaTex Indus., Inc. v. Techniche Sols., 479 F.3d 1320, 1326 (Fed. Cir. 2007))).

[148] *See Lifetime Indus.*, 869 F.3d at 1377-80.

[149] *Id.* at 1379-80.

[150] 35 U.S.C. § 271(b).

infringement.[151] Thus, a finding of induced infringement requires proof that "(1) a third party directly infringed the asserted claims of the ... patents; (2) [the defendant] induced those infringing acts; and (3) [the defendant] knew the acts it induced constituted infringement."[152]

Contributory Infringement

Broadly speaking, contributory infringement bars selling or importing a material component of a patented invention, where the component has no substantial noninfringing use.[153] To prove contributory infringement, a patent owner must prove (1) "that there is direct infringement"; (2) "that the accused infringer had knowledge of the patent"; (3) "that the component has no substantial noninfringing uses"; and (4) "that the component is a material part of the invention."[154]

Enforcing a Patent

Patent owners can enforce their patents in two main ways. First, the patent owner may file a civil action in a federal district court alleging direct or indirect patent infringement.[155] Second, if the patent owner believes that another party is importing articles that infringe its patent, it may file a complaint in the International Trade Commission.[156]

District Court Enforcement

The primary method of patent enforcement is to file a civil action in federal district court. The process begins when a patent owner files a complaint alleging that another person has infringed its patent.[157] Generally speaking, the three primary issues in district court litigation will be *claim construction*, *infringement*, and *validity*. For claim construction, the parties will litigate any disputed patent claim constructions—that is, the manner in which a patent claim is interpreted—and the assigned judge will issue an order ruling how the disputed claim terms will be construed.[158] Following claim construction by the judge, whether the accused product(s) infringe the patent claims, as construed by the judge, is generally tried to a jury.[159]

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[151] Limelight Networks, Inc. v. Akamai Techs., Inc., 572 U.S. 915, 920 (2014) (holding that induced infringement requires direct infringement); Glob.-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011) ("[I]nduced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement."); Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1332 (Fed. Cir. 2016).

[152] *Power Integrations*, 843 F.3d at 1332.

[153] *See* 35 U.S.C. § 271(c) ("Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.").

[154] Fujitsu Ltd. v. Netgear Inc., 620 F.3d 1321, 1326 (Fed. Cir. 2010).

[155] 28 U.S.C. § 1338.

[156] 19 U.S.C. § 1337(a)(1)(B)-(E).

[157] *See, e.g.*, Lifetime Indus., Inc. v. Trim-Lok, Inc., 869 F.3d 1372, 1375 (Fed. Cir. 2017).

[158] Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) ("We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.").

[159] *See* Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc) (reviewing jury verdict of infringement).

In defense, the party accused of infringement may argue that the patent did not, in fact, meet the statutory requirements for patenting when it issued. This is referred to as an argument that the patent is "invalid."[160] Because an invalid patent is not legally enforceable, a judgment that the patent is invalid will lead to a finding of no liability.[161] The issue of invalidity is also typically tried to a jury.

If the jury finds that the patent is infringed and not invalid, then the patent owner is entitled to a remedy. Available remedies include money damages and a court order that the infringer cease infringement (an "injunction").[162] The minimum amount of money damages is a "reasonable royalty,"[163] generally set at the amount that the parties would have agreed to for the infringer to license the patent at the time infringement began.[164] In certain circumstances, the patent owner may also be entitled to recover any profits she can prove were lost due to the infringement.[165] If the infringing behavior was "egregious," moreover, then the damages award may be increased up to triple the amount awarded by the jury.[166] To receive an injunction, a patentee must prove (1) that it has suffered an irreparable injury; (2) that monetary damages are inadequate to compensate for that injury; (3) that the balance of hardships favors an injunction; and (4) that an injunction is in the public interest.[167]

In "exceptional" cases, the trial judge may also, in her discretion, award the prevailing party its attorney's fees.[168] The Supreme Court has held that an exceptional case is one that "stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."[169]

International Trade Commission Enforcement

The U.S. International Trade Commission (ITC)—an independent federal agency—administers Section 337 of the Tariff Act of 1930 (Section 337), among other statutes, which allows it to "investigate and issue decisions on unfair methods of competition and unfair acts in the importation and/or sale of imported articles."[170] Section 337 establishes that the importation into, or sale within the United States of articles that infringe a valid U.S. patent, copyright, or trademark are unlawful actions the ITC may address.[171] Although Section 337 investigations are

[160] 35 U.S.C. § 282(b).

