Patent Case Management Judicial Guide

Third Edition

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Federal Judicial Center 2016

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This chapter surveys the procedures for obtaining patents and the substantive law governing patent litigation. It also provides an overview of the patent system and a starting point for researching patent law. After reviewing an actual patent document, the chapter summarizes prosecution, the process through which the U.S. Patent and Trademark Office (USPTO) grants patents to inventors. Patent cases often require courts to examine the prosecution history that led to the issuance of a patent.

The prosecution section provides a window into the USPTO to provide an appreciation of how patents are examined. The chapter then reviews the law regarding patent validity. The right to exclude others from practicing an invention is available only if several requirements are met. The chapter then discusses patent enforcement: infringement of a patent claim, defenses to a charge of infringement, and remedies. The chapter concludes by examining the wider battlefield for patent litigation existing outside of the district court—the appellate process and proceedings before the International Trade Commission, the USPTO, other U.S. courts, and foreign courts. Appendix A provides a glossary of patent law terms. Appendix B lists common acronyms.

14.1 The Patent

A patent grants its owner the right to exclude others from making, using, selling, offering to sell, importing, or offering to import the claimed invention within or into the United States. § 271.[1] Because a patent provides only a right to exclude, a patentee does not have an affirmative right to practice the invention. Inventors sometimes cannot make their patented inventions without infringing other patents on underlying technology. Such blocking patents in turn spur substantial licensing activity. As befits a right to exclude, a patent "ha[s] the attributes of personal property." § 261.

Unlike copyrights or trade secrets, a patent must issue from the USPTO after a proper application has been made by the inventor. The requirements of patentability are set forth in Title 35 of the U.S. Code, reflecting the omnibus codification of patent law completed in 1952 as well as numerous subsequent amendments, the most substantial of which is the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA), enacted on September 16, 2011.

14.1.1 The Patent Document

Patents issued by the USPTO follow a common format dictated by the World Intellectual Property Organization (WIPO).

1. Unless otherwise indicated, all section references are to the Patent Act (35 U.S.C. (2012)).

Figure 14.1
Page One of a Standard Patent Application

US005205473A

United States Patent [19]
Coffin, Sr.

[11] **Patent Number: 5,205,473**
[45] **Date of Patent: Apr. 27, 1993**

[54] **RECYCLABLE CORRUGATED BEVERAGE CONTAINER AND HOLDER**

[75] Inventor: **David W. Coffin, Sr.**, Fayetteville, N.Y.

[73] Assignee: **Design By Us Company**, Philadelphia, Pa.

[21] Appl. No.: **854,425**

[22] Filed: **Mar. 19, 1992**

[51] **Int. Cl.**[5] **B65D 3/28**
[52] **U.S. Cl.** ..... **229/1.5 B**; 206/813; 220/441; 220/DIG. 30; 229/1.5 H; 229/DIG. 2; 493/296; 493/907
[58] **Field of Search** ..... 229/1.5 B, 1.5 H, 4.5, 229/DIG. 2; 220/441, 671, 737–739, DIG. 30; 493/287, 296, 907, 908; 209/8, 47, 215; 206/813

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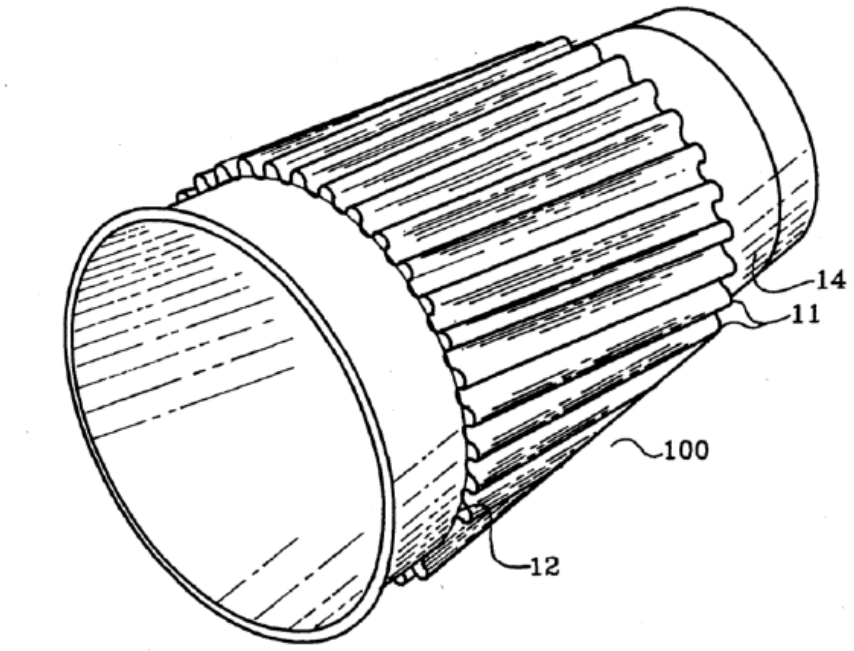
Primary Examiner—Gary E. Elkins
Attorney, Agent, or Firm—Synnestvedt & Lechner

[57] **ABSTRACT**

Corrugated beverage containers and holders are which employ recyclable materials, but provide fluting structures for containing insulating air. These products are easy to hold and have a lesser impact on the environment than polystyrene containers.

18 Claims, 8 Drawing Sheets



14.1.1.1 The First Page—Administrative Details

As reflected in Figure 14.1, the first page of a U.S. patent contains a header, an abstract, and a representative drawing. The header contains bibliographic information categorized using the Internationally (agreed) Numbers for the Identification of (bibliographic) Data (INID) classification system. Field 19 (labeled [19]) indicates the office or organization publishing the document, here the U.S. Patent Office. Field 11 shows the patent number. Every patent has a unique number assigned by the Patent Office in the order they issue. Parties often abbreviate patents to their last three numbers for convenience. Thus, Patent No. 5,205,473 becomes "the '473 patent." Field 45 contains the date the patent issued.

Fields 50–58 provide technical information, such as the domestic classification ([52]), title ([54]), a list of prior art documents cited during prosecution by the examiner or by the applicant ([56]), the abstract ([57]), and the technical field of search ([58]). The header also contains information showing the history and ownership of the patent. Fields 60–68 provide references to other legally or procedurally related domestic patent documents. (The '473 patent does not have any such references.) Fields 70–76 reveal the names of the inventors, assignees, and attorney or agents.

14.1.1.2 Drawings

Immediately following the first page are the drawings (if any), which illustrate the claimed invention. The drawings are routinely labeled with numbers to facilitate describing the invention and its components in the patent's specification.

14.1.1.3 The Specification

The specification describes the claimed invention. Section 112 lists a number of formal requirements that the specification must meet for a patent claim to be valid. *See* § 14.3.3. The specification begins by repeating the title of the invention, then listing any related patent applications. The specification typically proceeds by explaining the "field of the invention," another general description of the kind of invention the patent discloses. The "background of the invention" discusses the prior art in the field and the problems the prior art could not address. The "summary of the invention" briefly describes what the patentee has accomplished in the claimed invention. A "brief description of the drawings" commonly follows.

The "detailed description of the invention" is the heart of the specification and the "consideration" the public receives in exchange for the patent grant. It seeks to describe the invention in such detail that a person having ordinary skill in the art could practice the invention. It often explains the invention by explaining the drawings. All specifications must also disclose the "preferred embodiments" and "best mode" for practicing the invention.

14.1.1.3.1 Claims

The specification concludes with claims. The claims are commonly analogized to the "metes and bounds" of a property deed and serve the same purpose: to delineate

the scope of the asset which, in the patent context, is an invention. Each claim represents the legal right to exclude others from making, using, selling, offering to sell, importing, or offering to import the claimed process, machine, manufacture, or composition of matter. A patent may, and often does, contain many claims, which usually become increasingly specific.

An "independent claim" stands on its own. A "dependent claim" refers to a single earlier claim or claims and adds further limitations. To understand all of the limitations of a dependent claim, it is necessary to read that claim together with the claim(s) on which it depends.

In a case for patent infringement, only some claims may be asserted. Some might not be infringed; further, some may even be invalid. It is important to recognize that each claim bestows distinct legal rights. Invalidity or noninfringement of one or more claims will not necessarily undermine other claims in the same patent.

Patent claims have a unique structure. Each claim must be stated as a single sentence. They begin with a preamble, which briefly describes the nature of the claimed invention. For example, a claim for a paper clip could begin, "A device for keeping papers together . . . ." In some circumstances, the preamble can act as an additional limitation on the scope of the claimed invention. *See* § 5.2.3.2.5.

The claim then has a transitional phrase, which demarcates the preamble from the list of restrictions or limitations that define the claimed invention. Patents often feature the same transitions, which have developed highly specific meanings in the case law. The transition "comprising" is understood to mean "including but not limited to"—that is, that the claim covers the listed limitations, as well as anything that includes all of the limitations and additional features. The transition "consisting of" means that the claim covers only the combination of the limitations listed and does not cover something that incorporates additional material along with all of the listed restrictions. The transition "consisting essentially of" covers not only products containing the recited limitations, but also those combining modest amounts of additional, unspecified substances, the presence of which would not materially affect the basic and novel properties of the expressly recited ingredients.

After the transition, the claim has a body that lists the limitations or restrictions of the claimed invention. Patentees typically use a method of peripheral claiming to delineate the outer boundaries of the claimed invention. Thus, the claim limitations or restrictions define what remains in the claim. The claim's body lists all of the features that must be present in the claimed invention and how these restrictions interact with each other.

As an illustration, consider a patent claim for a coffee cup insulator covered by the '473 patent illustrated in Table 14.1.

Table 14.1
Illustration of a Patent Claim

Preamble	A recyclable, insulating beverage container holder,
Transition	comprising
Body	a corrugated tubular member comprising cellulosic material and at least a first opening therein for receiving and retaining a beverage container, said corrugated tubular member comprising fluting means for containing insulating air; said fluting means comprising fluting adhesively attached to a liner with a recyclable adhesive.

Some claims contain words or structures, which, like the transitions, have specific, well-understood meanings. A means-plus-function claim defines one or more elements of the claim as a "means for [performing a] function," as allowed by § 112(f). This special type of claim format is interpreted based on how the structure, materials, or acts are described in the specification and to encompass "equivalents thereof" as of the time of filing. *See* §§ 5.2.3.5; 14.4.1.4.1.1.

Claims can follow other formats. As noted above, a dependent claim refers to one or several prior claim(s) and adds further limitations. A Jepson claim recites the elements of the prior art, then the transition "the improvement of which comprises," followed by the further restrictions that represent the advance over the prior art. A Markush claim covers a genus of related compositions sharing a common trait, such as "a chemical compound of the formula COOH–CH2-R, where R is selected from the group consisting of R_1, R_2, and R_3." Markush claims arise principally in the field of chemistry.

Interpreting the scope of claims is one of the principal challenges of patent litigation. The substantive law regarding how to interpret claim terms is presented in Chapter 5.

14.2 Patent Prosecution and the Patent Lifecycle

14.2.1 Institutional Aspects

14.2.1.1 The Patent Office

The USPTO is a federal agency in the Department of Commerce responsible for administering the patent and trademark laws. The USPTO's primary function is to examine inventors' applications and to determine whether to issue a patent. The USPTO also promulgates rules regarding the examination process and records all transfers of patent rights, in similar fashion to a state recordation office under Article 9 of the Uniform Commercial Code.

The USPTO employs over 7,000 scientists and engineers to examine patent applications. Examiners possess a science or engineering degree and are divided by Technology Centers (or group art units). A patent examiner need not hold a law degree, and the majority of patent examiners do not. The USPTO does, however, pro-

vide all examiners with training in patent law and procedure. New examiners also serve an apprenticeship period working with an experienced examiner.

The USPTO maintains an extensive website at http://www.uspto.gov/, which provides resources regarding the patent examination process and a searchable database of patents.

14.2.1.2 The Patent Bar

The USPTO requires practitioners who prepare and prosecute patent applications on behalf of others to pass a patent bar exam. To sit for the patent bar, applicants must possess scientific or technical training. One does not need to hold a law degree. Nonattorney members of the patent bar are called patent agents. Collectively, practitioners before the USPTO are known as patent prosecutors. The distinction between an inventor's prosecution counsel and trial counsel is critical to protective orders and the scope of attorney–client privilege. *See* §§ 4.2.5, 4.6.7–9.

Most litigated patents will have been drafted and prosecuted by a professional. Nonetheless, the USPTO does allow inventors to pursue their own application even if they have not passed the patent bar.

14.2.1.3 The Patent Trial and Appeal Board (PTAB)

The PTAB comprises the USPTO director, the deputy director, the commissioner for patents, the commissioner for trademarks, and administrative patent judges. Pursuant to the AIA § 7, the PTAB replaced the Board of Patent Appeals and Interferences (BPAI) as of September 16, 2012.[2] In addition to handling appeals from examiner rejections, the PTAB conducts several new administrative proceedings introduced under the AIA: postgrant review, covered business-method (CBM) review, inter partes review (IPR), and derivation proceedings. The PTAB also handles any interferences[3] or appeals of inter partes reexaminations that were filed before they were phased out under the AIA. Applicants may appeal decisions of the PTAB to the Federal Circuit.

The PTAB is often one of the first bodies to respond to changes in the substantive law of patent validity. For example, the PTAB was at the forefront of interpreting the Supreme Court's *KSR* opinion regarding obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Despite the PTAB's familiarity with patent law, district courts owe its decisions no formal deference. Only the Federal Circuit creates binding precedent for the district courts when adjudicating patent cases. Nevertheless, the PTAB is an experienced and specialized agency tribunal such that a district court may find its rulings persuasive.

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2. For the sake of consistency, this guide will use the acronym PTAB even when referring to the BPAI's decisions or actions before September 16, 2012.

3. An "interference proceeding" is an adversarial administrative adjudication that determines which of two or more inventors seeking a patent on the same invention has priority. *See* § 135. Any party to an interference proceeding that is dissatisfied with the PTAB decision can pursue a remedy in a district court. *See* § 146.

14.2.1.4 Laws Governing the USPTO and the Manual of Patent Examining Procedure (MPEP)

The patent statute is found in Title 35 of the U.S. Code. The USPTO's rules and regulations implementing the patent laws are codified in Title 37 of the Code of Federal Regulations.

The Manual of Patent Examining Procedure (MPEP) is the USPTO's operating manual for patent examiners. *See* http://www.uspto.gov/web/offices/pac/mpep/index.htm. Because most USPTO examiners are not attorneys, patent prosecutors will often cite the MPEP rather than case law during the course of patent prosecution. However, the MPEP does not carry the force of law.

Where the substantive patent law is uncertain, the USPTO issues guidelines to help examiners apply the law consistently. For example, there are guidelines governing the subject-matter requirement (MPEP § 2106), utility requirement (MPEP § 2107), and written description requirement (MPEP § 2163). Such guidelines represent the USPTO's interpretation of the law in those areas, but they are not substantive rulemaking and do not have the force and effect of law. While such guidelines may be persuasive on an issue, a district court is free to reach its own interpretation. Courts must, however, defer to USPTO interpretations of its procedures to the extent they are permissible under the governing statute. *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335–37 (Fed. Cir. 2008) (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

14.2.2 Filing a Patent Application

The process of patent procurement is commonly referred to as patent prosecution. Prosecution often consists of a lengthy and detailed interaction between the applicant and the USPTO examiner. During this process, the applicant attempts to convince the examiner that the applicant's invention meets the statutory requirements for patentability.

14.2.2.1 Overview of Patent Examination

Patent prosecution begins with an inventor having an idea that she believes is patentable. Although inventors may represent themselves before the USPTO, most retain a patent attorney or agent to prepare and prosecute their application. The application contains a description of the invention and claims outlining the bounds of the intellectual property right sought by the inventor. The prosecutor must also submit an Information Disclosure Statement (IDS) listing all prior art material to patentability of which the inventor or any person associated with prosecution is aware.

The USPTO assigns the application to an examiner in the most pertinent Technology Center. In addition to confirming that all formalities have been complied with, the examiner conducts a prior art search and assesses whether the proposed claims meet the requirements for patentability (§§ 101, 102, 103, and 112).

The first Office action almost always rejects the patent application. The examiner cites the relevant patent law authority and succinctly explains the reasons for rejection. At this point, the examiner bears the burden of establishing a prima facie case of unpatentability. The applicant then has the opportunity to respond to the Office action. *See* 37 C.F.R. § 1.111. Arguments made to overcome the examiner's rejections are commonly referred to as "traversing" the rejections. The applicant may argue that the examiner has mischaracterized the specification or the prior art and that the application, or portions thereof, should be allowed as submitted. In the alternative, the applicant may amend the claims.

The examiner may accept the applicant's amendments or arguments and allow the application in whole, or allow only some claims. If the applicant is unable to traverse, the examiner issues a so-called final rejection. In practice, the rejection is rarely the end of prosecution, which will generally continue until the applicant chooses to abandon the application or the examiner grants the claims. It is common for applicants to "continue" examination of the application, as discussed below. Alternatively, the applicant can appeal the examiner's rejection to the PTAB, and further still to the Federal Circuit.

Patent prosecution is an ex parte proceeding—only the applicant and the USPTO are directly involved. The examiner's actions play a significant role in shaping the contours of many patents. Patent prosecution operates much like a negotiation between the applicant and the USPTO.

The average prosecution pendency is three years, although it is not uncommon for prosecution to last five years or longer. The length of time required to prosecute the patent depends on any number of resource, strategic, and other factors and does not correlate with the "strength" of the patent claims.