[161] Viskase Corp. v. Am. Nat. Can Co., 261 F.3d 1316, 1323 (Fed. Cir. 2001) ("[A]n invalid claim can not be infringed ...." (quoting Richdel, Inc., v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed. Cir. 1983))). *See also* Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1929 (2015) ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics.")

[162] 35 U.S.C. §§ 281 (remedies generally), 283 (injunction), 284 (damages).

[163] *Id.* § 284.

[164] *See, e.g.*, Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 904 F.3d 965, 977 (Fed. Cir. 2018).

[165] Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1283 (Fed. Cir. 2017).

[166] Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923, 1931 (2016).

[167] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

[168] 35 U.S.C. § 285.

[169] Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014).

[170] William P. Atkins & Justin A. Pan, *An Updated Primer on Procedures and Rules in 337 Investigations at the U.S. International Trade Commission*, 18 U. BALT. INTELL. PROP. L.J. 105, 106-07 (2010).

[171] 19 U.S.C. § 1337(a)(1)(B)-(E).

not limited to behavior arising from IP, in recent years many such investigations "have focused on either patent, unregistered trademark, or trade secret claims."[172]

Section 337 investigations are somewhat similar to civil infringement actions in district court, with some important differences. Unlike infringement actions in district court, where the court primarily adjudicates disputes between the parties, in Section 337 investigations the ITC itself investigates whether there were unfair methods of competition or unfair acts in importation.[173] Thus, an investigative attorney from the ITC's Office of Unfair Import Investigations participates as a party in the process, along with the complainant and respondent.[174]

Moreover, in order to be entitled to relief, the party who files the Section 337 complaint "must show that a U.S. industry that is dedicated to exploitation of the asserted IP rights either exists or is in the process of being established."[175] To meet this domestic industry requirement, a complainant must establish that she is performing activities based in the United States that exploit the particular IP rights (the "technical element") and that she has significant investment in exploitation of the IP rights (the "economic element").[176]

Section 337 investigations are evaluated based on the complaint filed by a private party.[177] First, the ITC performs a pre-institution investigation to determine whether the complaint provides an adequate basis for a full investigation.[178] If the ITC determines that the complaint establishes such a basis, then a full investigation begins and is overseen by an administrative law judge (ALJ).[179] Following this process, the ALJ issues an initial determination whether a violation of Section 337 has been shown; that determination may be reviewed by the ITC Commissioners, and the Commissioners' determination may then be appealed to the Federal Circuit.[180]

If a Section 337 violation is established, possible remedies include (1) a general exclusion order, which forbids importation of products regardless of the source; (2) a limited exclusion order, which forbids importation of those products by specific companies designated in the complaint; (3) cease-and-desist orders that enjoin activities by U.S. entities; (4) temporary exclusion or cease-and-desist orders during the pendency of the investigation; and (5) consent orders, where the parties agree to an outcome.[181] The U.S. President may disapprove any exclusion or cease-and-desist order within sixty days of issuance; if he does not, then the order goes into effect.[182]

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[172] Atkins & Pan, *supra* note 170, at 107 ("The majority of Section 337 investigations have focused on either patent, unregistered trademark, or trade secret claims, in part because these types of rights are not subject to recordation with the U.S. Customs Service."). While most recent cases have involved allegations of patent infringement, the ITC has also adjudicated cases involving alleged trademark infringement or dilution, trade dress misappropriation and infringement, false designation of origin, copyright infringement, and misappropriation of trade secrets, among others. *Id.* at 108-09 (collecting cases).

[173] 19 U.S.C. § 1337(b); 19 C.F.R. §§ 210.9-210.10.

[174] Atkins & Pan, *supra* note 170, at 116. *See also* 19 C.F.R. § 210.3.

[175] Atkins & Pan, *supra* note 170, at 120 (citing 19 U.S.C. § 1337(a)(2)).

[176] *Id.* at 121; *see, e.g.*, InterDigital Commc'ns, LLC v. ITC, 707 F.3d 1295, 1298 (Fed. Cir. 2013); 19 U.S.C. § 1337(a)(3).

[177] Atkins & Pan, *supra* note 170, at 112; 19 C.F.R. § 210.8.

[178] Atkins & Pan, *supra* note 170, at 112; 19 C.F.R. § 210.9.

[179] Atkins & Pan, *supra* note 170, at 113; 19 U.S.C. § 1337(b).

[180] Atkins & Pan, *supra* note 170, at 113.

[181] *Id.* at 129-33.

[182] *Id.* at 135 (citing 19 U.S.C. § 1337(j)). Such disapprovals are reportedly rare. *Id.*

Specialized Dispute Procedures for Certain Pharmaceuticals

Congress has also implemented several specialized procedures for certain pharmaceutical patent disputes, with the general goal of encouraging early resolution of disputes relating to market entry of small-molecule drugs and large-molecule biological products (i.e., "biologics").[183] Generally, these disputes are between brand-name drug and biological product manufacturers (the brands), whose products are generally protected by patents, and generic drug or biosimilar manufacturers (the generics), which market competing pharmaceuticals once the brands' products are no longer protected by patents. The procedures differ depending on whether the pharmaceutical is regulated as a drug or as a biologic.[184]

The Hatch-Waxman Act governs the dispute process for small-molecule drugs.[185] In order to market a new drug, the manufacturer must submit and the Food and Drug Administration (FDA) must approve a new drug application (NDA). The NDA must demonstrate, among other things, that the drug is safe and effective for its intended use, and must list any patents claiming the drug or method of using the drug that could reasonably be asserted in infringement litigation.[186] A generic drug manufacturer may later file an abbreviated new drug application (ANDA) that relies on the FDA's approval of a drug with the same active ingredient (the "reference listed drug," or RLD) to establish safety and efficacy.[187] The ANDA may also certify that the RLD is either not protected by patents or that applicable patents are invalid and/or not infringed.[188] Under certain circumstances, patent law treats the filing of an ANDA as an "artificial" act of patent infringement,[189] allowing for the resolution of patent disputes (for example, whether any patent covering the RLD is invalid) before the generic product is marketed to the public. If the brand manufacturer sues the generic manufacturer within forty-five days following the generic's ANDA filing, FDA generally cannot approve the ANDA for thirty months while the parties litigate the patent dispute—a period often referred to as the "thirty-month stay."[190]

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) governs the dispute resolution procedure for biologics and biosimilars.[191] In order to market a biologic, a manufacturer must submit and FDA must approve a biologics license application (BLA). Under the BPCIA, a biosimilar manufacturer may rely on a sufficiently similar, already licensed biologic (the "reference product") when applying for a manufacturing license. Unlike Hatch-Waxman, however, regulatory approval of biologics is not directly contingent on the parties' resolution of

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[183] Often, new pharmaceuticals are marketed under patent protection by brand-name manufacturers of drugs and biologics. These specialized procedures are also designed to encourage follow-on production of competing (generally less expensive) generic drugs and products that are biosimilar to the biologics. *See generally* CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, coordinated by Kevin J. Hickey, at 27-35.

[184] For a summary comparison, see CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey.

[185] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) (codified as amended at 21 U.S.C. §355 and 35 U.S.C. §156, 271 and 282).

[186] 21 U.S.C. § 355(d).

[187] Pub. L. No. 98-417, § 101, 98 Stat. 1585.

[188] 35 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

[189] *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990); 35 U.S.C. § 271(e)(2)-(6). The "artificial" act of infringement (filing an application with FDA) is distinguished from traditional direct patent infringement—making, using, selling, or importing the patented invention. *See* 35 U.S.C. § 271(a).

[190] *See* 35 U.S.C. § 271(a); *Caraco Pharm.* Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407-08 (2012).

[191] Pub. L. No. 111-148, tit. VII, 124 Stat. 199, 804-21 (2010).

any patent disputes. Instead, biosimilar patent disputes may be resolved through the BPCIA's "patent dance," "a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement."[192] After the biosimilar manufacturer submits its application with FDA, the biosimilar applicant and reference product manufacturer may exchange information regarding the patents that each party believes are relevant along with related positions on infringement and validity.[193] Depending on the extent of their participation in this information exchange, each party may have the opportunity to litigate the patents at the conclusion of the patent dance, or later on, when the biosimilar is marketed.[194] Injunctive relief to compel the biosimilar applicant to engage in the patent dance is unavailable under federal law.[195]

Patent Invalidation and Cancellation

As explained above, PTO examines patent applications for compliance with the various statutory requirements before allowing patents to issue.[196] If it is later determined that an issued patent did not meet those requirements, the patent is held invalid and cannot be enforced.[197] There are two primary fora in which an issued patent can be invalidated or cancelled: (1) through district court litigation; or (2) through specialized administrative proceedings before the PTO.