Under the AIA, applicants may seek prioritized examination starting September 26, 2011 upon payment of an additional fee. AIA § 11. For applications considered important to the national economy or national competitiveness, the USPTO may prioritize examination at no extra cost to the applicant. AIA § 25.

14.2.2.2 The Application

Most applicants choose to file a nonprovisional patent application. Nonprovisional applications are the "regular" type of patent applications and are often referred to as "applications." Alternatively, applicants may file a provisional or Patent Cooperation Treaty (PCT) patent application prior to submission of the nonprovisional application. These types of applications are described further below.

14.2.2.2.1 Elements of a Nonprovisional Patent Application

The general requirements for a nonprovisional patent application include: (1) a written specification, including one or more claims; (2) an oath or declaration that the named inventor or inventors are believed to be the original and first inventor or inventors of the claimed subject matter; (3) drawings as required to support the application; and (4) applicable fees (e.g., filing fee, search fee, examination fee, and application-size fee). *See* 37 C.F.R. § 1.51; § 111; *see also* MPEP § 601.

Under the AIA, if an uncooperative or unavailable inventor is under an obligation to assign the invention, the assignee (who is typically the inventor's employer) may file a substitute statement in lieu of an oath or declaration. This provision became effective September 16, 2012, and applies to all applications filed on or after that date. AIA § 4.

14.2.2.2.2 Disclosure of Prior Art

14.2.2.2.2.1 Prior Art Disclosure by Applicant—Information Disclosure Statement

Applicants present prior art to the USPTO using an Information Disclosure Statement. *See* 37 C.F.R. § 1.97. The inventor and those assisting the inventor with the application process are not required to perform an exhaustive search of the prior art, but they must disclose all pertinent information of which they are aware. *See* 37 C.F.R. § 1.56. This requirement is part of the applicants' general duty of candor and good faith in dealing with the USPTO, which exists for the duration of patent prosecution. The USPTO will not issue a patent when faced with either fraudulent conduct or a failure to disclose material information through bad faith or intentional misconduct. *See id.* Such "inequitable conduct" can also render an issued patent unenforceable in later litigation. In some cases, applicants requesting accelerated examination must perform a preexamination search of the prior art and submit the results to the USPTO.

14.2.2.2.2.2 Prior Art Disclosure by Third Parties—Preissuance Submissions

The AIA provides a window during examination for third parties to submit prior art, along with a concise statement of relevance for each submitted document. These preissuance submissions became available September 16, 2012, for any applications pending on or filed after that date. AIA § 8.

14.2.2.2.3 Priority Date

The first filing of a patent application anywhere in the world describing an enabled invention usually establishes the "priority date" for that invention. The definition of prior art, which varies by country, is often keyed to the priority date. Some U.S. applications claim "foreign priority," which means that their priority date is derived from an earlier-filed foreign application.

With the enactment of the AIA, priority dates are treated differently for prior art purposes depending on whether the application was filed prior to March 16, 2013, under the first-to-invent regime, or on or after that date when the first-to-file rules govern. *See* § 14.3.4.

14.2.2.2.4 Nonstandard Applications

A patent application can also mature from several other types of filings. The most important is the provisional application. The USPTO began accepting provi-

sional patent applications on June 8, 1995. *See* § 111(b). Provisional applications must contain a specification and required drawings, but need not contain claims or an oath or declaration. Provisional applications are less expensive to prepare and file than a nonprovisional application and preserve a priority filing date for a later filed nonprovisional application. Provisional applications are not examined by the USPTO and are subject to abandonment after twelve months.

An applicant can also file an application under the Patent Cooperation Treaty (PCT) to establish a priority date to an invention. Under the PCT, applicants can file a single application in a qualified patent office to initiate prosecution in all signatory countries. Over 130 nations have signed the PCT.

Finally, inventors can claim priority for U.S. patent applications based on filings in certain foreign countries, including any World Trade Organization (WTO) member state. *See* § 119. The applicant has twelve months from the time of the foreign filing to submit a U.S. national application claiming the same invention.

14.2.2.3 Restriction Requirements and Divisional Applications

If a nonprovisional application claims multiple independent and unique inventions, the examiner may "restrict" the application. *See* 37 C.F.R. § 1.142. Restriction requires the applicant to elect which invention it intends to pursue in the pending application. The other inventions can be examined in separate "divisional" applications that maintain the priority date of the original application. The examiner can also require a restriction if a reply to an office action introduces claims that are distinct from and independent of the invention previously claimed. *See* 37 C.F.R. § 1.145. The applicant can attempt to overcome the restriction requirement on the grounds that the examiner can assess all claims without performing an extra prior art search (*see* 37 C.F.R. § 1.143), but such arguments are typically unsuccessful. However, the examiner can also rejoin restricted claims upon allowance. Restriction is a procedural matter: a patent's validity does not depend on whether it claims multiple inventions. Restriction and division practice does, however, explain the typical manner in which one specification and written description can spawn a family of patents.

14.2.2.4 Publication

Until 2000, pending U.S. patent applications were held in secret by the USPTO until issuance. Under this system, patent applicants could draw out prosecution in secret for many years. Such "submarine" patents could emerge out of nowhere many years or even decades after filing, resulting in unfair surprise to others who began using the claimed invention during the secret pendency. Furthermore, if the patent did not issue or the inventor believed trade secrecy to be more advantageous than patenting, the applicant could abandon the application and maintain the invention as a trade secret.

The American Inventors Protection Act of 1999 brought the U.S. into harmony with most foreign patent offices by requiring the USPTO to publish nonprovisional patent applications eighteen months after their filing date. Published applications are available at the USPTO's website. *See* http://www.uspto.gov/patft/index.html. An

applicant can opt out of publication only by certifying that the applicant has not and will not file any foreign applications on the same invention. Thus, applicants can maintain patent applications being pursued solely in the United States as trade secrets until issuance.

14.2.3 The Prosecution History or "File Wrapper"

The archive of written communications between the USPTO and the applicant during patent prosecution is called the "prosecution history" or "file wrapper." The file wrapper is available through the USPTO's Patent Application Information Retrieval (PAIR) system, *available at* http://portal.uspto.gov/external/portal/pair. This "procedural history" is important because, in addition to the patent's specification, correspondence between the patentee and the USPTO during prosecution is a primary source used to interpret claim language during litigation. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); § 5.2.2.1.1. Furthermore, the patentee is estopped from recovering through reexamination or during litigation (under the doctrine of equivalents) any subject matter surrendered during prosecution. The following sections explain the file wrapper's contents.

14.2.3.1 Office Actions

The patent examiner's responses are known as "office actions." These statements document the examiner's decisions and underlying reasons. The applicant can respond to the examiner's rejection arguments. This record of office actions and responses determines if and to what extent a patentee narrowed the scope of his or her claimed invention to overcome a rejection. It also bears on whether the patentee engaged in inequitable conduct. *See* § 14.4.2.3.1.

14.2.3.1.1 Affidavits

The applicant may attempt to overcome certain rejections through the use of affidavits. Rule 131 affidavits are used to establish inventorship before the date of prior art arising under § 102(a), (e), or (g). *See* 37 C.F.R. § 1.131. This process is known as "swearing behind" the prior art reference. Rule 131 requires an oath or declaration by the inventor along with supporting evidence. Misrepresentations in Rule 131 affidavits may violate the applicant's duty of good faith and candor, rendering the patent unenforceable. For patent applications subject to the first-to-file regime established under the AIA, "swearing behind" is not possible. *See* § 14.3.4.2.1.

Rule 132 affidavits contain information seeking to traverse rejections. *See* 37 C.F.R. § 1.132. These are commonly used to submit expert testimony responding to an obviousness rejection.

14.2.3.1.2 Interview Report

Applicants may request a telephone or face-to-face interview with the examiner. *See* 37 C.F.R. § 1.133. The applicant may be required to submit a written report of the meeting, although the report can be general. Many practitioners rely on inter-

views to expedite prosecution by personally engaging the examiner. Some practitioners also use interviews to limit the amount of written correspondence entering the prosecution history.

14.2.3.2 Request for Continued Examination (RCE)

Applicants generally have one opportunity to traverse the examiner's rejections before receiving a final rejection. After receiving a final rejection, applicants will often file a RCE in order to submit further arguments, claim amendments, or Information Disclosure Statements. *See* 37 C.F.R. § 1.114. An RCE provides applicants with another round of examination in the same application; it is not uncommon to see patents issue from applications in which multiple RCEs were filed. Instead of filing an RCE, applicants can pursue the rejected claims in a continuation application, or they can appeal the examiner's decision to the PTAB.

14.2.3.3 Continuation Applications

A continuation application is a second application for an invention claimed in a prior application. To qualify as a continuation application and claim the benefits of the earlier "parent" application's priority date, the application must be filed while the parent is still pending (i.e., not issued or abandoned), expressly refer to the parent application, identify at least one common inventor, and encompass the same disclosure of the parent application without adding any new matter. *See* § 120. The same invention must be claimed, but the scope of the claims can vary. However, the patent term of the continuation is limited to twenty years from the filing of the earliest application to which it claims priority.

Applicants often use continuation applications to pursue rejected claims or new claims that are different (usually broader) in scope from those in the parent application. A continuation application might also be used when the examiner allows some claims but rejects others: the applicant can cancel the rejected claims and pursue them in a continuation application, while allowing the remaining claims to issue as a patent.

14.2.3.4 Continuation-in-Part (CIP) Applications

A CIP is similar to a continuation application but introduces new subject matter to the parent application. For example, the inventor may add new data and descriptive material to support the claims. Alternatively, the inventor may have made improvements to the claimed invention and wish to add them in a CIP application. Claims to the new subject matter do not get the advantage of the priority date of the parent application. The relevant consideration is whether the claims are supported by the disclosure of the parent application under the test set forth in § 112. Claims that are so supported can rely on the parent application's priority date, whereas the other claims have the priority date of the CIP filing. Accordingly, some references might count as prior art for some of the claims in the CIP, but not qualify as prior art for other claims in the same application that are supported by the parent application's disclosure. Regardless of when material is added, all claims in a patent expire

on the same date—typically twenty years from the earliest parent application's filing date. *See* § 14.2.4.

14.2.3.5 PTO Petition and Appeals

Applicants who reach an impasse with an examiner over procedural issues may petition the director of the USPTO. Such procedural issues include requests for time extensions, reviving abandoned applications, or reviewing a restriction requirement. Petitions are typically resolved in an informal manner by group directors in the USPTO.

An applicant may appeal a final rejection to the PTAB. *See* § 134. In upholding the rejection, the PTAB may consider any issue of patentability, including written description, enablement, novelty, and nonobviousness. The applicant may appeal adverse decisions of the PTAB to the Federal Circuit. *See* § 141. Alternately, the applicant may bring a civil action against the director to the U.S. District Court for the Eastern District of Virginia.[4] *See* § 145; AIA § 9. The district court can overturn PTAB decisions and order the USPTO to issue a patent. The Federal Circuit also hears appeals from the district court. A civil suit may be more expensive than a direct appeal to the Federal Circuit, but has the advantage that new evidence can be submitted to the district court, whereas the Federal Circuit only considers the USPTO record.

14.2.4 Patent Duration

A patent whose application was filed on or after June 8, 1995, expires twenty years after the earliest effective U.S. filing date, *see* § 154(a)(2), unless subject to various extensions discussed below. Prior to this date, patents expired seventeen years from the issuance date. For patents that were granted or pending before June 8, 1995, the patent expires either twenty years after the date of filing or seventeen years from issuance, whichever is later. *See* § 154(c)(1). All claims in a CIP application expire based on the effective filing date of the parent application, regardless of whether a claim's priority derives from the CIP application or its parent.

This change in the patent term harmonized the U.S. patent laws with those in most other nations. It also partially addressed the problem of "submarine patents." Under the old law, a patentee could use continuation practice to keep a patent application pending for years (or sometimes decades) until an unsuspecting third party began practicing the claimed invention. The patentee could then get the submarine patent issued and sue for infringement. The current law alleviates this abuse by tying patent duration to the filing date, thereby imposing the costs of delayed prosecution upon the applicant. In addition, the doctrine of prosecution laches can be raised as a defense in cases of undue prosecution delay. *See* § 14.4.2.3.4.1.

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4. Prior to September 16, 2011, applicants were able to appeal a PTAB decision to the U.S. District Court for the District of Columbia.

The actual patent term commences the date that the patent issues. Thus, the effective term of the patent will be less than twenty years due to the pendency of prosecution. Nonetheless, provisional rights allow a patentee to collect a reasonable royalty from an infringer who had actual knowledge of a published patent application back to the date of actual notice. *See* § 154(d); § 14.4.3.2.

14.2.4.1 Patent-Term Adjustments

A patent's duration can be extended to account for certain delays occurring during prosecution. *See* § 154(b). Section 154(b)(1)(A) compensates the patentee for undue delays in prosecution: if the USPTO fails to deliver the first office action within fourteen months of the filing date or if the examiner fails to respond to an office action reply within four months, then additional time will be tacked on the patent term. Similarly, § 154(b)(1)(B) extends the patent term if patent prosecution lasts more than three years, not including continuations, interferences, and appeals. Section 154(b)(1)(C) extends the patent term if a patentee successfully overcomes adverse rulings at interference or appeals proceedings, or if the patent was subject to a secrecy order. Patent term adjustments are, however, limited by delays caused by the patentee. *See* § 154(b)(2).

14.2.4.2 Patent-Term Restoration

A patent's term can be extended by statutory patent-term restorations. For example, the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, extends the patent term for drug-related inventions up to five years when the commercial use of the claimed invention was delayed by regulatory approval. *See* § 156.

14.2.5 Postissuance Corrections and Administrative Proceedings

The failure of the patentee, or in some cases the USPTO, to properly address errors in an issued patent can result in adverse consequences at trial, such as the inability to receive damages or even complete loss of patent rights. Several administrative options exist at the USPTO for patentees to correct errors in the patent document after the patent has issued, as well as for third parties to challenge the validity of issued patents: disclaimer, certificate of correction, supplemental examination, post-grant review, covered business-method review (CBMR), reissue, reexamination, and inter partes review (IPR).

14.2.5.1 Disclaimers

Under § 253, a patentee (without deceptive intent) may disclaim any complete patent claim by filing a request with the USPTO. A patentee may also disclaim or dedicate to the public the entire patent term or any remaining portion of the patent term. The latter process is called a "terminal disclaimer." This process is frequently used when the USPTO rejects a patent application as obvious over an earlier patent

or application by the same person. By filing the terminal disclaimer, the applicant agrees that the later filed application will expire at the same time as the prior patent (or application).

14.2.5.2 Certificate of Correction

Minor errors in an issued patent, such as typographical errors, omissions of an assignee, or printing of an original rather than amended claim, can be corrected with a Certificate of Correction. *See* §§ 254 (correction of USPTO mistake); 255 (correction of applicant mistake). These corrections cannot add new matter or change the scope of a patent claim such that reexamination would be required.[5]

Prior to the enactment of the AIA, a patent's named inventors could be corrected only upon showing that the error was made without deceptive intent. *See* § 256. Beginning September 16, 2012, inventorship errors may be corrected regardless of whether the error resulted from deceptive intent. AIA § 20.

Failure to inspect and correct an issued patent can be costly for the patentee. In *Southwest Software, Inc. v. Harlequin, Inc.*, 226 F.3d 1280 (Fed. Cir. 2000), the USPTO neglected to include a 330-page appendix with the issued patent. *Id.* at 1287. The accused infringer raised the issue during litigation. *Id.* at 1287–89. The patentee subsequently had the patent corrected under § 254. *Id.* at 1287. Nonetheless, the Federal Circuit held that a correction is only effective for causes of action arising after it was issued and remanded the case to determine whether the specification failed to satisfy the best mode and enablement requirements absent the appendix. *Id.* at 1295–97. The court stated, "[I]t does not seem to us to be asking too much to expect a patentee to check a patent when it is issued in order to determine whether it contains any errors that require the issuance of a certificate of correction." *Id.* at 1296.

14.2.5.3 Supplemental Examination

The AIA added § 257 to Title 35, under which a patentee may seek supplemental examination to have the USPTO consider any additional information relevant to patentability. AIA § 12. The USPTO will grant supplemental examination if a "substantial new question of patentability" exists. A patent cannot be held unenforceable based on conduct relating to information that had not been considered or was incorrect during a prior examination if the information was subsequently considered or corrected during a supplemental examination. This procedure allows patentees to submit additional information or prior art in order to avoid potential inequitable conduct claims so long as the supplemental examination is completed before the patentee files suit. However, supplemental examination cannot be used to cure pre-

5. For example, the Court of Customs and Patent Appeals, which handled appeals of PTO rejections prior to the creation of the Federal Circuit, held that a patentee could correct, through a Certificate of Correction, a chemical name in a specification whose errors resulted from translation from Japanese to English. *See In re Oda*, 443 F.2d 1200 (C.C.P.A. 1971).

existing allegations of inequitable conduct. Supplemental examination became available for all patents on September 16, 2012.

14.2.5.4 Reissue

Whereas certificates of correction address minor, nonsubstantive alterations of an issued patent, reissue proceedings allow a patentee to correct a substantive defect in the specification or to narrow or broaden the scope of an issued patent. Reissue may occur when, because of error without deceptive intent, a patent is "deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." § 251. Under the AIA, reissue applications may be filed on or after September 16, 2012 without regard to deceptive intent. AIA § 20.

In pursuing reissuance of a patent, the patent owner files a reissue application and an oath attesting to the alleged error(s). The patent is then reprosecuted and may reissue in original or amended form. During the proceeding, the USPTO can reject any claims in the patent, not only those amended by the patentee. As a result, the entire patent loses its presumption of validity during the reissue process. The reissued patent is subject to invalidation in the same manner as the original patent (which is surrendered when the reissue patent is granted). Moreover, an accused infringer may defend on the grounds that the reissue itself was invalid.

The USPTO assigns reissued patents a new number, with the prefix "Re"—for example, "U.S. Patent No. Re. 50,000." Unlike the original proceedings, CIP applications (i.e., addition of new matter) are not allowed, and third parties are notified of the reissue request and may submit evidence and arguments. The duration of a reissued patent term cannot extend beyond that of the original patent.

The USPTO requires the patentee to provide an oath or declaration attesting to at least one error in the original patent. *See* 37 C.F.R. § 1.175.[6] Thus, reissue cannot be used to revive a patent rendered unenforceable because of inequitable conduct. The issued patent must contain "a defective specification or drawing," or the patentee must have claimed "more or less than he had a right to claim." § 251. Most patents are reissued to amend the claims, often to overcome newly discovered prior art that would invalidate one or more claims. Rather than filing a disclaimer that surrenders an entire claim or claims, the patentee can request reissuance with narrower claims that avoid the prior art. Furthermore, a reissue may be filed for the sole purpose of adding new dependent claims while leaving the original claims unchanged. *See In re*

6. The patentee is also held to a duty of candor regarding the reasons for the mistake. In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556 (Fed. Cir. 1989), the patentee asserted a patent that was reissued with additional dependent claims. The original patent agent stated the additional claims were omitted from the original patent because of difficulty contacting the inventor, yet the record showed that the agent and inventor communicated regularly during prosecution. *Id.* at 1561. As a result, the Federal Circuit invalidated all claims added or amended during reissue, but did not disturb the unchanged claims from the original patent. *Id.* at 1566.

Tanaka, 640 F.3d 1246 (Fed. Cir. 2011). During the two-year window following issuance, a patentee can also attempt to broaden the scope of claim coverage, assuming that the original specification supports the amendments.

14.2.5.4.1 Narrowing Reissues

A patent owner may seek to narrow the scope of a patent at any point during the life of a patent.

14.2.5.4.2 Broadening Reissues

Broadening reissues are sought when the patentee's error is claiming less than the original specification, and presumably the prior art, would allow. The original specification must provide adequate written description for and must enable and disclose the best mode for the broader claim. A patentee has two years from the date of issuance to seek broader claims. § 251. The courts have construed this to mean "broader in any respect," so that an attempt to broaden a single claim limitation must be made within the two-year period, even if other amendments narrow the claim's overall scope. *See Ball Corp. v United States*, 729 F.2d 1429 (Fed. Cir. 1984). A patentee who has timely filed a broadening reissue application may continue to make broadening amendments outside the two-year window. *See In re Doll*, 419 F.2d 925 (C.C.P.A. 1970). But a patentee who sought a reissue within two years on other grounds cannot then seek to broaden claims outside the statutory period. *See In re Graff*, 111 F.3d 874 (Fed. Cir. 1997) (distinguishing *Doll* where the public was timely notified that the patentee sought broadened claims). A patentee's rights to enforce a broadening reissue are constrained by the doctrine of intervening rights. *See* § 252; § 14.2.5.5.2.2.

14.2.5.4.2.1 The Recapture Rule

The recapture rule is a judicially created limitation on broadening reissues that works similarly to prosecution history estoppel. *See* § 14.4.1.4.2.1.2. The rule bars a patentee from seeking reissue claims that regain subject matter that was surrendered to obtain allowance during the original prosecution. Surrendering subject matter to overcome patentability rejections does not constitute an "error" within the meaning of the patent laws. *See Ball Corp. v United States*, 729 F.2d 1429 (Fed. Cir. 1984).[7]

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7. In *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992 (Fed. Cir. 1993), Mentor had patented a condom catheter that transferred adhesive from the outer to inner surface during unrolling. The transfer limitation was added during prosecution to overcome an obviousness rejection. *Id.* at 995. After the patent issued, Mentor timely filed a broadening reissue application without the transfer limitation, asserting as error that it was entitled to the broader claim. *Id.* at 996. In a subsequent infringement action, the Federal Circuit held that Mentor's deliberate and intentional amendments made during initial prosecution to overcome issues of patentability were not errors within the meaning of the reissue statute and hence the broader reissued claim was invalid under the recapture rule. *Id.*

14.2.5.4.2.2 Intervening Rights

Although reissue claims that are "substantially identical" to those of the original patent "have effect continuously from the date of the original patent," § 252 ¶ 1, claims that were modified at reissue, for any reason, are subject to a reliance-type interest referred to as intervening rights. *See* § 252 ¶ 2. This doctrine recognizes that third parties may rely on the claims of an issued patent and thus provides a safe harbor to parties practicing subject matter covered by the amended claims. Unlike the recapture rule, which can invalidate claims in a reissued patent, intervening rights are applied on a party-by-party basis.

The patent laws codify two types of intervening rights: absolute and equitable. Under the absolute intervening rights doctrine, a court may allow a party who "made, purchased, offered to sell, or used" anything prior to reissue to continue to use or sell that thing. § 252. These rights do not allow a party to make new items after the reissue is granted, only to use or sell products that were already in existence. In addition, there are no intervening rights for subject matter that was claimed in the original patent.

Equitable intervening rights allow a court to authorize continued practice of an invention claimed in a reissue patent "to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue." *Id.* Again, these rights do not apply for inventions claimed in the original patent. As an example, a district court may provide equitable relief when a party has invested heavily in practicing the invention claimed at reissue. Such relief is subject to review by the Federal Circuit for abuse of discretion.[8]

Intervening rights can also apply when claims are narrowed. For example, a third party may practice a claimed invention in the belief that the applicable claims in the original patent are invalid. The patentee may later reissue the patent with narrowed claims that overcome the presumed invalidity arguments but still read on the third party's activities. Under such circumstances, a court may apply the intervening rights doctrine to the narrowed reissue patent.

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8. In *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 756 F.2d 1574 (Fed. Cir. 1985), Seattle Box patented a system for bundling oil pipes. Industrial Crating acquired materials to bundle pipes in such a way that did not literally read on Seattle Box's claims. *Id.* at 1580. After bringing suit for infringement, Seattle Box obtained a broadening reissue that arguably covered Industrial Crating's system. *Id.* at 1575. Industrial Crating assembled its bundles after the reissue was granted, and the district court denied the defense of intervening rights. *Id.* at 1576. The Federal Circuit reversed, holding that equitable intervening rights applied. *Id.* The Federal Circuit noted that Industrial Crating relied on advice of counsel when designing around the original patent and that it had pending orders for the unassembled inventory before the reissue was granted. *Id.* at 1580. The court observed that "the new reissue claims in this case present a compelling case for the application of the doctrine of intervening rights because a person should be able to make business decisions secure in the knowledge that those actions which fall outside the original patent claims are protected." *Id.*

14.2.5.5 Reexamination

Reexamination is an administrative proceeding that can be initiated by the patentee, third parties, or the USPTO director, in which the USPTO reevaluates the validity of an issued patent. Prior to the AIA, the patent statute authorized two forms of reexamination: (1) ex parte, *see* §§ 302–307; and (2) inter partes, *see* pre-AIA §§ 311–318. The AIA left ex parte reexamination in place, but replaced inter partes reexamination with inter partes review (IPR), *see* § 14.2.5.6, though all inter partes reexaminations filed prior to September 16, 2012, will continue to completion. Reexaminations are limited to patentability issues raised by prior art patents and/or printed publications, as the USPTO is considered an expert in determining patentability over published prior art. Other issues affecting patentability, such as written description, enablement, "on sale" or public-use activities, or inequitable conduct, may require testimony and discovery, and thus are perceived as better handled through litigation.

14.2.5.5.1 The Reexamination Process

Reexaminations are handled by the USPTO's Central Reexamination Unit (CRU), which has its own staff of examiners. The USPTO created the CRU in 2005 to improve the quality of reexamination proceedings and to reduce their pendency. By statute, all reexaminations must be handled with "special dispatch." § 305; pre-AIA § 314.

A request for reexamination must provide new, noncumulative information affecting the patentability of a claim. Within three months of filing, the USPTO must issue a decision on whether to order a reexamination. For an ex parte reexamination, the threshold for ordering reexamination is whether the reexamination request raises a "substantial new question of patentability" (SNQ). § 303(a). Prior to the enactment of the AIA on September 16, 2011, the SNQ standard also applied to inter partes reexamination petitions. After the enactment of the AIA, however, the inter partes reexamination threshold was changed to "a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request." AIA § 6. The new threshold applies to inter partes reexaminations filed after September 15, 2011.

Unlike regular prosecution or reissue proceedings, there is no continuation practice in reexaminations. The patentee can appeal adverse rulings to the PTAB, and thereafter to the Federal Circuit. *See* §§ 305–306; pre-AIA §§ 314–315.

A reexamination terminates with the issuance of a "Reexamination Certificate" that becomes part of the official patent document and states the result (cancelation, confirmation, and/or amendment of claims) of the reexamination proceeding. § 307; pre-AIA § 316. If a patent claim is reaffirmed in reexamination, courts are likely to view it as stronger, thus benefiting the patentee. As with reissue, the doctrine of intervening rights applies to any claims added or amended during reexamination. *See* § 307, pre-AIA § 316.

14.2.5.5.2 Ex Parte Reexamination

Anyone can file a request for an ex parte reexamination. Once the USPTO orders an ex parte reexamination, the patentee may file a preliminary statement including proposed amendments or new claims so long as the amendments are supported by the original filing (§ 304) and do not enlarge claim scope. *See Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577 (Fed. Cir. 1995) (invalidating patent where the USPTO allowed broadened claim scope during reexamination). If a third party requested the reexamination, it may respond to the patentee's preliminary statement, but any further proceedings in the reexamination involve only the patentee and the examiner. § 305. In practice, patentees often decline to submit preliminary statements to limit third-party participation. After the preliminary statement and reply period, ex parte reexamination resembles regular prosecution between an examiner and the patentee.

14.2.5.5.3 Inter Partes Reexamination

As a result of the enactment of the AIA, inter partes reexamination was phased out over a one-year transition period, beginning September 16, 2011. Starting September 16, 2012, inter partes review replaced inter partes reexamination. Inter partes reexaminations filed prior to September 16, 2012, will not, however, be converted into inter partes review proceedings, even if the proceedings have extended beyond September 16, 2012.

Inter partes reexamination was available only for patents granted on applications filed on or after November 29, 1999. *See* 37 C.F.R. § 1.913; *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1332–34 (2008). Unlike ex parte reexamination, requests for inter partes reexamination could not be filed by the patentee. Pre-AIA § 311; Pre-AIA 37 C.F.R. § 1.913. Inter partes reexamination allowed extensive involvement by the third-party requester throughout the proceedings, including appeal of adverse decisions to the PTAB and the Federal Circuit. Pre-AIA §§ 314–315.

Once the USPTO ordered an inter partes reexamination, the third-party requester was estopped from later arguing invalidity in a civil action on any ground that it raised, or could have raised, during the reexamination proceeding. Pre-AIA § 315(c). However, the third-party requester remained free to challenge the patent claims on other grounds, including newly discovered prior art unavailable to the third-party requester or the USPTO during the reexamination. *Id.*

14.2.5.5.4 Reexamination and Concurrent Litigation

It is not uncommon for an accused infringer to file a reexamination request for one or more of the patents-in-suit during litigation. Because reexaminations must proceed with "special dispatch" (§ 305; pre-AIA § 314), the USPTO Director cannot stay reexamination in light of concurrent litigation. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426–27 (Fed. Cir. 1988). In contrast, district courts "have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a USPTO reexamination." *Id.* The USPTO prioritizes reexaminations of patents involved in litigation.

During a reexamination proceeding, the USPTO evaluates patentability issues under a "preponderance of the evidence" standard, whereas the district court must still apply the "clear and convincing" standard to invalidate a patent claim undergoing reexamination. *See Ethicon*, 849 F.2d at 1427.

A district court's finding that a patent was not proven invalid does not ordinarily create collateral estoppel effects on other courts or the USPTO during reexamination. *Ethicon*, 849 F.2d at 1429 n.3; *see also In re Swanson*, 540 F.3d 1368, 1379 (Fed. Cir. 2008) ("As properly interpreted a 'substantial new question of patentability' refers to a question which has never been considered by the USPTO; thus, a substantial new question can exist even if a federal court previously considered the question."). In contrast, a final, nonappealable court decision finding invalidity bars enforcement of the patent in subsequent proceedings (*see Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971)), and the USPTO may discontinue the reexamination. *See Ethicon*, 849 F.2d at 1429.

14.2.5.6 Inter Partes Review (IPR)

IPR replaced inter partes reexaminations on September 16, 2012. AIA § 6 (amending §§ 311–319). In an IPR, a third party may seek cancellation of at least one claim based on § 102 or 103 using only prior art patents or printed publications. IPR may be requested by anyone who is not the patent owner, and who has not previously filed a declaratory judgment action challenging the validity of the patent. The USPTO will grant IPR if the petition shows "a reasonable likelihood" that the petitioner would prevail on at least one claim being challenged. The USPTO's decision on whether to institute an IPR is unappealable. *See In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271 (Fed. Cir. 2015). IPR is handled by the PTAB rather than by the CRU, and appeals are taken directly to the Federal Circuit.

During IPR, the standard for proving invalidity is by a preponderance of the evidence, the parties may engage in limited discovery, and the patentee has an opportunity to provide comments and/or propose claim amendments that do not enlarge claim scope. With regard to patents filed under the AIA's first-to-file regime (and not patents filed prior to March 16, 2013), a petition for IPR cannot be filed until after the later of: (1) the closing of the postgrant review (PGR) window, that is, nine months after the grant (or reissue) of a patent, or (2) the termination of any PGR. The statute requires the USPTO to issue a final determination of the IPR no later than a year after instituting the proceeding; this deadline may be extended up to six months for good cause.

If, after filing a petition for IPR, the petitioner initiates a civil action seeking a declaratory judgment of invalidity of the same patent, the civil action is automatically stayed. The automatic stay is lifted if the patentee moves the court to lift the stay or asserts the patent against the petitioner in a civil action or in a counterclaim. Because the automatic stay provisions apply to "civil actions" rather than counterclaims, a petitioner is able to assert invalidity counterclaims while seeking IPR. A petition for IPR may not be filed more than one year after the date on which the patentee served the petitioner with a complaint for infringement of the patent.

In any subsequent proceeding in the USPTO, the district courts, or the ITC, the petitioner is estopped from raising issues that it had raised or reasonably could have raised during IPR. If the parties settle during IPR, there is no estoppel effect. In a manner similar to reissue claims, intervening rights attach to new or amended claims that emerge from IPR.

14.2.5.7 Postgrant Review (PGR)

Under §§ 321–329, AIA § 6, anyone other than the patentee may petition for postgrant review of a patent within nine months of grant or reissue based on any ground of invalidity. The PTAB will institute a postgrant review if it determines that it is more likely than not that at least one of the claims is unpatentable, or the petition raises a legal issue important to other patents or patent applications. If multiple postgrant review petitions are filed, the USPTO may consolidate them. The denial of a petition is unappealable.

The standard for proving invalidity in a postgrant review proceeding is by a preponderance of the evidence. The AIA provides limited discovery for the parties. The patentee has an opportunity to provide comments and/or propose claim amendments, but claim scope may not be enlarged. The statute requires the USPTO to issue a final determination no later than a year after instituting the proceeding; this deadline can be extended up to six months for good cause. In any subsequent proceeding in the USPTO, the district courts, or the ITC, the petitioner is estopped from raising issues that it had raised or reasonably could have raised during postgrant review. If the parties settle during postgrant review, there is no estoppel effect.

A party that has previously filed an action seeking a declaratory judgment of invalidity cannot petition for postgrant review. If, during the postgrant review proceeding, the petitioner files a declaratory judgment action, that action is stayed unless the patentee counterclaims for infringement. If the patentee files an action to assert the patent within three months of issuance, a court may not delay consideration of a motion for preliminary injunction on the ground that a postgrant review petition has been filed or that a postgrant review proceeding has been instituted. In a manner similar to reissue claims, intervening rights attach to new or amended claims that emerge from postgrant review. *See* § 14.2.5.4.2.2.

Postgrant review proceedings apply to claims with effective filing dates after March 15, 2013.

14.2.5.7.1 Covered Business-Method Review (CBMR)

The AIA provides for a variant of the postgrant review proceeding for business-method patents of all filing dates. Under the Transitional Program for Covered Business Method Patents, CBMR may be requested for a business-method patent that has been asserted against the requester, either in court or with allegations of infringement. AIA § 18. Courts may stay concurrent district court proceedings pending a CBMR, but the decision whether to grant a stay is subject to interlocutory review. This transitional program began September 16, 2012, and ends September 16, 2020.

Like postgrant review, and unlike IPR, patent validity can be challenged on any ground. Additionally, no time-bar exists in CBMR; a petitioner does not have to file within a certain period of time from being named defendant in a suit or from an accusation of patent infringement. The estoppel provision is also weakened. A petitioner is estopped from arguing any ground *actually* raised in CBMR in subsequent district court or ITC proceedings. However, a petitioner still faces estoppel based on anything that reasonably could have been raised in subsequent proceedings at the USPTO.

14.2.5.7.2 Postgrant, Inter Partes, and Covered Business-Method Review and Concurrent Litigation

Similar to reexamination, accused infringers commonly file a review request for one or more of the patents-in-suit during litigation. Reviews must ordinarily be completed within twelve months from an institution decision (with an outer bound of eighteen months upon showing of good cause) and cannot be stayed. Much of the analysis to stay a case pending a review is the same as with reexamination; however, one important exception applies.