District Court Litigation

A common defense to an allegation of patent infringement is that the patent is invalid and should not have been issued because it did not meet the requirements for patenting.[198] For example, an accused infringer may claim that the patented invention was not actually novel or that the patent claims are indefinite. Because issued patents are presumed to be valid,[199] facts surrounding invalidity must be proven by clear and convincing evidence—a higher burden than the preponderance-of-the-evidence standard generally used in civil litigation.[200]

An accused infringer may also argue that the patent is unenforceable due to "inequitable conduct" during patent prosecution before the PTO.[201] Inequitable conduct occurs when the patentee, in the course of prosecuting the patent, acts "with the specific intent to deceive the PTO" and that, but for that deception, the PTO would not have allowed the patent to issue.[202] For example, "[i]n a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference."[203]

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[192] Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1670 (2017); 42 U.S.C. § 262(*l*).

[193] *Sandoz*, 137 S. Ct. at 1671-72.

[194] *Id.* at 1672.

[195] *Id.* at 1675. Rather, the exclusive remedy for the biosimilar applicant's failure to commence the patent dance is provided by 42 U.S.C. § 262(*l*)(9)(C), which provides that, in that situation, "the reference product sponsor, but not the [biosimilar] applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." *Id.*

[196] *See* discussion *supra* in "Patent Requirements."

[197] 35 U.S.C. § 282(b).

[198] *See* discussion *supra* in "District Court Enforcement."

[199] 35 U.S.C. § 282.

[200] Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

[201] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

[202] *Id.*

[203] *Id.* (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

PTO Administrative Proceedings

Congress has also enacted a number of specialized administrative proceedings for reviewing and potentially cancelling issued patents.[204]

Ex Parte Reexamination

"Any person at any time" may file a request for the PTO to reexamine an issued patent.[205] The request must be based on "patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent."[206] If the PTO Director determines that the request raises "a substantial new question of patentability affecting any claim of the patent," then she may institute an ex parte reexamination.[207] If a reexamination is initiated, it proceeds in the same manner as the initial examination; in other words, the examiner may reject the claims on the basis of the new prior art, the applicant may amend the claims, etc.[208] As in initial examination, claim terms are given their broadest reasonable construction consistent with the specification.[209] Unlike other methods of post-issuance review, however, the person who sought reexamination is not involved in the process once the PTO decides to initiate reexamination.

Post-Grant Review

As part of the AIA's major changes to the patent regime in 2011, Congress also created post-grant review (PGR), an administrative proceeding that can result in cancellation[210] of an issued patent.[211] Within nine months after a patent issues,[212] anyone other than the patent holder may file a petition with the PTO requesting the PTO to initiate PGR to review the validity of the patent.[213] The petition may request review of the patent based on any of the requirements for patenting.[214] For example, the petition may argue that the patent is not directed to patentable subject matter under Section 101; that the claims are indefinite under Section 112; or that the claims would have been obvious under Section 103.[215]

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[204] These proceedings have been upheld over constitutional challenges arguing that patents can be invalidated only by a federal court. Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1370 (2018); Patlex Corp. v. Mossinghoff, 758 F.2d 594, 596 (Fed. Cir. 1985).

[205] 35 U.S.C. § 302.

[206] *Id.* § 301.

[207] *Id.* § 303(a). The PTO Director may also determine whether a substantial new question of patentability exists on her own initiative. *Id.*

[208] *Id.* § 305. For more detail regarding initial examination, see discussion *supra* in "Patent Requirements."

[209] *In re* Man Mach. Interface Techs. LLC, 822 F.3d 1282, 1286 (Fed. Cir. 2016) ("In reexamination, claims are given their broadest reasonable interpretation ("BRI") consistent with the specification.").

[210] Although the terminology is different, there is no practical difference between a district court invalidating a claim during litigation and the PTO cancelling a claim following an administrative proceeding. The result is the same: the patent can no longer be enforced.

[211] 35 U.S.C. §§ 321-29.

[212] *Id.* § 321(b).

[213] *Id.* § 321(a).

[214] *Id.* § 282(b).