In addition to the three traditional considerations courts weigh to decide whether to stay a case, Congress added a fourth to be considered when litigation is copending with CBMR of a patent: "whether a stay, or the denial thereof, will reduce the burden of litigation on the parties and the court." AIA § 18. As mentioned above, the grant or denial of a stay is subject to interlocutory review.

Table 14.2 summarizes the principal features of and differences between the AIA review procedures.

Table 14.2
Significant Differences Between AIA Reviews

AIA Review	Inter Partes	Postgrant	Business-Method
Evidentiary Standard	Petitioner to prove invalidity by the preponderance of the evidence		
Grounds for Review	§ 102, § 103	Any defense relating to invalidity	
Prior Art Limited to:	Patents and printed publications	No Limits	
Threshold to Institute Review	Reasonable likelihood that one or more claims invalid	More likely than not, at least one claim is unpatentable, or petition raises a novel legal question of patentability.	
Time to Institution	Maximum of 6 months		
Time to Decision	Maximum of 12–18 months from institution decision		
Claim Amendments	Patent owner may cancel claims or propose a reasonable number of substitute claims. Presumption that only one substitute claim will be required for each challenged claim		
Claim Construction	"Broadest reasonable construction in light of specification"		
Stay Considerations:	1) Stay simplify issues and streamline trial? 2) Is discovery complete, trial date set? 3) Stay tactically advantage moving party or unduly burden nonmoving party?		*AIA Consideration:* 4) Stay reduce burden on the parties and the court?
Estoppel in Subsequent Civil Action	Any ground raised or that reasonably could have been raised		Any ground *actually* raised
Effect of Settlement	Estoppel provisions do not apply.		

14.2.6 The Presumption of Validity

The 1952 Patent Act codified the judge-made presumption that the rigor of the USPTO's examination process should render an issued patent presumptively valid. Thus, a patent is presumed valid and a party asserting invalidity must prove the facts to establish a claim's invalidity by clear and convincing evidence. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011); *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 973–74 (Fed. Cir. 1986).

The "clear and convincing" standard applies to questions of fact and not to questions of law. The factual and legal aspects of an invalidity claim may be separated "by using instructions based on case-specific circumstances that help the jury make the distinction or by using interrogatories and special verdicts to make clear which spe-

cific factual findings underlie the jury's conclusions." *Microsoft*, 131 S. Ct. at 2253 (Breyer, J. concurring) (citing Fed. R. Civ. P. 49 and 51).

Where the references asserted against a claim's validity were not presented to the USPTO examiner, "the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain." *Microsoft*, 131 S. Ct. at 2251. The Federal Circuit has similarly observed that the burden of proof may "be facilitated" or more easily met if the examiner never considered the asserted reference. *Kaufman*, 807 F.2d at 973; *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1393 n.4 (Fed. Cir. 1984). In such situations, "the jury may be instructed to evaluate whether the evidence before it is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence." *Microsoft*, 131 S. Ct. at 2251.

14.3 Validity

A patent claim must meet five requirements to issue as part of a valid patent: (1) patentable subject matter, (2) utility, (3) disclosure, (4) novelty, and (5) nonobviousness. Failure to clear any one of these hurdles will invalidate the patent claim.

14.3.1 Patentable Subject Matter (§ 101)

Section 101 authorizes protection for "any" "process, machine, manufacture, or composition of matter" or "improvement thereof . . . subject to the conditions and requirements of this title." Although the Patent Act has not excluded any subject matter for much of U.S. history,[9] courts have long recognized subject-matter eligibility limitations. These limits emerged during the early to mid-nineteenth century as Anglo-American, common-law-trained jurists fleshed out the relatively terse patent law eligibility requirements.

Thus, the contours of these doctrines are found not in the text of the Patent Act but rather in two centuries of jurisprudence that has ebbed and flowed with technological advance, perspectives on scientific discovery, and concerns about the patent system stifling new inventions. Patent-eligibility doctrines lost salience from the early 1980s through 2009 as the Federal Circuit substantially liberalized the scope of patentable subject matter. The Supreme Court was dormant in patentable subject-matter jurisprudence during this period. The Supreme Court reentered the arena in 2010 and has since issued four significant opinions reinvigorating patentable subject-matter eligibility limitations and, in so doing, making this area ripe for litigation. *See Bilski v. Kappos*, 561 U.S. 593 (2010); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). Most patents in effect today issued during the period in which subject-matter

9. As noted in §§ 14.3.1.3.1–2, the AIA excludes patents on tax strategies and human organisms.

eligibility was perceived to be very broad. Hence, the courts have seen a large and growing number of challenges to patent validity based on § 101 since 2010.

Navigating the boundaries of patentable subject matter entails careful study of the Supreme Court's recent decisions as well as the history leading up to those cases. The Supreme Court's predilection for considering all of its prior patentable subject-matter cases to be consistent poses notable interpretive challenges. Thus, it will be useful to examine the case law through a variety of lenses. The next section states the core principles undergirding modern Supreme Court jurisprudence. The following sections trace the history of these doctrines, examine particular subject-matter areas, and explore the challenges of applying patent-eligibility doctrines.

14.3.1.1 Modern Core Principles: Ineligible Subject Matter and Inventive Application

The Supreme Court's most recent patentable subject-matter decision, *Alice*, synthesizes two centuries of jurisprudence into a two-part test:

> Step 1: Does the patent claim a patent-ineligible law of nature, natural phenomena, or abstract idea?
>
> Step 2: If so, does the claim contain an inventive concept sufficient to transform the ineligible law of nature, natural, phenomena, or abstract idea into a patent-eligible application of the ineligible subject matter?

Alice, 134 S. Ct. at 2354. The exclusion of claims covering laws of nature, natural phenomena, and abstract ideas reflects the concern, sometimes referred to as the preemption rationale, that patents not unduly inhibit further discovery by tying up basic building blocks of human ingenuity. Step 2 requires that the patentee not merely *apply* the law of nature, natural phenomena, or abstract idea, but rather do so in an *inventive* manner. The application cannot be routine or conventional, but must be inventive above and beyond the discovery of the underlying law of nature, physical phenomena, or algorithm.

This characterization of patent eligibility potentially excludes some of the most important and difficult technological discoveries from patent protection: the discovery of laws of nature. During earlier eras, inventors could obtain patents on applications of such discoveries even if their *application* was conventional. The Supreme Court's recent jurisprudence, however, excludes routine or conventional applications of breakthrough scientific biomedical or algorithmic discoveries from patent eligibility. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (invalidating a patent on noninvasive prenatal diagnostic methods on the ground that the *application* of the discovery that cell-free fetal DNA existed in maternal blood was not inventive); *cf. id.* at 1380 (Linn, J. concurring) (observing that "[t]his case represents the consequence—perhaps unintended—of that broad language [in the Supreme Court's *Mayo* decision] in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain").

The requirement of not merely *application* but *inventive* application of patent-ineligible subject matter overlaps with the § 103 nonobviousness requirement. Upon closer examination, however, the inventiveness required for § 101 eligibility is dis-

tinct from and arguably more demanding than § 103 nonobviousness analysis. According to *Mayo*, the inventive application requirement treats the patentees' discovery of the law of nature, physical phenomena, abstract ideas, or algorithms (in *Flook*) as known (even where it was not), whereas § 103 nonobviousness focuses on "the differences between the claimed invention and the prior art." *See* § 14.3.5.3.3. The rationale for this distinction apparently derives from the notion that laws of nature, physical phenomena, and abstract ideas are basic building blocks of human ingenuity. They are not invented by humans but merely discovered. The fact that § 101 of the Patent Act confers patent eligibility on "[w]hoever invents or *discovers* any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ," however, only adds to the confusion.

As the evolution of these doctrines reveals, the Supreme Court's emphasis on *inventive* application rests on a questionable jurisprudential foundation. *See generally* Jeffrey A. Lefstin, 67 *Inventive Application: A History*, Fla. L. Rev. 565 (2015). Nonetheless, unless and until the doctrine's provenance is rectified, lower courts must work within this framework. Understanding the evolution of patent-eligibility jurisprudence illuminates the current state of the law and provides some guidance in applying the inventive application doctrine.

14.3.1.2 The Evolution of Patentable Subject-Matter Limitations

Like the modern Patent Act, the nation's first patent statutes authorized the granting of patents for a broad range of subject matter—"any new and useful art, machine, manufacture, or composition of matter"[10]—without express subject-matter limitations. Courts came to recognize that patentability of broad scientific principles and abstract claims created the need for patent-eligibility and scope limitations—what we today consider § 112 concerns. These concepts were intertwined in the early jurisprudence and continue to overlap today.

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10. *See* Patent Act of 1793, Act of Feb. 21, 1793, 1 Stat. 318. This language parallels the modern subject matter categories with the replacement of the term "art" with "process." This shift reflects the evolution of language as opposed to substantive change. *See* H.R. Rep. No. 82-1923, A Bill to Revise and Codify the Laws Relating to Patents and the Patent Office, and to Enact into Law Title 35 of the United States Code Entitled "Patents," at 5–6, 82d Cong., 2d Sess. (1952). The concept of a "useful art" during the nation's formative period connoted guilds and trades utilizing what we would today call "technology." During the nineteenth century, courts defined "art" as "a new process or method of working or of producing an effect or result in matter." *See* George Ticknor Curtis, A Treatise on the Law of Patents for Useful Inventions, as Enacted and Administered in the Unites States of America 28 (3d ed. 1867). In explaining the substitution of "process" for "art," the drafters of the 1952 Act explained that the change was not substantive. Section 100 of the 1952 Act defined "process" to include "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *See generally* Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land:* Bilski*'s Superficial Textualism and the Missed Opportunity to Ground Patent Interpretation and Return Patent Law to Its Technology Mooring*, 63 Stan. L. Rev. 1289 (2011).

14.3.1.2.1 Early Development of Patent-Eligibility Limitations

In the years following the nation's founding, English cases substantially influenced American jurisprudence. The United States inherited many English legal traditions. This was especially true of intellectual property law, which closely followed English formulations and interpretations.

With the industrial revolution gaining momentum, courts on both sides of the Atlantic struggled to deal with the patentability and scope of path-breaking inventions such as the steam engine, hot blast furnace, sewing machine, telegraph, and telephone. The patenting of the hot blast process, which industrial historians came to view as "the most important single innovation in the industry in the age of iron," *see* Alan Birch, The Economic History of the British Iron and Steel Industry 1784–1879, 181 (1968), would prove especially important to patent-eligibility doctrine.

Scottish inventor James Beaumont Neilson challenged the conventional wisdom that hot-blast furnaces would function most effectively if they were fed cold air. Neilson's patent claimed preheating of air entering furnaces, and this preheating revolutionized the production of iron by substantially reducing the fuel required and enabling the use of raw coal and lower-quality ores. His brief specification provided few details and declared that "[t]he form or shape of the receptacle is immaterial to the effect," as were the composition of the air vessel and the manner of applying heat.

He would sue numerous ironmakers for patent infringement, leading to the important decision in the English Court of the Exchequer, *Neilson v. Harford* (1841), that continues to reverberate in U.S. patentable subject-matter jurisprudence today. The patent was attacked on two principal grounds: (1) that it was not sufficiently described; and (2) that a patent for injecting hot air into the furnace, instead of cold, and thereby increasing the intensity of the heat, was a patent for a principle, and that a principle was not patentable. The jury found that a skilled artisan could, based on the specification, construct an improved hot blast furnace. Therefore, the patent was sufficiently described.

The second issue would prove especially important. In upholding the patent, Judge Baron Parke explained:

> It is very difficult to distinguish it from the specification of a patent for a principle, and this at first created in the minds of the court much difficulty; but after full consideration we think that the plaintiff does not merely claim a principle, but a machine, embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces, and his invention then consists in this: by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before cold air, in a heated state to the furnace.

The court reasoned that since the principle worked regardless of the dimensions of the receptacle in which the air was preheated before injection into the furnace, Neilson's invention applied the principle and hence, even though very broad (and arguably preemptive of the preheating principle), was patent-eligible. It is notable that the English court did *not* require *inventive* application of the law of nature

(that preheating air before injection into a hot-blast furnace will allow for more efficient fuel usage and higher temperatures) for patent eligibility. The preheating receptacles and bellows were in the prior art. Rather it was recognition and application of the natural law that provided the basis for patent eligibility, not the inventiveness (or lack thereof) of the means of harnessing the natural law.

U.S. decisions followed this approach, barring protection for a mere "principle," "motive" force, or "new power" in the abstract. The Supreme Court explained in *Le Roy v. Tatham*, a case involving improved machinery for manufacturing lead pipe and a new property (the manufacture of wrought pipe from solid lead), that

> [a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.
>
> In all such cases, the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in *applying* them to useful objects. . . .

55 U.S. 156, 1775 (1853) (emphasis added). The case approvingly discussed the *Neilson* case. *See id.* at 175–76; *see also id.* at 180–82, 185 (Nelson, J. dissenting).

The U.S. Supreme Court addressed *Neilson* in *O'Reilly v. Morse*, 56 U.S. 62 (1853), a case concerning the patenting of the telegraph. In addition to claims relating to the particular apparatus, Morse sought protection for "the use of the motive power of the electric of galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances. . . ." *Id.* The breathtaking scope of this final claim led the Court to consider the principles enunciated in *Neilson v. Harford*. *Id.* at 62–63. While endorsing the requirement that patents must apply a law of nature, the Court nonetheless distinguished Neilson's claim from Morse's final claim. *Id.* Whereas the effect that Neilson claimed (improving the functioning of a hot-blast furnace) produced the desired effect for "whatever might be the form of the receptacle, or the mechanical contrivances for heating it, or for passing the current of air through it, and into the furnace," Moore had "not discovered, that the electric or galvanic current will always print at a distance, no matter what may be the form of the machinery or mechanical contrivances through which it passes." *Id.* at 116–17. Thus, Morse's final broad claim was invalid for reasons that we would today characterize as overbreadth (§ 112 written description), not ineligible subject matter (§ 101). Yet the Court's invocation of *Neilson* would take on great significance in American patent-eligibility jurisprudence a century later.

By the end of the nineteenth century, American patent-eligibility doctrine merely required that the patentee "carry the principle into effect, however simple and self-evident such means may be." *See* David Fulton, The Law and Practice Relating to Patents, Trade Marks and Designs 41 (1902); *see also* Robert Frost, A Treatise on the Law and Practice of Letters Patent for Inventions 36 (1891) ("Prin-

ciples in a concrete form, together with a mode of applying them to a new and useful purpose, may form the subject of a grant of letters patent. . . . It is not necessary that the means, as well as the principle, should be new, for the novelty of the invention consists in applying the new principle by the means specified."). This view continued well into the twentieth century. *See* Caesar & Rivise, Patentability and Validity, §§ 33, 34 (1936) (observing that "[i]n the cases where the inventor was required to be also the discoverer of the law or force utilized, it appeared that the application or utilization of the law became self-evident as soon as the principle was formulated").

14.3.1.2.2 *Funk Brothers* (1948): The Emergence of Inventive Application

The *inventive* application eligibility concept first emerged in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). The claimed invention concerned bacteria cultures used to fix nitrogen in leguminous (pea and bean) plants, which is essential to promoting plant growth. At the time that the claimed invention was made, it was known that bacteria of the genus *Rhizobium* naturally exist in symbiotic association with leguminous plants. *Id.* at 128. Farmers routinely mixed *Rhizobium* cultures with leguminous plants to enhance nitrogen fixation. *Id.* at 129. Unfortunately, particular species of the *Rhizobium* genus infect only particular legumes. *Id.* Attempts at mixing different *Rhizobium* species into a single commercial product generally proved unsuccessful, as the bacteria species exerted inhibitory effects on each other when mixed together. *Id.* As a result, farmers would need to apply separate cultures for each leguminous crop, raising their costs and complicating the application of the bacteria. *Id.* at 129.

The inventor discovered that particular combinations of naturally occurring *Rhizobium* bacteria were not inhibitory and, therefore, could be packaged together into a product that could be applied across leguminous plant varieties more conveniently. *Id.* at 130. The patent broadly claimed the method of producing the bacteria mix as well as a broad composition of matter: "[a]n inoculant for leguminous plants comprising a plurality of selected mutually noninhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific." *Id.* at 128 n.1. The composition-of-matter claim covered all mutually noninhibitory combinations of the *Rhizobium* genus. *Id.* at 137.

A divided Supreme Court invalidated the patent on the ground that it did "not disclose an invention or discovery within the meaning of the patent statutes." *Funk Brothers*, 333 U.S. at 132. Justice Douglas's majority opinion began its analysis by restating well-established patent-eligibility jurisprudence:

> [P]atents cannot issue for the discovery of phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the quality of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If

> there is to be invention from such a discovery, it must come from the *application* of the law of nature to a new and useful end.

Id. at 130 (citations omitted; emphasis added). The following paragraph, however, introduces the idea that merely applying a law of nature is insufficient.

> Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. *The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle.* But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants.

Id. at 131 (emphasis added). Justice Douglas acknowledged that the inventor had applied the law of nature, but nonetheless invalidated the claim as insufficiently inventive in its application of the newly discovered natural principle. *Id.* The Court noted that

> a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 90, 91 (1941), and cases cited; 35 U.S.C. § 31. The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention.

Id. at 131–32.