[215] *Id.*

Although the PTO's Patent Trial and Appeal Board (PTAB) applied the "broadest reasonable construction" standard for some time,[216] the PTAB now applies the *Phillips* standard for claim construction.[217] After a PGR petition is filed, the patent owner may file a preliminary response arguing that the patent claims meet all patenting requirements.[218] Based on the petition and any response, the PTO Director determines whether "it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[219] If so, the PTAB may institute review.[220] The PTAB may also institute review if the petition "raises a novel or unsettled legal question that is important to other patents or patent applications."[221] The PTAB's decision whether to institute review may not be appealed.[222]

If the PTAB institutes review, the patent owner may file a full response to the petition; the petitioner may file a reply; and, generally, the patent owner may file a sur-reply.[223] The patent owner may also file a motion to amend the claims.[224] Following the sur-reply, the PTAB holds a hearing where the petitioner and patent owner present arguments regarding whether the patent meets the relevant requirements for patenting.[225] Following the hearing, the PTAB issues a final written decision determining whether the patent is valid.[226] The final written decision may be appealed to the Federal Circuit.[227] If, after all appeals, the patent claims are held invalid, then the PTO issues a certificate cancelling those claims.[228]

Inter Partes Review

Inter partes review (IPR) is another administrative proceeding introduced in the AIA, and the most-used PTO proceeding by an overwhelming margin.[229] The process for IPR is nearly

[216] Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2139 (2016).

[217] Personalized Media Commc'ns, LLC v. Apple Inc., 952 F.3d 1336, 1340 n.2 (Fed. Cir. 2020) ("Per recent regulation, the Board applies the Phillips claim construction standard to IPR petitions filed on or after November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b)). Because Apple filed its IPR petition before November 13, 2018, we apply the broadest reasonable interpretation standard.").

[218] 35 U.S.C. § 323.

[219] *Id.* § 324(a). The PTO Director has delegated this authority to PTAB. 37 C.F.R. § 42.4 ("The Board institutes the trial on behalf of the Director."); Thryv, Inc v. Click-To-Call Techs., LP, 140 S. Ct. 1367, 1371 (2020) ("The Director has delegated institution authority to the Patent Trial and Appeal Board.").

[220] 35 U.S.C. § 324(a). Notably, the decision whether to institute is permissive, rather than mandatory. *Id.* (stating that "the director may not institute" PGR "*unless*" the petitioner demonstrates that it is more likely than not that at least one claim is unpatentable, but not mandating institution (emphasis added)).

[221] *Id.* § 324(c).

[222] *Id.* § 324(e); *Thryv*, 140 S. Ct. at 1372-74; Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2139 (2016). *See also* CRS Legal Sidebar LSB10454, *No Judicial Review of Certain Patent Office Decisions, Supreme Court Holds*, by Kevin T. Richards.

[223] *Patent Trial and Appeal Board Consolidated Trial Practice Guide*, U.S. PAT. & TRADEMARK OFF. (Nov. 2019), at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf. *See also* 35 U.S.C. § 326(a) (giving PTO Director the power to promulgate regulations governing PGR).

[224] 35 U.S.C. § 326(a)(9).

[225] *See id.* § 326(a)(10).

[226] *Id.* § 328(a).

[227] *Id.* § 329.

[228] *Id.* § 328(b).

[229] *Trial Statistics*, U.S. PAT. & TRADEMARK OFF. (June 2019), at https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-06-30.pdf (stating that IPR petitions account for 93% of all administrative proceeding petitions).

identical to PGR, with two primary differences.[230] The first difference is the time window for filing an IPR. Whereas a PGR must be filed within the first nine months after a patent issues,[231] an IPR may be filed only *after* the later of nine months after the patent issues (and when any PGR regarding the patent concludes) through the time the patent expires.[232]

The second difference is the grounds for cancellation that may be presented in an IPR. Whereas a PGR petition may challenge whether a patent claim meets any of the patenting requirements, an IPR may challenge a patent claim only on the basis of anticipation (Section 102) or obviousness (Section 103), and may rely only on prior art patents or printed publications (and not other forms of prior art, such as public uses).[233] Procedurally, however, IPR is the same as PGR: a person (other than a patent's owner) files a petition; the patent owner may file a preliminary response; and the PTAB decides whether to initiate IPR.[234] If IPR is instituted, the patent owner files a response; the petitioner files a reply; the patent owner files a sur-reply; and the PTAB holds a hearing on the issues.[235] The PTAB then issues a final written decision, which may be appealed to the Federal Circuit.[236]