In a concurring opinion, Justice Frankfurter offered an alternative basis for invalidation reminiscent of the *Morse* decision. In his view, the patent was invalid not for unpatentable subject matter but rather for want of adequate identification of successful combinations of mutually noninhibitory bacteria. *Funk Brothers*, 333 U.S. at 133. He went on to observe that

> [i]t only confuses the issue . . . to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

Id. at 134–35.[11]

Following *Funk Brothers*, several appellate decisions implemented its holding, treating newly discovered scientific principles to be unpatentable and requiring *inventive* application of such principles. *See, e.g.*, *Davison Chem. Corp. v. Joliet Chems., Inc.*, 179 F.2d 793 (7th Cir. 1950); *In re Arnold*, 185 F.2d 686 (C.C.P.A. 1950); *Nat'l Lead Co. v. W. Lead Prods. Co.*, 324 F.2d 539 (9th Cir. 1963).

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11. Justices Burton and Jackson dissented, finding the product claims within the scope of patentable subject matter and adequately disclosed. *Funk Brothers*, 333 U.S. at 136.

14.3.1.2.3 The New Technological Age

With the dawning of the digital age, the Supreme Court returned to patent-eligibility cases. The inventor in *Gottschalk v. Benson*, 409 U.S. 63 (1972), claimed an algorithm for converting binary-coded decimal numerals into pure binary numerals. In upholding the USPTO's rejection of the patent on subject-matter grounds, a unanimous Court, drawing upon *Le Roy*, *Morse*, and *Funk Brothers*, articulated three principles for determining whether a process is patentable: (1) "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work," *id*. at 67; (2) "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines," *id*. at 70; and (3) algorithms may not be patented so as to avoid the practical effect of "wholly pre-empt[ing a] mathematical formula," *id*. at 71. Echoing concerns raised by various amicus briefs, the Court concluded by calling on Congress to take up the question of whether and to what extent computer programs ought to be patentable. *See id*. at 71–73.

Six years later in *Parker v. Flook*, 437 U.S. 584 (1978), the Supreme Court addressed whether a procedure for updating an alarm limit—measuring the present value of a process variable (such as temperature), using an algorithm to calculate an updated alarm-limit value, and adjusting the updated value—was eligible for patent protection. Writing for the majority in a sharply divided opinion, Justice Stevens expressly embraced the *inventive application* doctrine in upholding the USPTO's rejection of the claim. In an apparent misinterpretation, the Court grounded the doctrine on the statement in *Neilson* that "'*the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it . . . .*'" *Flook*, 437 U.S. at 592 (quoting *Morse*, quoting *Neilson*). Based on this sentence from *Neilson*, the Supreme Court reasoned that "this case must also be considered as if the principle or mathematical formula were well known" and that patent eligibility required sufficient inventiveness beyond the application of the algorithm to be within the scope of patentable subject matter. *Id*. at 592, 594–95. As the Court declared:

> Even though a phenomenon of nature or mathematical formula may be well known, an *inventive application* of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other *inventive concept* in its application.

Id. at 594 (emphasis added).

Justice Stevens countered suggestions that such an approach "improperly imports considerations of 'inventiveness'" from §§ 102 and 103 into the § 101 analysis, noting that "[t]he obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious." *Id*. at 594.

Like the Court's opinion in *Benson*, the majority opinion concluded with a call for Congress, with its access to empirical evidence, rather than the courts, to take on the patentability of computer programs. *Id.* at 595–96. The opinion also invoked an

interpretive principle of parsimony: "'[W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language.'" *Id.* at 595 (quoting *Deepsouth Packing Co. v. Laitram Corp*., 406 U.S. 518, 531 (1972)).[12]

Justice Stewart, with whom Chief Justice Burger and Justice Rehnquist joined, did not see the patent at issue as preempting use of the algorithm, but rather as a potentially patentable application of it. *Id.* at 599. He criticized the majoring opinion for excluding a process from the scope of patentable subject matter because "*one step* in the process would not be patentable subject matter if considered in isolation," observing that "thousands of processes and combinations have been patented that contained one or more steps or elements that themselves would have been unpatentable subject matter." *Id*. (citation omitted; emphasis in original). The majority opinion responded to this contention by noting that the process is unpatentable "not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention." *Id*. at 594.

In the midst of the controversy over the patentability of computer software, the Supreme Court confronted the patentability of genetically modified organisms. *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The inventor claimed a self-replicating bacterium into which he had injected oil-degrading plasmids that could be used in dispersing oil spills. *Id.* at 305. The USPTO rejected the claim on the grounds that microorganisms are "products of nature" and living things, both of which make them ineligible for patent protection under § 101. *Id.* at 306. The Court of Customs and Patent Appeals reversed, upholding the claim under the standards set forth in *Flook*. *Id.*

The Supreme Court affirmed the appellate court decision, opening the way for patent protection for genetically modified organisms. *Id.* at 318. Writing for the majority, Chief Justice Burger characterized the Constitution's grant of patent legislative authority and § 101's text broadly. *Chakrabarty*, 447 U.S. at 307–08. While recognizing the unpatentability of "laws of nature, physical phenomena, and abstract ideas," the Court judged Chakrabarty's claim to a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity "having a distinctive name, character [and] use"—to "plainly" qualify for patent eligibility. *Id*. at 309–10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). Drawing a contrast to *Funk Brothers*, the Court noted that Chakrabarty "has produced a new bacterium with markedly different characteristics from any found in nature and one having the po-

12. The Court was quite aware of the larger policy concerns surrounding the case. In discussing the procedural background to the case, the Court observed that "[t]he Acting Commissioner of Patents and Trademarks filed a petition for a writ of certiorari, urging that the decision of the Court of Customs and Patent Appeals will have a debilitating effect on the rapidly expanding computer 'software' industry, and will require him to process thousands of additional patent applications." *Flook*, 437 U.S. at 587–88.

tential for significant utility. His discovery is not nature's handiwork, but his own." *Id*. at 310.

Moreover, *Chakrabarty* interpreted the scope of patent-eligible subject matter expansively, stressing that § 101 encompasses any invention falling within the four designated categories. *Id.* at 308–09. The Supreme Court also looked to the legislative history of the 1952 Patent Act, from which it concluded that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[13] *Id.* at 309.

Propelled in part by *Chakrabarty*'s broad reading of patent eligibility, the pendulum swung decisively in the opposite direction of *Flook* three years after it was rendered. The USPTO rejected a patent application claiming a process for molding raw, uncured, synthetic rubber into cured precision products using a computer program, a known algorithm to calculate the cure time, and continuous measurement of the internal temperature. After the Court of Customs and Patent Appeals overturned the § 101 rejection, the USPTO sought certiorari based on the *Flook* decision:

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13. The full passage from which this quotation was taken is arguably less expansive. The "anything under the sun" phrase arises in the section of the House Report describing "Part II" of Title 35, which "relates to patentability of inventions and the grant of patents." H.R. Rep. No. 82-1923, at 6. This discussion begins with four paragraphs explaining § 101: the first two deal with the subject matter categories; the second two focus on the final clause of § 101.

The first and longest paragraph begins by stating that Section 101 "specifies the type of material that can be the subject matter of a patent," thus implying that there are types of material that are not within the scope of patentable subject matter. The second paragraph explains that the definition of "process" was added in § 100 "to make it clear that 'process or method' is meant, and also to clarify the present law as to the patentability of certain types of processes or methods as to which some insubstantial doubts have been expressed." *See id*. The next two paragraphs explain the final clause of Section 101:

> Section 101 sets forth the subject matter that can be patented, "subject to the conditions and requirements of this title." The conditions under which a patent may be obtained follow, and section 102 covers the conditions relating to novelty.
>
> A person may have "invented" a machine or manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.

H.R. Rep. No. 82-1923 at 6 (1952). Given the order of paragraphs as well as the transition, the final sentence, from which the Supreme Court draws in *Chakrabarty*, augments and reinforces the preceding paragraph—which addresses the final clause of § 101, not the preceding paragraphs that deal with the contours of patent eligible processes. Furthermore, the prefatory clause of that sentence appears to limit the dependent clause ("which may include anything under the sun that is made by man") to the statutory classes of "machine" or "manufacture." These categories plainly fall within the ambit of "useful Arts." Note that the prefatory clause does not include the other statutory categories: "process" and "composition of matter." Nor does this sentence call for maximal subject matter. Rather, it merely emphasizes the importance of meeting additional requirements for patentability.

> In both cases applicants seek to patent a process the only novel feature of which is an algorithm embodied in a computer program. The primary difference between the two cases is in the manner in which the claims have been drafted: although Flook's claims focused on the algorithm and recited only minor post-solution activity, the claims here recite in general terms the entire conventional rubber molding process.

Petitioner's Brief, *Diamond v. Diehr*, 6 No. 79-1112 (June 10, 1980) (summary of argument).

Writing for the majority, Justice Rehnquist explained that processes have been eligible for patent protection since the 1793 Act and referenced the statement from *Benson* that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70). The Court concluded that "a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter." *Id.* Justice Rehnquist purported to distinguish *Benson* and *Flook* before proclaiming that "[o]ur earlier opinions lend support to our present conclusion that a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer." *Id.* at 187. The Court emphasized that process claims are properly analyzed

> as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Id. at 188–89. In so doing, Justice Rehnquist swept away the requirement of *inventive* application. He reiterated, however, that "a mathematical formula as such" is not patentable nor is attempting to limit the use of a formula to a particular technological environment, citing *Benson* and *Flook*. *Id.* at 191. The touchstone for patentability of a process embodying a mathematical formula, according to the majority opinion, is significant postsolution activity—that is, "transforming or reducing an article to a different state or thing." *Id.* at 191–92.

Justice Stevens, joined by Justices Brennan, Marshall, and Blackmun, vehemently dissented, emphasizing that the majority eviscerated the inventive application doctrine. To the dissenters, if the inventor's "method is regarded as an 'algorithm' as that term was used" in *Benson* and *Flook*, "and if no other inventive concept is disclosed in the patent application," then the claim falls outside the scope of patentable processes under § 101. *Id.* at 213–14. Moreover, the dissenters contended that "the postsolution activity described in the *Flook* application was no less significant than the automatic opening of the curing mold involved in this case." *Id.* at 215.

14.3.1.2.4 The Rise of the Federal Circuit and Dismantling of Patentable Subject-Matter Limitations

Over the ensuing nearly three decades, the evolution of patent-eligibility doctrine shifted to the Court of Appeals for the Federal Circuit, established in 1982. Perhaps bearing out concerns that a national appellate patent tribunal would favor expansion of patent protection, the Federal Circuit gradually eroded patent-eligibility limitations. Building off of *Diehr*, the Federal Circuit gradually chipped away at the postsolution activity necessary to bring software-related claims within § 101. *See, e.g.*, *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994). Similarly, the Federal Circuit endorsed the USPTO's policy of patent eligibility of DNA molecules. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991). In a departure from prior jurisprudence, the Federal Circuit "la[id the] ill-conceived [business-method] exception to rest." *State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998). The Supreme Court declined to weigh in on these controversies.

The *State Street Bank* decision sent shockwaves through the financial community, sweeping away more than a century of jurisprudence holding that business methods were unpatentable. Financial institutions became concerned that their investment strategies, which were maintained as trade secrets and hence could not qualify as prior art, could be held to infringe later-developed patents. As a result, they sought legislation excluding business methods from the scope of patentable subject matter. Intellectual-property trade organizations, however, resisted any changes to § 101. As a compromise, Congress established the § 273 prior-user defense as a safe harbor for the financial community. *See* First Inventor Defense Act of 1999, Pub. L. 106-113, app. A, 113 Stat. 1501, 552, 555. The legislation did not take a position on the scope of patentable subject matter.

The Federal Circuit's loosening of patent-eligibility doctrines brought about a vast expansion in the range of patents being sought and granted. The USPTO shifted its position from skepticism about expansive patent eligibility to openness and even enthusiasm, resulting in a flood of software, DNA, and business-method patents. Entrepreneurs and venture capitalists came to see patenting as a valuable tool for developing (or at least claiming) Internet-related businesses. The late 1990s witnessed an unprecedented growth of start-up businesses based on speculative initial public offerings secured, in part, on patent portfolios.

The bursting of the Internet stock bubble in the early 2000s produced a vast shake-out, causing widespread bankruptcies and the auctioning and sale of Internet-related patents. This led to the emergence of patent assertion entities—patent-holding companies and nonpracticing entities seeking to monetize Internet-related patents. Lawsuits by patent-assertion entities produced a tidal wave of patent-eligibility challenges as well as calls by Silicon Valley companies, policy makers, and scholars for policy reform.

The Federal Circuit issued several decisions cautiously reinvigorating patent-eligibility limitations. *See, e.g.*, *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007) (holding that a watermarked electromagnetic signal does not fall into any of the four categories of patent-eligible subject matter); *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007), *amended by* 554 F.3d 967 (Fed. Cir. 2009) (noting the "'[t]he *obligation* to determine

what type of discovery is sought to be patented [so as to determine whether it is 'the kind of "discoveries" that the statute was enacted to protect'] *must precede* the determination of whether that discovery is, in fact, new or obvious'" (citing *Parker v. Flook*, 437 U.S. 584, 593 (1978) (emphasis added by Federal Circuit); and affirming rejection of a business-method patent under § 101 as merely relying on mental steps). Most notably, the Federal Circuit, sitting en banc, attempted to clarify the boundaries of patentable subject matter under § 101. *See In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

Bilski claimed a method of managing risk of commodity prices—a business method that could be implemented using a computer. *Id.* at 949. In an effort to harmonize the Supreme Court's *Benson*, *Flook*, and *Diehr* precedents, the Federal Circuit devised the "machine-or-transformation" ("MoT") test "to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself." *Id.* at 954. Under the MoT test, a claimed process is patent-eligible under § 101 if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.* The court concluded that the Bilski patent failed both prongs—it was not tied to a "particular" machine, and transformation of legal obligations or relationships, business risks, or other abstractions were not within the types of tangible changes eligible for patent protection—and it hence was unpatentable. *Id*. at 963–66.

14.3.1.2.5 The Supreme Court's Revival of Subject-Matter Limitations

The Supreme opened a new chapter in patent-eligibility jurisprudence with its grant of review in the *Bilski* case. Many groups and individuals filed amicus briefs, with arguments ranging from the unpatentability of business methods as falling outside of the "useful arts" and hence beyond Congress's legislative authority to a textual argument that § 101 encompasses "any" process. The Court's ultimate decision in *Bilski* would prove anticlimactic and unilluminating. *See Bilski v. Kappos*, 561 U.S. 593 (2010); Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land:* Bilski*'s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 Stan. L. Rev. 1289 (2011).

While affirming the Federal Circuit's decision holding Bilski's hedging patent application invalid, the Supreme Court rejected the MoT test as the *sole* test of patent eligibility of process claims. *Bilski,* 561 U.S. at 603. The Supreme Court characterized the MoT test as a "useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101," but too rigid in view of the broad statutory definition in § 100(b) of "process." *Id.* at 603–04. While recognizing the jurisprudentially developed exclusions for laws of nature, natural phenomena, and abstract ideas, the Court nonetheless warned that the judiciary does not have "*carte blanche* to impose other limitations that are inconsistent with the

text and the statute's purpose and design." *Id*. at 603.[14] On similar grounds, the majority rejected the argument that business methods are categorically excluded from patent eligibility.[15] *Id*. at 606–08.

The majority ruled that Bilski's broad independent claim to hedging was "an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea." *Id*. at 611–12. The Court further rejected Bilski's narrower dependent claims as unpatentable by reference to *Flook*, which "established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." *Id*.

Justice Stevens, joined by Justices Ginsburg, Breyer, and Sotomayor, filed an extensive opinion concurring in the judgment, but contending that the Patent Act and jurisprudence have long categorically excluded business methods from patent eligibility. *Id.* at 613.

In contrast to the cautious ruling in *Bilski*, the Supreme Court's next patentable subject-matter case, *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), strongly reinvigorated patent-eligibility limitations. The patentee claimed a process for administering a particular drug, determining the resulting level of the drug in the patient's blood, and setting forth ranges for decreasing, maintaining, or increasing the dosage of the drug. *Id.* at 1295. Writing for a unanimous Court, Justice Breyer held the patent invalid on the ground that the claimed invention does little more than apply a law of nature. *Id.* at 1294.

The decision revives the inventive application framework set forth in *Flook*, a test that had been supplanted by *Diehr*. In so doing, the Court based the decision, as it did in *Flook*, on a misreading of *Neilson v. Harford*, stating that "the claimed process [in *Neilson*] included not only a law of nature but also several unconventional

14. The Supreme Court stressed that "[i]n disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text." *Id*. at 612–13. The Court emphasized, however, that "nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past." *Id*. at 612.

15. It reinforced this textual focus with the inference that Congress would not have enacted the § 273 prior-user defense if it did not consider business methods patentable. *Id.* at 607. A more plausible inference is that Congress side-stepped the scope of § 101 and created the prior-user defense as a way to defuse a politically divisive question quickly. Congress placed § 273 in Part III of Title 35, which addresses enforcement rights, not the conditions under which a patent may be obtained. Furthermore, in defining the term "method" for purposes of the prior-user defense, Congress avoided altering the definitions governing patentable subject matter in § 100. *See* 35 U.S.C. § 100(a) (providing definitions of terms "[w]hen used in this title"). Instead, Congress included a definition of "method" in § 273(a), "[f]or purposes of *this* section," which deals only with the limited defense. *Id*. (emphasis added).

steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle." *See id*. at 1300. To the contrary, the *Neilson* case upheld the broad claim to an application of a law of nature notwithstanding that the application of the natural law was conventional. *See* §§ 14.3.1.2.1, 14.3.1.2.3. Beyond this misapprehension, the Court glossed over the undeniable tension between *Flook* and *Diehr*.