Covered Business Method Review

The AIA also introduced cover business method review (CBM), a time-limited administrative proceeding for reviewing patents relating to methods of doing business.[237] CBM review follows many of the same procedures as PGR,[238] with several differences. A CBM review petition may be filed only by a party who "has been sued for infringement of the patent or has been charged with infringement under that patent" and may be filed only against a patent that is the subject of the suit.[239] Moreover, the patent must claim a "covered business method," which the statute defines as "a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions."[240] The CBM review program will sunset on September 16, 2020, absent congressional extension.[241]

Comparison of PTO Proceedings

Table 1 summarizes the four methods of challenging patents administratively at the PTO.

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[230] Another difference is that the standard for instituting IPR is "that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," 35 U.S.C. § 314(a), instead of PGR's standard of "that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable," *id.* § 324(a).

[231] *Id.* § 321(c).

[232] *Id.* § 311(c).

[233] *Id.* § 311(b).

[234] *Id.* § 312-14, 316, 318.

[235] *Id.* § 318.

[236] *Id.* § 319.

[237] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 331, § 18(a) (2011).

[238] *Id.* § 18(a)(1)(A).

[239] *Id.* § 18(a)(1)(B).

[240] *Id.* § 18(d)(1).

[241] *Id.* § 18(a)(3).

Table 1. PTO Post-Issuance Proceedings

Proceeding	Filing Deadline	Challenger	Grounds	Evidentiary Threshold	Sunset Date
Ex Parte Reexamination	None.[242]	Anyone,[243] including the PTO Director on his/her own initiative.[244]	Novelty or nonobviousness on the basis of patents or printed publications.[245]	Substantial new question of patentability.[246]	None.
PGR	Nine months after issuance or reissuance of a patent.[247]	Anyone except the patent owner.[248]	Patent-eligible subject matter; novelty; nonobviousness; indefiniteness; written description; enablement.[249]	More likely than not that at least one of the challenged patent claims is unpatentable.[250]	None.
IPR	The later of (1) nine months after patent grant; and (2) termination of any PGR.[251]	Anyone except the patent owner.[252]	Novelty or nonobviousness on the basis of patents or printed publications.[253]	Reasonable likelihood that the petitioner would prevail with respect to at least one of the challenged claims.[254]	None.

[242] 35 U.S.C. § 302 ("Any person at any time may file a request for reexamination ....").

[243] *Id.*

[244] *Id.* § 303(a).

[245] *Id.* § 302 ("Any person at any time may file a request for reexamination by the [PTO] of any claim of a patent on the basis of any prior art cited under the provisions of section 301."); *id.* § 301 (allowing any person at any time to cite "prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent").

[246] *Id.* § 303(a).

[247] *Id.* § 321(c).

[248] *Id.* § 321(a) ("[A] person who is not the owner of a patent may file with the [PTO] a petition to institute a post-grant review of the patent.").

[249] *Id.* § 321(b); *id.* § 282(b)(2), (3).

[250] *Id.* § 324(a).

[251] *Id.* § 311(c).

[252] *Id.* § 311(a) ("[A] person who is not the owner of a patent may file with the [PTO] a petition to institute an inter partes review of the patent.").

[253] *Id.* § 311(b) ("A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.").

[254] *Id.* § 314(a).

Proceeding	Filing Deadline	Challenger	Grounds	Evidentiary Threshold	Sunset Date
CBM	None (other than sunset date).[255]	A person or the person's real party in interest or privy who has been sued or charged with infringement under the challenged patent.[256]	May challenge only a covered business method patent.[257] May raise patent-eligible subject matter; novelty; nonobviousness; indefiniteness; written description; or enablement issues. If challenging a pre-AIA patent, may rely only on certain types of prior art.[258]	More likely than not that at least one of the challenged claims is unpatentable.[259]	Sept. 16, 2020[260]

Source: Created by CRS based on Title 35 of the *U.S. Code*.

Considerations for Congress

Just as the Supreme Court has seemingly taken an increased interest in patent law in recent years, as indicated by the rise in the number of patent law cases for which it has granted certiorari,[261] Congress has also recently enacted several major patent reforms. Congress enacted the AIA in 2011, which introduced a number of new administrative procedures for challenging patents and restructured the substantive patent laws.[262] Congress also enacted specialized procedures governing patent disputes involving drugs (the Hatch-Waxman Act)[263] and biologics (BPCIA).[264] To the extent that Congress wishes to further reform the law governing patents, it could do so under the powers granted to it in the Constitution.[265] Indeed, various reforms have been proposed over the past several years.