The Supreme Court turned to the patent eligibility of genetic sequences in the following term. The patentee in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), had obtained patents on claims to isolated deoxyribonucleic acid (DNA) sequences associated with predisposition to breast cancers and ovarian cancers and for diagnostic methods of identifying mutations in those DNA sequences. *Id.* at 2112–13. The patentee also obtained claims on complementary DNA (cDNA) compositions derived from the naturally occurring DNA molecules.[16] *Id.* Writing for a unanimous Supreme Court, Justice Thomas held that isolated DNA involving a naturally occurring genomic DNA segment was unpatentable as a natural phenomenon, but that cDNA derived from such genomic DNA was patentable due to human intervention.[17] *Id.* at 2116–19.

The Court did not reach step two of the *Mayo/Alice* test on the ground that cDNA was not naturally occurring and therefore not drawn to a judicial exception. cDNA, however, contains the same genetic information as naturally occurring mRNA and Myriad did not create or alter this information. Moreover, the act of reverse-transcribing natural mRNA into cDNA was known, routine, and conventional when the Myriad patents were filed in 1994. *See* Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-*Alice *Jurisprudence of Abstractions*, 16 N.C. J.L. & Tech. 647, 678–79 (2015).

The Supreme Court took another patent-eligibility case the following term. In *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), the Supreme Court addressed patent claims reminiscent of those at issue in *Bilski*. The patentee had obtained patents for mitigating settlement risk in financial transactions using a computer system as a third-party intermediary. The en banc Federal Circuit was

16. The PTO and the Federal Circuit considered DNA sequences derived from living organisms to be patentable so long as the patentee could establish credible utility. *See, e.g.*, *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005). The legal basis for this view traces back a century to a Judge Learned Hand decision upholding a patent on a purified form of adrenaline (isolating the extract in the form of a chemical base) as distinct from the natural substance, *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912) (reasoning that the purified form of the naturally occurring substance "became for every practical purpose a new thing commercially and therapeutically").

17. DNA sequences are composed of regions that code for proteins (exons) and regions that do not (introns). cDNA molecules are synthesized by removing introns. cDNA is most often synthesized from mature (fully spliced) messenger RNA (mRNA) using the enzyme reverse transcriptase. *See* Complementary DNA, Wikipedia <https://en.wikipedia.org/wiki/Complementary_DNA>.

deeply divided on the interpretation of *Bilski* and *Mayo*. Writing for a unanimous Supreme Court, Justice Thomas reaffirmed the inventive application approach revived in *Mayo*: "We have described step two of this analysis as a search for an "'inventive concept'"—i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."" *Id*. at 2355. Applying this framework, the Court concluded that the representative method claim does no more than implement the abstract idea of intermediated settlement on a generic computer and that the system and media claims add nothing of substance to the underlying abstract idea. *Id*. at 2355–60.[18]

14.3.1.3 Patent-Eligibility Conundrums

Notwithstanding the Supreme Court's renewed attention to patent eligibility, the *Bilski*, *Mayo*, *Myriad*, and *Alice* decisions provide relatively little guidance on how to determine whether a claim contains a patent-ineligible natural law, physical phenomenon, or abstract idea and, if so, whether there is a sufficient inventive concept or inventive application to bring the claim within § 101 eligibility. The Federal Circuit's early applications of this regime reinforce the "know it when you see it" quality of the Supreme Court's two-step test. *See, e.g.*, *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014) (emphasizing under step 1 that the claim is "rooted in the computer technology" and hence not abstract; and basing step 2 analysis on a bald assertion that the claimed invention is "not merely the routine or conventional use of the Internet" without discussion of prior art); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715 (2014) (noting that "[a]s the Court stated in *Alice*, '[a]t some level, "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas"); *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293). We acknowledge this reality, and we do not purport to state that all claims in all software-based patents will necessarily be directed to an abstract idea. Future cases may turn out differently."). Several district court decisions have grappled with these issues. *See, e.g.*, *Ameritox Ltd. v. Millennium Health, LLC*, 88 F. Supp. 3d 885 (W.D. Wisc. 2015); *Cal. Inst. of Tech. v. Hughes Commc'ns, Inc.,* 59 F. Supp. 3d 974 (C.D. Cal. 2014); *Cogent Med., Inc. v. Elsevier Inc.*, 70 F. Supp. 3d 1058 (N.D. Cal. 2014).

Among the issues that remain to be resolved are: (1) to what extent does § 101 eligibility turn on subsidiary factual determinations (e.g., whether an application of a natural law is routine or conventional) and claim construction; (2) at what stage of litigation should district courts address § 101 eligibility; and (3) what is the continuing relevance of *Diehr* and can it be reconciled with *Flook*, *Mayo*, *Myriad*, and *Alice*. What is clear is that we are at the beginning of a new patent-eligibility era in which lower courts will need to develop case-management techniques for assessing whether

18. Echoing Justice Stevens' concurrence in *Bilski*, Justice Sotomayor, joined by Justices Ginsburg and Breyer, concurred in the holding based on the view that business methods do not qualify as a "process" under § 101. *Id*. at 2360.

patent claims involving natural laws, physical phenomena, and abstract ideas can surmount the § 101 inventive application hurdle and when and on what basis that determination should be made.

14.3.1.4 Subject Matter Expressly Excluded by Statute

For the first time in U.S. history, the AIA introduced two statutory exclusions to patentable subject matter, effective September 16, 2011.

14.3.1.4.1 Tax Strategies

Strategies for "reducing, avoiding, or deferring tax liability" are deemed to be within the prior art. This does not apply to claims directed to preparing tax returns or inventions "used solely for financial management" to the extent that they are severable from any tax strategy. AIA § 14. This provision is effective September 16, 2011, and applies to applications pending or filed on or after that date.

14.3.1.4.2 Human Organisms

Claims "directed to or encompassing a human organism" are barred. This provision is effective September 16, 2011, and applies to applications pending or filed on or after that date. AIA § 33.

14.3.2 Utility (§ 101)

Section 101 requires that an invention be "useful" to be patentable. Whether an invention meets the utility requirement is decided from the perspective of a person having ordinary skill in the art. Because most inventions have a clear utility (and "inventions" of questionable utility will typically be flagged during prosecution), the utility requirement rarely arises in litigation. Utility can arise where a claimed invention does not work for its intended purpose. The two areas in which utility tends to arise in litigation with some frequency are in the fields of chemistry and biotechnology, where inventors seek to obtain patents on compositions of matter before they have conclusive evidence of their utility.

The Supreme Court provided the framework for addressing this question in *Brenner v. Manson*, 383 U.S. 519 (1966). The patentee sought protection for an adjacent homologue[19] of a steroid demonstrated to have tumor-inhibiting effects in mice. *Id.* at 520–22. The inventor had yet to establish such properties for the compound at issue and there was high unpredictability of compounds in the relevant field of chemistry. *Id.* at 532. In rejecting the patent on the basis of lack of proven utility, the Supreme Court commented that

19. A homologue is a member of a chemical series whose compounds differ structurally from each other only by a repeating unit, such as a methylene bridge—CH_2—or a peptide residue. Homologues that are "adjacent" differ from each other by just one of the repeating unit.

> the basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Id. at 534–35. The Court required patentees to establish credible, specific, and substantial utility.

Thus, chemical compounds are not rendered useful merely because they have analogues that are useful. Utility in such cases will depend on the degree of predictability within the art and structural similarity between the claimed compound and others known to have useful properties. Clinical data is not generally required to show the utility of chemical compounds.

An invention must be useful for something more than further research on the product of the invention. If an invented chemical compound, for instance, is being studied extensively as a possible cancer treatment, but no potential to treat cancer has actually been shown, the chemical does not meet the utility requirement, nor is a process to make that chemical useful. The product of the process must have utility for the process to have utility. "Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of the monopoly are not capable of precise delineation. . . . Such a patent may confer power to block whole areas of scientific development, without compensating benefit to the public." *Id.* at 534. Additionally, an invention must have proven usefulness beyond use as a chemical probe where the results of such a probe are unknown or where the results of that probe are known to lack utility. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

Note, however, that an invention does not need to be better than other technology, nor must it show commercial success to possess substantial utility. Nor do courts judge the morality of a claimed invention in assessing utility. *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728 (Fed. Cir. 2002).

14.3.3 Disclosure (§ 112)

Paragraph 1 of § 112 sets forth the disclosure requirement:

> The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as *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 same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention (emphases added).

As interpreted by the Federal Circuit, this provision comprises three distinct requirements: (1) written description—that the specification conveys to a person having ordinary skill in the art that the inventor "possessed" the claimed invention as of the time of filing the application; (2) enablement—that the specification enables a person having ordinary skill in the art to make and use the invention; and (3) best mode—that the specification reveals the best mode of which the inventor is aware of making and using the invention.

14.3.3.1 Written Description

The written description requirement serves to "prevent an applicant from later asserting that he invented that which he did not." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). The patentee must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). Having "possession of the invention" means that the patentee invented what is claimed. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

Although written description and enablement issues often rise and fall together, the written description requirement is separate and distinct from enablement. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement."). As a result, an invention may be described without being enabled, and vice versa. The written description requirement "plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described." *Id.* at 1352.

Compliance with the written description requirement is "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. The adequacy of the written description is a question of fact, and is highly dependent on the context; the nature and scope of the claims; the complexity and predictability of the relevant technology; the extent and content of the prior art; and the maturity of the science or technology. *Id.*

The patentee need not follow any specific form of disclosure in providing a written description of the invention. *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). However, a description that merely renders the invention obvious is insufficient. *See Goeddel v. Sugano*, 617 F.3d 1350, 1356 (Fed. Cir. 2010) ("The question is not whether one skilled in this field of science might have been able to produce [the claimed subject matter] by building upon the teachings of the [prior art], but rather whether that application 'convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'") (*quoting Ariad*, 598 F.3d at 1351). In some cases, the drawings alone may be adequate to satisfy the written description requirement. *Vas-Cath*, 935 F.2d at 1564.

14.3.3.1.1 Policing Continuation Practice

The Federal Circuit has applied the written description requirement to police efforts by patentees to expand the scope of their patent beyond what they had initially contemplated as their invention. Some patentees will keep continuation and/or continuation-in-part applications pending for several years in order to pursue additional claims that capture their rivals' products introduced into the marketplace during the pendency of those applications. If the subject matter of the additional claims does not have written-description support in the specification of a prior related application from which priority is accorded, the additional claims will be invalid (even if the

specification enables one skilled in the art to make and use the claimed subject matter). *See Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011) (claims added eight years after priority date lacked support in written description); *see also* § 132(a).

14.3.3.1.2 Biotechnology Patents

Beginning in the mid-1990s, the Federal Circuit required that biotechnology patents disclose specific gene sequences in the application even when the functional properties of the gene (such as the protein it codes for) were already known. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993). Some have characterized these cases as erecting a "super-enablement" standard for biotechnology inventions. *See* Janice M. Mueller, *The Evolving Application of the Written Description to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615 (1998). More recently, the Federal Circuit has eased this standard by allowing patentees to satisfy the written description requirement by placing several versions of the claimed nucleotide sequences in a public depository. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *see also Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) (noting that the requirements for "written description" evolve with the fields of invention).

Demonstrating adequate written-description support for a genus is "a problem that is particularly acute in the biological arts." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352–53 (Fed. Cir. 2010) (en banc). "[A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350 (citation omitted). "[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species." *Id.* ("The claims here recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-[K]B binding to NF-[K]B recognition sites in response to external influences. But the specification does not disclose a variety of species that accomplish the result.").

14.3.3.2 Enablement

To satisfy the enablement requirement, the specification must set forth the "manner and process of making and using [the invention], in such full, clear, concise and exact terms as 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 same." § 112, ¶ 1. The purpose of the enablement provision is to ensure that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190,

1195–96 (Fed. Cir. 1999). Enablement is determined as of the effective filing date of the patent.[20] *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003). Accordingly, after-arising technology should not be considered in the enablement inquiry. Enablement is a question of law based on underlying findings of fact. *See In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

Enablement is often a matter of degree. Courts evaluate compliance with the enablement requirement by considering whether the specification teaches those skilled in the art to make and use the invention without "undue experimentation." *In re Vaeck*, 947 F.2d at 495 (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). As the Federal Circuit has noted, "[t]hat some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" *Id.* In determining what constitutes undue experimentation, courts apply a standard of reasonableness, taking into account the nature of the invention and the state of the art. Factors to be considered in making such a determination include:

(1) The quantity of experimentation necessary,

(2) The amount of direction or guidance presented,

(3) The presence or absence of working examples,

(4) The nature of the invention,

(5) The state of the prior art,

(6) The relative skill of those in the art,

(7) The predictability or unpredictability of the art, and

(8) The breadth of the claims.

In re Wands, 858 F.2d at 737. These factors are "illustrative, not mandatory." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). It is not necessary that the patent specification teach what is well known in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

A broad claim construction can result in invalidity due to lack of enablement. When two embodiments are "distinctly different," each must be separately enabled. *See Auto. Tech. Int'l v. BMW*, 501 F.3d 1274 (Fed. Cir. 2007) (comparing two columns and five figures of specification for a mechanical sensor with one short paragraph and one figure for an electronic sensor, with uncontradicted expert testimony indicating undue experimentation was required to enable the electronic sensor).

Furthermore, courts have interpreted the "how to use" prong of § 112 as incorporating the utility requirement of § 101. *Rasmusson v. Smithkline Beecham Corp.*, 413 F.3d 1318, 1322–23 (Fed. Cir. 2005). Accordingly, an applicant's failure to disclose how to use an invention may be rejected under either § 112 for lack of enablement or § 101 for lack of utility. *Id.* at 1323.

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20. The "effective filing date" of an application is the earlier of the actual filing date or the filing date of an application from which priority is accorded.

14.3.3.3 Best Mode

For proceedings commenced on or after September 16, 2011, the AIA eliminates the failure to disclose the best mode as a basis for invalidating the patent during litigation. AIA § 15. This does not affect USPTO examination, such that the USPTO may still reject an application for failure to disclose the best mode.

The best mode requirement of § 112(a) demands that the specification set forth "the best mode contemplated by the inventor of carrying out his invention." This requirement restrains inventors from applying for patents while concealing known preferred embodiments of their inventions from the public. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002). The Federal Circuit has interpreted best mode to require "an inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out the invention" defined by the claims. *See Bayer AG v. Schein Pharm., Inc.*, 301 F.3d 1306, 1314–15 (Fed. Cir. 2002) (quoting *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962)).

Compliance with the best mode requirement is a question of fact. *Bayer*, 301 F.3d at 1312. The test for compliance involves a two-prong inquiry: (1) did the inventor possess a best mode for practicing the invention at the time of filing the application; and (2) if the inventor possessed a best mode, is his disclosure adequate to enable a person having ordinary skill in the art to practice the best mode of the invention. *See Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927–28 (Fed. Cir. 1990). While the first prong is subjective and examines the inventor's state of mind at the time of filing, the second prong is objective and focuses on the scope of the claimed invention and the level of skill in the art. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001). Best mode violations are found where there is either a "failure to disclose a preferred embodiment, or else failure to disclose a preference that materially affected making or using the invention." *Bayer*, 301 F.3d at 1316.

An inventor is typically not required to update the best mode disclosure based on findings made subsequent to the filing date, even if his or her patent application is still pending. Regarding continuation applications, the inventor need not update the best mode disclosure if the material in a continuation application is "common subject matter" with that of the original application. *See Transco v. Performance Contracting, Inc.*, 38 F.3d 551 (Fed. Cir. 1994). An inventor need only update the best mode in a continuation application if the claim feature associated with that best mode first appeared or first received adequate written description in that later filing.

14.3.3.4 Claim Definiteness

Section 112(b), formerly § 112, ¶ 2, provides that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." This requirement ensures that the patentee adequately notify the public of the scope of his or her invention. "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus v.*

Biosig Instruments, Inc., 134 S. Ct. 2120, 2123 (2014). The definiteness standard recognizes that "absolute precision is unattainable." *Id.* It "must take into account the inherent limitations of language" and allow a "modicum of uncertainty" so as to provide appropriate incentives for innovation. *Id*. at 2128. For example, terms of degree such as "substantially," "about," or "closely approximate" do not necessarily render the claim indefinite, so long as the term "provide[s] enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014). Nonetheless, the Supreme Court recognized that a patent must be precise enough to afford public notice of claim scope, otherwise there would be a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Nautilus*, 134 S. Ct. at 2128.

14.3.4 Novelty and Statutory Bars (§ 102)

With the enactment of the AIA, the regime under which patents are awarded in the U.S. changed on March 16, 2013, from a first-to-invent system (i.e., awarding a patent to the inventor having the earliest date of invention) to a first-to-file system (i.e., awarding a patent to the inventor who files his application first). AIA § 3. The change from a first-to-invent system to a first-to-file system is not retroactive. As a result, the first-to-invent regime will coexist in parallel with the first-to-file regime for at least the next couple of decades.

To establish a first-to-file system, § 102 was completely rewritten under the AIA. The amended version of § 102 will apply to any application having at least one claim with an effective filing date on or after March 16, 2013. The version of § 102 that was in effect under the first-to-invent regime prior to the enactment of the AIA will apply to applications in which all claims have effective filing dates before March 16, 2013. Accordingly, the discussion of novelty requirements under § 102 in this section will be presented separately for each regime: § 14.3.4.1 covers the first-to-invent regime, while § 14.3.4.2 covers the first-to-file regime.