For example, Congress could modify the patentable subject matter requirement under Section 101. As explained above,[266] some stakeholders have criticized the Supreme Court and Federal

[255] Pub. L. No. 112-29, 125 Stat. 331, § 18(a)(1), (a)(1)(A) (2011) (stating that CBM proceedings will be governed by the PGR procedures, except that the § 321(c) deadline for filing does not apply).

[256] *Id.* § 18(a)(1)(B).

[257] *Id.* § 18(a)(1)(E); *id.* § 18(d)(1) (defining a "covered business method patent" as "a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions").

[258] *Id.* § 18(a)(1)(C).

[259] *Id.* § 18(a)(1); 35 U.S.C. § 324(a).

[260] Pub. L. No. 112-29, 125 Stat. 331, § 18(a)(3) (2011).

[261] *See* discussion *supra* in note 46 and accompanying text.

[262] *See generally id.*

[263] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[264] Pub. L. No. 111-148, tit. VII, 124 Stat. 199, 804-21 (2010).

[265] U.S. CONST. art. I, § 8, cl. 8 (empowering Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries").

[266] *See* discussion *supra* in "Patentable Subject Matter."

Circuit for allegedly not applying the governing two-step test in a predictable manner,[267] and some judges on the Federal Circuit have suggested that reform is necessary.[268] Although potential draft language was circulated before the three days of hearings on Section 101 last summer,[269] ultimately no bill was introduced.

PTAB administrative reviews are another area of potential and proposed reform. For example, the proposed Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 (STRONGER Patents Act; S. 2082) would make it harder to invalidate patents in PTAB proceedings by applying the presumption of validity and increasing the burden of proof, among other changes.[270] Conversely, other stakeholders argue that recent changes in PTAB procedures have made it too difficult to invalidate patents and thus undermine the purpose of those reviews.[271] Those stakeholders urge Congress to examine the frequency with which the PTAB exercises its discretion to deny administrative review without addressing the merits of the challenge.[272]

Other reforms are aimed at addressing perceived misuses of the patent system by various entities. For example, the proposed Advancing America's Interests Act (H.R. 8037) aims to "modernize the ITC process"[273] by, among other things, limiting the scope of activities that meet the domestic industry requirement for invoking ITC jurisdiction.[274] According to one sponsor, this will ensure that the ITC "is not misused by patent licensing entities."[275] As another example, there have been several proposals in the 116th Congress to address alleged misuse of the patent system by pharmaceutical manufacturers.[276]

As technologies grow and change, additional areas of patent law may interest Congress and may prove ripe for reform. For example, if use of AI devices continues to rise, Congress could overturn the PTO's decision that AI devices may not be listed as inventors on patent applications.[277] Whatever changes occur, the importance of patents and IP to the American economy suggests that patent law will remain an area of interest and activity in the years to come.

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[267] *See, e.g.*, Michel, *supra* note 112, at 277-80.

[268] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019) (denying en banc rehearing of the Section 101 issue, with opinions by eight judges); Richards, *supra* note 113.

[269] Press Release, Office of Senator Thom Tillis, *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act* (May 22, 2019), at https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act.

[270] Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019, H.R. 3666, 116th Cong. (2019).

[271] Britain Eakin, *Congress Urged To Probe 'Badly Misguided' PTAB Denials*, LAW360 (June 30, 2020), at https://www.law360.com/articles/1288087/congress-urged-to-probe-badly-misguided-ptab-denials.

[272] *Id.*

[273] Press Release, Office of Congresswoman Suzan DelBene, *DelBene, Schweikert Introduce Legislation to Modernize ITC Process to Protect American Industry, Workers, and Consumers* (Aug. 14, 2020), at https://delbene.house.gov/news/documentsingle.aspx?DocumentID=2645.

[274] Advancing America's Interests Act, H.R. 8037, 116th Cong. (2020).

[275] *DelBene, Schweikert Introduce Legislation*, *supra* note 273.

[276] *See generally* Richards, *supra* note 8, at 32-41.

[277] *See* discussion *supra* in "Inventorship Requirements."

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