14.3.4.1 The First-to-Invent Regime

For patent applications in which all claims have effective filing dates prior to March 16, 2013, the novelty requirement is governed by the pre-AIA version of § 102. Accordingly, all references to § 102 in this subsection (§ 14.3.4.1), will refer to the pre-AIA version.

Section 102 sets forth two sets of novelty requirements for a patent to issue: (1) that the inventor was the first to invent (§ 102(a), (e), (f), and (g)); and (2) that the inventor filed their application in a timely manner (§ 102 (b), (c), and (d)).

The first set of requirements, referred to as the anticipation or lack of novelty bars, seeks to ensure that a patent issues only to the first inventor. This goal is accomplished by using the applicant's date of invention as the relevant baseline for analysis. Prior art containing all elements of the claimed invention that became publicly available (or filed as part of a patent application or known, but not abandoned, suppressed, or concealed) will anticipate, and thereby defeat, the patent claim. By

contrast, the second set of requirements, known as statutory bars, and related timely filing provisions promote prompt disclosure by requiring that the patentee file an application within one year of various triggering events.

Whether a reference anticipates the applicant's invention is a question of fact. *See Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). A finding of anticipation requires the reference to contain each and every limitation of the claimed invention either expressly or inherently.[21] If even one limitation of the claimed invention is missing from the prior art reference, § 102 does not invalidate the claim—although the claim may still be vulnerable under the nonobviousness requirement. *See* § 14.3.5.

If a single reference discloses a species of a claimed genus,[22] a claim to the entire genus is anticipated. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 987 (Fed. Cir. 2000); *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). The opposite is not always true; the disclosure of a genus in a single prior art reference does not necessarily anticipate a claimed species that is a member of that genus. *See Atofina v. Great Lakes Chem. Co.*, 441 F.3d 991, 999 (Fed. Cir. 2006).

14.3.4.1.1 First to Invent—§ 102(a)

Section 102(a) precludes patentability where the "invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country," before the applicant's date of invention. Note the geographic limitations on the prior art covered by § 102(a): whereas knowledge or use must occur

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21. A finding of anticipation requires that a prior art reference enable a person having ordinary skill in the art to make or use the claimed invention. *See Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366 (Fed. Cir. 2006). This "enablement" standard is not as strict as that applied under § 112. Unlike that enablement requirement, an enabling reference under § 102 need not disclose utility, only the claimed invention's limitations. *Id.* A claim is anticipated if each element of the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). There are, however, several exceptions to the inherency doctrine. In *Tilghman v. Proctor*, 102 U.S. 707 (1880), the Supreme Court declined to invalidate a patent based on a prior art machine (a steam engine) that might have accidentally and unwittingly produced a claimed fatty acid that proved useful as a cleansing substance. Nor does mere probabilistic inherency, *see Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), nor the presence of an unrecognized de minimis quantity of a claimed substance in the prior art, *see In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964), anticipate later patent applications. *See also Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45 (1923). The Federal Circuit has, however, interpreted these exceptions and qualifications to the inherency rule narrowly. *See Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (observing that "[c]ases dealing with 'accidental, unwitting, and unappreciated' anticipation . . . do not show that inherency requires recognition").

22. A genus is a category made up of multiple species that share a common characteristic. Chemical and biotechnology inventions are often claimed using genus and species formats.

in the United States to bar patentability, a patent or printed publication from anywhere in the world can invalidate a patent. The courts have developed nuanced interpretations of § 102(a), particularly the phrases "known or used" and "printed publication."

14.3.4.1.1.1 "Known or Used"

Knowledge or use must have been available to the public to qualify as prior art under § 102. *See Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). Courts generally balance several factors—the number and credibility of observers, the intent of the discloser (i.e., whether the inventor sought to keep the information secret), the number of disclosures, and the extent to which the observers understood the invention—in determining whether a disclosure or use was "public." The evidence that knowledge or use was public is judged by the clear-and-convincing standard. In addition, "[t]he nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983). Secret knowledge or use (including classified government research and articles under submission to journals) does not qualify for purposes of § 102(a). The effective date of a knowledge or use reference is the day on which it was presented to the public. Because it is aimed at determining whether anyone preempted the patentee, § 102(a) does not treat knowledge or use by the applicants themselves as a reference; it only refers to knowledge or use "by others."

14.3.4.1.1.2 Printed Publication

A printed publication has been interpreted to mean a reference that is "sufficiently accessible to the public interested in the art." *See Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988). Accordingly, dissemination and public accessibility are the determinative factors regarding whether a reference is "published." "Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Id.* at 1569. Whether a reference qualifies as a printed publication under § 102 is a question of law based on underlying factual determinations. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1321 (Fed. Cir. 2002).

The Federal Circuit has construed sufficient accessibility broadly, finding a single thesis cataloged (by subject matter) in a German university library accessible to those interested in the art exercising reasonable diligence constituted "sufficient accessibility" to bar patentability under § 102(b). *In re Hall*, 781 F.2d 897, 900 (Fed. Cir. 1986). Even a temporarily displayed reference that was neither distributed nor indexed may be sufficiently accessible to constitute a printed publication. *See In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). Relevant factors to analyze include:

(1) the length of time the display was exhibited,

(2) the expertise of the target audience,

(3) the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and

(4) the simplicity or ease with which the material displayed could have been copied.

Id. Whether "printed publication" encompasses new technologies such as websites remains to be conclusively decided, but the Federal Circuit has noted that the phrase "has been interpreted to give effect to ongoing advances in the technologies of data storage, retrieval, and dissemination." *In re Hall*, 781 F.2d at 898.

14.3.4.1.2 Novelty—First to Invent—§ 102(g)

Section 102(g) addresses situations where two or more researchers independently discover the same invention, with the goal of granting a patent only to the first person to "invent" who does not abandon, suppress, or conceal the invention from the public. The somewhat opaque statutory provision provides that a patent shall issue unless:

> (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

The following schematic representation of § 102(g) shows how courts interpret this language:

(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that
   a. before such person's invention thereof the invention was
   b. made by such other inventor and
   c. not abandoned, suppressed, or concealed, or

(2) [in the context of an invalidity defense to patent infringement]
   a. before such person's invention thereof, the invention was
   b. made in this country by another inventor who
   c. had not abandoned, suppressed, or concealed it.

(3) In determining priority of invention [under either branch] of this subsection, there shall be considered not only
   a. the respective dates of conception and reduction to practice of the invention, but also

b. the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Subsection (1) deals with interferences, proceedings ordinarily conducted within the Patent Office (and only rarely in federal district court) when multiple inventors simultaneously claim the same invention. Subsection (2) is the more relevant provision for district courts. Defendants in infringement proceedings typically scour the field of technology to identify evidence that someone other than the patentee invented the claimed invention prior to the patentee's date of invention. Such evidence invalidates the issued patent claim if the invention was made in the United States before the patentee's date of invention and the first inventor did not abandon, suppress, or conceal the invention.

To make these principles operational, we need precise definitions of the following terms: (i) "conception," (ii) "reduction to practice," (iii) "reasonable diligence," and (iv) "abandoned, suppressed, or concealed."

14.3.4.1.2.1 Conception

A conception of the claimed invention is "the complete performance of the mental part of the inventive art," a "definite and permanent idea of the complete and operative invention." *See Townsend v. Smith*, 36 F.2d 292, 295 (C.C.P.A. 1929). It represents the idea of the invention and does not require tests, models, or prototypes. Nonetheless, it must contain all limitations of the claimed invention as it is thereafter reduced to practice. To deter fraud, the law requires corroboration of any inventor testimony regarding conception, reduction to practice, or diligence. *See Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1577–78 (Fed. Cir. 1996). Often this corroborating evidence takes the form of contemporaneous witnessed notebooks or records by someone skilled in the art. *See, e.g.*, *Hahn v. Wong*, 892 F.2d 1028, 1032–33 (Fed. Cir. 1989). Without some form of corroborating evidence, an inventor's testimony is ignored. While before the Patent Office, an inventor may file a Rule 131 affidavit (*see* 37 C.F.R. § 1.131) to establish a date of invention. The patentee must corroborate this date.

14.3.4.1.2.2 Reduction to Practice

A reduction to practice can be actual or constructive. A prototype or working embodiment of the claimed invention that is "suitable for [the invention's] intended purpose" serves as an actual reduction to practice. *See Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996). Proving that a prototype was "suitable for its intended purpose" will vary, depending on the complexity of the invention. A simple mechanical device may require only a drawing, while a chemical invention may require extensive experimental data. Patent law recognizes a patent application as a constructive reduction to practice, provided it describes and enables a person of ordinary skill in the art to practice the invention without undue experimentation.

14.3.4.1.2.3 Reasonable Diligence

"Reasonable diligence" is only at issue when the inventor was first to conceive but second to reduce to practice. In this specific context, the first-to-conceive inventor must have been reasonably diligent in working to reduce the invention to practice between the time "just prior" to the later inventor's date of conception until the first-to-conceive inventor's reduction to practice. *See, e.g.*, *Griffith v. Kanamaru*, 816 F.2d 624 (Fed. Cir. 1987). Once the first-to-conceive has reduced to practice, their further diligence is no longer relevant, although they must not abandon the invention through undue delay in filing a patent application. *See* § 14.3.4.1.2.4.

Whether an inventor was reasonably diligent is a case-by-case determination, but prior cases establish some guideposts. *Griffith* held that a delay of three months after conception before embarking on efforts to reduce the invention to practice while waiting for additional funding and the arrival of a graduate student was not reasonable. 816 F.2d at 628–29. Other factors to consider include the complexity of the invention, the need for other experiments, work on similar inventions, and the inventor's health.

14.3.4.1.2.4 Abandoned, Suppressed, or Concealed

Section 102(g) nullifies evidence of prior invention if such earlier inventor abandoned, suppressed, or concealed the invention. Whether an invention has been abandoned, suppressed, or concealed is a question of intent, but an unreasonably long delay in filing for a patent creates an inference that the inventor intended to suppress the invention. *See Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334 (Fed. Cir. 2001) (a two-and-a-half-year delay did not); *Peeler v. Miller*, 535 F.2d 647 (C.C.P.A. 1976) (a four-year delay in applying for a patent destroyed priority). While § 102(g) prevents an inventor from claiming an early priority date on an invention he or she later suppressed, it does not prevent an inventor from claiming a later date when he or she resumes work on the invention. In such cases, the earlier, suppressed work is ignored and the inventor can rely on the resumed work to establish new dates of conception and reduction to practice. *See Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985) (en banc).

By invalidating a claimed invention because of a prior invention that might not have been publicly disclosed, § 102(g) cuts against the principle that novelty is judged on the basis of public knowledge. The invention priority rule of § 102(g) seeks to balance that principle with the "first to invent" principle. The requirement that prior invention not have been "abandoned, suppressed, or concealed" provides the fulcrum for effectuating this balance.

14.3.4.1.2.5 Section 102(g)—Summary

The § 102(g) invention priority rule can be restated as follows:

(1) The first to reduce the invention to practice has priority by default.

(2) Filing a valid patent application is a constructive reduction to practice.

(3) The second person to reduce to practice can prevail only if they were the first to conceive and were diligent from a time prior to the other inventor's conception through to their own reduction to practice.

(4) Any reduction to practice that was abandoned, suppressed, or concealed cannot defeat patentability by another.

14.3.4.1.3 Novelty—"Secret Prior Art"—§ 102(e)

The possibility of secret prior art invalidating a patent also arises under § 102(e) whereby confidential patent applications within the Patent Office can be used to invalidate later filings.[23] If a patent application discloses but does not claim a later filed claimed invention and is later published, the application constitutes § 102(e)(1) prior art as of its filing date.[24] If the application later issues as a patent, such application constitutes § 102(e)(2) prior art as of its filing date. The policy rationale behind § 102(e) is that if another's earlier filed patent application describes the applicant's claimed invention, the applicant was not the first inventor of that subject matter. The fact that the knowledge was not publicly known is outweighed by the Patent Office's knowledge of the invention and its unique role in making patent determinations.

14.3.4.1.4 Novelty—Derivation—§ 102(f)

Section 102(f) precludes an applicant from obtaining a patent on inventions that he did not invent. This section is referred to as the "derivation" provision, meaning that an applicant may not patent subject matter derived from another. *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997). Section 102(f) is not limited to public knowledge but may also concern private communications between the applicant and another. *Id.* at 1401–02. Proof that another derived the invention requires showing both prior conception of the invention and disclosure of that conception to the applicant. *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997). Because there are no geographic limitations in § 102(f), prior conception and disclosure to the applicant can occur anywhere in the world.

14.3.4.1.5 Statutory Bars—Timely Filing—§ 102(b)

Section 102(b) arises frequently in patent litigation. The provision encourages timely filing of patent applications to expand the public's knowledge more quickly and prevent inventors from extending the effective life of their patent through delay in filing for protection. Section 102(b) states that a person shall be entitled to a pa-

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23. A patent is considered "secret prior art" when its contents cannot become known until the date of publication or issuance, even though its effective date is the filing date. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 982 n.3 (Fed. Cir. 1989).

24. If the pending application *claims* (and not merely discloses) the same invention, then it constitutes § 102(g) prior art and will provoke an interference if such conflict is recognized by an examiner.

tent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . . ."

The section recognizes three types of prior art: "printed publication," "public use," and offers for sale. Printed publications can come from anywhere in the world. The second and third categories of reference, public use or offers for sale, only invalidate the claimed invention if they occur in the U.S. The second salient feature of this provision is the critical date: one year prior to the date of the application. Any reference before the critical date—whether originating from the inventor or a third party—invalidates the patent claims that "read on" the reference. Each of these concepts has generated substantial jurisprudence. "Printed publication" and "public use" were discussed above with respect to § 102(a), *see* § 14.3.4.1.1, and their meanings are the same under § 102(b). "On sale" is unique to § 102(b).

14.3.4.1.5.1 Experimental Use

To accommodate circumstances in which inventors need to experiment in publicly accessible areas in making certain types of inventions, courts developed an "experimental use" exception to § 102(b)'s "public use" bar. *See City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877).[25] The determination of whether an otherwise public use is experimental depends on balancing the following circumstances: "the number of prototypes and duration of testing, whether records or progress reports were made concerning the testing, the existence of a secrecy agreement between the patentee and the party performing the testing, whether the patentee received compensation for the use of the invention, and the extent of control the inventor maintained over the testing." *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120–21 (Fed. Cir. 1996). Of these factors, the Federal Circuit has emphasized the degree of control the inventor maintained because if it is absent, the inventor "is not experimenting." *Id.* at 1120. Any experimentation must be in regard to establishing that the claimed invention works for its intended purpose, and not, for example, for refining a product to improve marketability. *See In re Smith*, 714 F.2d 1127 (Fed. Cir. 1983). Once reduction to practice is achieved, the experimental use exception ends and § 102(b)'s one-year grace period begins to run.

14.3.4.1.5.2 On Sale Bar

Section 102(b)'s "on-sale bar" can be triggered by behavior that also runs afoul of the "public use" bar, in which case both provisions invalidate the claim. The more difficult and contentious cases involve offers or sales that do not occur in public. Such information is typically revealed through pretrial discovery.

The on-sale bar can be strict in its application. A single offer to sell technology can invalidate the patent, and it can be made by anyone, even a third party unknown

25. This type of "experimental use" applicable to § 102(b) is distinct from the "experimental use" defense to patent infringement. *See* § 14.4.2.2.2.

to the patentee. *See, e.g.*, *Abbott Labs. v. Geneva Pharm.*, 182 F.3d 1315 (Fed. Cir. 1999). The invention does not even have to be built. The Supreme Court interpreted the on-sale bar to require only that the invention be "ready for patenting" when subject to a commercial offer for sale. *Pfaff v. Wells Elecs.*, 525 U.S. 55 (1998). An invention is "ready for patenting" if it has been actually reduced to practice by being physically constructed or if there are "drawings or other descriptions of the invention sufficiently detailed to enable a person skilled in the art to practice the invention." *Id.* at 67.

Some additional nuances in the jurisprudence favor the patentee. First, the statute states that the "invention" must be placed on sale. The courts have interpreted this to mean that the offer for sale must involve an embodiment of the invention. Licensing activity does not trigger the on-sale bar so long as there is no embodiment of the invention at issue. *See In re Kollar*, 286 F.3d 1326 (Fed. Cir. 2002). For process claims, the process has to be carried out or performed to constitute a sale. *Kollar*, 286 F.3d at 1332–33 ("[B]ecause the . . . Agreement did not involve the sale of a product of the claimed process, but rather provided . . . a license to practice the claimed process and 'information defining an embodiment' of that process, that agreement did not trigger the on-sale bar.") (footnote omitted). Second, the invention must be subject to a genuine commercial offer for sale. A patentee does not violate the on-sale bar by distributing advertisements and data sheets to prospective buyers while fielding requests for samples from salesmen in the field because this behavior does not rise to the level of an "offer." *See, e.g.*, *Linear Tech. Corp. v. Micrel Inc.*, 275 F.3d 1040 (Fed. Cir. 2001).[26] The Federal Circuit has incorporated the Uniform Commercial Code and "traditional contract law principles" to determine whether an offer is genuine for purposes of applying the on-sale bar. Third, an offer to sell must be between unrelated parties. Hence, offers between a parent and a subsidiary do not trigger the bar. *See Ferag AG v. Quipp Inc.*, 45 F.3d 1562 (Fed. Cir. 1995).

The on-sale bar is subject to a territorial restriction. Only if the claimed invention is "on sale in this country" is the patent claim invalid. Determining whether an invention is "on sale in this country" can be difficult in the rapidly globalizing economy. For example, a foreign supplier's response that it was ready to fulfill a purchase order request of a patented invention before the critical date triggers the on-sale bar. *Hamilton Beach Brands v. Sunbeam Prods., Inc.*, 726 F.3d 1370 (Fed. Cir. 2013). As with deciding whether an offer was made, courts look to "traditional contract law principles" to determine the locus of an offer.

26. But note that a detailed advertisement can constitute a printed publication if it enables the invention.

14.3.4.1.6 Statutory Bars—Abandonment—§ 102(c)

Under § 102(c), an applicant is entitled to a patent unless he or she "has abandoned the invention."[27] This section is a loss-of-right provision. *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997). It refers to an inventor's express dedication of his or her invention to the public through either deliberate surrender or conduct showing an intent not to pursue patent protection. Abandonment under § 102(c) occurs only based on actions by the inventor after he or she has made the invention but before he or she has filed the patent application. *See id.* at 1404.

14.3.4.1.7 Statutory Bars—International Filing—§ 102(d)

Under § 102(d), a patent may not issue where (1) the inventor filed a foreign patent application more than twelve months prior to filing the U.S. patent application, and (2) a patent issued from that foreign application prior to the U.S. filing date.[28] This provision encourages applicants to file their U.S. applications promptly after filing foreign applications. *See In re Kathawala*, 9 F.3d 942, 946 (Fed. Cir. 1993). Like § 102(c), violation of this provision results in the loss of right. *See OddzOn Prods, Inc.*, 122 F.3d at 1402. Owing to the Patent Cooperation Treaty (PCT), which facilitates and coordinates international patent prosecutions, patent invalidations under § 102(d) rarely occur today.

Validity of the foreign claims is immaterial to the § 102(d) determination. What matters to the inquiry is that the foreign patent issued "with claims directed to the same invention as the U.S. application." *In re Kathawala*, 9 F.3d at 945.

14.3.4.2 The First-to-File Regime

For patent applications having at least one claim with an effective filing date on or after March 16, 2013, the novelty requirement is governed by the amendments to Title 35 introduced in the AIA. *See* AIA § 3. Accordingly, all references to § 102 and other statutory provisions in Title 35 in § 14.3.4.2 will refer to the AIA-amended version, unless specified otherwise.

14.3.4.2.1 Novelty and Prior Art—§ 102(a)

Section 102(a), as amended by the AIA, provides as follows:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

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27. Abandonment under § 102(c) and that under § 102(g) are separate concepts. While § 102(c) relates to abandonment of the right to receive a patent, § 102(g) refers to abandonment of the invention itself. *See* § 14.3.4.1.2.4.

28. Foreign patents of others can constitute prior art references under § 102(a) and (b).

> (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

§ 102(a) (as amended by AIA § 3). Section 102(a) establishes novelty and awards priority based on the "effective filing date" of the claimed invention, which is "the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority. . . ." § 100(i)(1)(B) (as amended by AIA § 3). In essence, the "effective filing date" (also called the "priority date") for a claimed invention is the filing date of the earliest application in a family of related applications that provides support under § 112 for that claimed invention. If a U.S. application claims priority from a foreign application, the "effective filing date" may be the date on which that foreign application was initially filed.

Compared to the first-to-invent regime, the first-to-file version of § 102(a) broadens the scope of prior art and novelty-defeating events in several key respects: (1) it eliminates the ability to "swear behind" a prior art reference based on the date of invention; (2) it provides a novelty-defeating catch-all category ("or otherwise available to the public"); (3) novelty-defeating prior public use or "on-sale" events are not limited to activities in the U.S.; and (4) because the effective filing date includes the foreign priority date, U.S. patents and published applications claiming priority to a foreign application are considered prior art as of their foreign priority date (rather than their later U.S. filing date under the pre-AIA version of § 102). *See also* § 102(d) (as amended by AIA § 3). Nonetheless, the USPTO has interpreted the "or otherwise available to the public" language as limiting the other art referenced in 102(a)(1) to be only art that is "available to the public." Therefore, "secret sales," which were considered prior art prior to the AIA, are no longer considered prior art by the PTO.

14.3.4.2.2 Novelty—Grace Period and Exceptions to Prior Art—§ 102(b)

Section 102(b), as amended by the AIA, provides for a grace period as well as certain exceptions to prior art, as follows:

> (b) EXCEPTIONS.—
>
> (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
>
> (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

> (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—
>
> (A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
>
> (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

§ 102(b) (as amended by AIA § 3). Section 102(b)(1) gives priority to the first inventor to "disclose" the invention, whether directly or indirectly (e.g., by another who derived the invention from the applicant), if the inventor files an application within a year of the disclosure. If the U.S. application claims priority from a foreign application, the one-year grace period is measured from the foreign priority date. Notably, the statute does not define what qualifies as a "disclosure" for purposes of the grace period, thereby leaving it open to development through case law.

Section 102(b)(2) disqualifies certain patents and patent applications as prior art if the disclosed subject matter was derived from or previously "publicly disclosed" by the inventor (or a joint inventor), or shares a common owner with the claimed invention.

14.3.4.2.3 Novelty—Joint Research—§ 102(c)

Section § 102(c) provides that subject matter developed under a joint research agreement is deemed "commonly owned" for the purposes of the "common ownership" exception to prior art under § 102(b)(2)(C):

> (c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.— Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—
>
> (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
>
> (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
>
> (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

§ 102(c) (as amended by AIA § 3). The § 102(c) "joint research" exception to prior art applies if: (1) the joint research agreement was in effect before the effective filing date; (2) the invention resulted from activities within the scope of the joint research agreement; and (3) the patent application discloses the parties to the joint research

agreement. Notably, the § 102(c) "joint research" exception introduced under the AIA is analogous to the pre-AIA version of § 103(c) applicable to obviousness issues.

14.3.4.2.4 Effective Date of Patent Prior Art—§ 102(d)

Section 102(d) defines when patents and published applications may qualify as prior art:

> (d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—
>
> (1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
>
> (2) if the patent or application for patent is entitled to claim a right of priority under Section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under Section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

§ 102(d) (as amended by AIA § 3). Compared to the first-to-invent regime, the universe of patent prior art in the first-to-file regime is broader in a couple of major respects: (1) an applicant cannot "swear behind" a prior art patent or published application based on a prior invention date; and (2) U.S. patents and published applications claiming priority to a foreign application may qualify as prior art as of their foreign priority date (rather than being restricted to the U.S. filing date under the pre-AIA version of § 102).

14.3.4.2.5 Derivation Proceedings

Under the first-to-file regime, interference proceedings are replaced by "derivation proceedings" in which an inventor may challenge an earlier-filed third-party application or patent claiming subject matter that was derived from the inventor's own work. *See* AIA § 3 (amending §§ 135 and 291).

Derivation proceedings have timing restrictions. In the USPTO, a derivation proceeding must be requested within one year of the publication of a claim directed to the allegedly derived invention. *See* § 135. If a derivation proceeding is pursued as a civil action under § 146, the suit must be filed within a year of the issuance of the patent containing a claim to the allegedly derived invention. *See* § 291.

14.3.5 Nonobviousness—§ 103

14.3.5.1 Historical Development

Some measure of inventiveness has been required to receive a patent since the seminal case of *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850), where the Supreme Court held that the patent law's concept of "invention" required going beyond the

skill or ingenuity of an "ordinary mechanic acquainted with the business." *Id.* at 267. Over the following century, the "invention" requirement grew more stringent, leading to the controversial "flash of creative genius" test, *see Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941), and the "unusual or surprising consequences" test, *see Great A & P Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950). This high bar to patentability was ultimately replaced with a less stringent nonobviousness standard in the Patent Act of 1952.

14.3.5.2 Nonobviousness Standard

As explained in the previous section on novelty and statutory bars under § 102, *see* § 14.3.4, the regime under which patents are granted in the U.S. changed on March 16, 2013, from a first-to-invent system to a first-to-file system. AIA § 3. Under the AIA, § 103 was rewritten to conform to the first-to-file framework set forth in the amended version of § 102. The primary substantive difference in the two filing regimes for analyzing obviousness under § 103 is the relevant time at which obviousness is evaluated: Under the first-to-invent regime, obviousness is evaluated at the time of invention, whereas under the first-to-file regime, it is evaluated as of the effective filing date.

14.3.5.2.1 Nonobviousness Under the First-to-Invent Regime

The pre-AIA version of § 103(a) states that:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Id. The text provides some structure for the nonobviousness inquiry. Under the first-to-invent regime, obviousness must be determined at the time of invention from the perspective of a person having ordinary skill in the art. As suggested by the last sentence, the manner of invention is irrelevant. An invention is eligible for patent protection whether accidental or nearly instantaneous so long as it meets the test set forth in the first sentence of § 103(a).

The Supreme Court provided an analytical framework for nonobviousness in *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966), which required courts to make findings regarding the "scope and content of prior art," the "differences between the prior art and claims at issue," and the "level of ordinary skill in the pertinent art." *Id.* at 17. The Court also brought consideration of secondary factors—what might be deemed circumstantial evidence of inventiveness (such as long-felt need, failure of others, praise for the invention, and unexpected results)—into the determination of whether an invention was obvious at the time it was made. *Id.* at 17–18. In 2007, the Supreme Court reaffirmed the *Graham* framework and emphasized that the inquiry under § 103 is flexible, "broad" and open-ended. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

14.3.5.2.2 Nonobviousness Under the First-to-File Regime

Section 103, as amended under the AIA, states:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, 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 to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

§ 103 (as amended by AIA § 3). Compared to the pre-AIA version of § 103 that is applicable under the first-to-invent regime, the amended version of § 103 that is applicable to the first-to-file regime is a single paragraph that focuses the nonobviousness inquiry as of the effective filing date.

Much of the case law developed under the first-to-invent regime for evaluating obviousness is generally applicable under the first-to-file regime as well, by substituting the relevant time for evaluating obviousness to be the effective filing date rather than the date of invention.

14.3.5.3 Applying § 103

Courts generally assess nonobviousness by first ascertaining the level of ordinary skill in the art, then analyzing the pertinent prior art, and finally assessing the difference between the baseline of prior art and the claimed invention from the standpoint of a person having ordinary skill in the art as of the relevant time. Under the first-to-invent regime, obviousness is evaluated at the time the invention was made, whereas under the first-to-file regime, obviousness is evaluated as of the effective filing date.

14.3.5.3.1 Determining the Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, courts look to the inventor's educational level, the nature of the field's typical problems, the skill required to grapple with the prior solutions to the field's problems, the pace of innovation in the field, the sophistication of technology, and the educational level of people working in the field. *See Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983). In practice, the alleged infringer will argue that the level of ordinary skill is very high, so that the invention appears obvious to the person of ordinary skill, whereas the patentee will often suggest a very low level of ordinary skill, so that the invention instead appears nonobvious.

Some opinions make explicit determinations of the person of ordinary skill, as did the district court in *KSR* ("an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles," *Teleflex Inc. v. KSR Int'l*, 298 F. Supp. 2d 581, 590 (E.D. Mich. 2003)), although it is not uncommon for courts to leave this determination somewhat vague. For example, in *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693 (Fed. Cir. 1983), the parties conceded that each side's experts were persons

of ordinary skill in the art. Moreover, "a specific finding on the level of skill in the art is not . . . required where the prior art itself reflects an appropriate level and a need for testimony is not shown." *Litton Indus. Prods., Inc. v. Solid State Sys., Corp.*, 755 F.2d 158, 163–64 (Fed. Cir. 1985). Table 14.3 provides illustrative findings of the person of ordinary skill in the context of particular fields of invention:

Table 14.3
Illustrative Findings of a Person Having Ordinary Skill

Case	Field of Invention	Person Having Ordinary Skill
Micro Motion, Inc. v. Exac Corp., 741 F. Supp. 1426 (N.D. Cal. 1990)	devices that measure the flow rate of fluids, for example, in a pipeline	"A design engineer with a college degree in mechanical engineering or the equivalent, and who had several years of experience in the design and development of flow measurement and control instruments."
Sud-Chemie, Inc. v. CSP Techs., Inc., 2006 U.S. Dist. LEXIS 54873, 2006 WL 2246404 (S.D. Ind. Aug. 4, 2006)	polymer blends with specific structural qualities	"A Ph.D.-level scientist [in the field of polymer chemistry]."
Imperial Chem. Indus., PLC v. Danbury Pharmacal, Inc., 777 F. Supp. 330 (D. Del. 1991)	method for treating patients suffering from hypertension	"A person of ordinary skill in the art would be an individual with a Ph.D. degree in organic chemistry, with an emphasis in medicinal chemistry and experience with the techniques of drug development in general and specific experience with the development of beta-blockers."
Eli Lilly & Co. v. Teva Pharm. USA, Inc., 2004 U.S. Dist. LEXIS 14724, 2004 WL 1724632 (July 29, 2004)	method of treating patients suffering from premenstrual syndrome	"A hypothetical medical doctor (an OB/GYN, a family practice physician, or a psychiatrist) who: (1) regularly sees and treats patients suffering from PMS, and (2) is familiar with the relevant prior art."

Case	Field of Invention	Person Having Ordinary Skill
Rosen Enter. Sys., LP v. Icon Enters., Inc., 359 F. Supp. 2d 902 (C.D. Cal. 2005)	flip-down screens for cars	"The level of ordinary skill here is a technical knowledge of the design and installation of overhead flip-down display units for automobiles."
Windsurfing Int'l, Inc. v. Fred Ostermann GmbH, 613 F. Supp. 913 (S.D.N.Y. 1985), *aff'd in relevant part, Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986)	sails	"The hypothetical person of ordinary skill in the art of sailboat design in 1967 had either a combination of several years sailing experience and several years of practical experience designing and/or constructing sailboats or, alternatively, he possessed a college degree in design or engineering as well as a general knowledge of sailing."

14.3.5.3.2 Scope and Content of the Prior Art

Because § 103 does not expressly define what constitutes "prior art," courts have looked to § 102 for the classes of references that can qualify as "prior art" references for the § 103 inquiry. In most cases, a reference that could be prior art under § 102 can qualify as a reference for § 103 purposes. *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997). However, the range of prior art available for an obviousness analysis will be slightly different depending on whether the claim at issue was filed under the first-to-invent regime or the first-to-file regime.

Under the first-to-invent regime, it is worth noting that, notwithstanding the test of § 103, which measures obviousness as of the time of invention, § 102(b) references can also apply in making § 103 obviousness determinations, even though they are effective as of one year prior to the application filing date (and hence may postdate the time of invention). *See OddzOn Products*, 122 F.3d at 1402; *In re Foster*, 343 F.2d 980 (C.C.P.A. 1965); 2 Donald S. Chisum, Chisum on Patents § 5.03[2][b].

Both the first-to-invent and first-to-file regimes provide "joint research" exceptions to prior art. To prevent companies from having one group of employees' nonpublic research used as prior art against other employees' inventions, § 103(c), under the first-to-invent regime, excludes consideration of §§ 102(e), (f), and/or (g) references if it comes from the inventor, his or her firm, or someone with an assignment obligation to the patenting enterprise. The analogous provision under the first-to-file regime is provided under § 102(c).

A § 103 reference must also come from an "analogous art" to satisfy the presumption that a person having ordinary skill in the art would be familiar with it. Courts base this determination upon whether the reference is "from the same field of endeavor, regardless of the problem addressed," and if not, whether the reference is

"reasonably pertinent to the particular problem with which the inventor is involved." *See In re Clay*, 966 F.2d 656 (Fed. Cir. 1992); *see also In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994). A prior art reference qualifies as analogous art if it satisfies either inquiry. Table 14.4 illustrates this mode of analysis:

Table 14.4
Assessing Whether Prior Art Is Analogous

Case	Field of Invention	Reference	Same Field?	Same Problem?
AstraZeneca Pharms., LP v. Mayne Pharma (USA) Inc., 2005 U.S. Dist. LEXIS 26196, 2005 WL 2864666 (S.D.N.Y. Nov. 2, 2005)	Pharmaceutical formulation	Patent related to sludge formation in fuel	No	No
Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 2005 U.S. Dist. LEXIS 11621, 2005 WL 1398528 (D. Mass. June 10, 2005)	Sealing rings for large magnetic devices	Sealing rings for small magnetic devices	Yes	Yes

14.3.5.3.3 Differences Between Invention and Prior Art

Once the level of ordinary skill in the art and the applicable prior art have been identified, the trier of fact assesses the differences between the claimed invention and the prior art.

14.3.5.3.4 Secondary Considerations

The Supreme Court in *Graham* suggested a number of secondary considerations to guide the obviousness inquiry. As the Court reaffirmed in *KSR*, the list of secondary considerations is not exclusive; a court may look to "any secondary considerations that would prove instructive" as to whether an invention was obvious. *KSR*, 550 U.S. at 415. The Federal Circuit requires that there be a nexus between the proffered secondary consideration and the claimed invention. The Federal Circuit requires district courts to make findings regarding secondary considerations. *See Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.*, 807 F.2d 955 (Fed. Cir. 1986). Below are the most widely cited secondary considerations.

14.3.5.3.4.1 Long-Felt Need and Failure by Others

The *Graham* Court suggested that a claimed invention that solves a "long-felt need" within an industry would likely be nonobvious. Evidence that many others within the field have tried and failed to make the claimed invention suggests that the claimed invention was not obvious to a person of ordinary skill in the art. For example, in *Texas Instruments, Inc. v. United States International Trade Commission*, 988 F.2d 1165, 1178 (Fed. Cir. 1993), the evidence showed that the semiconductor industry had attempted but failed to package semiconductors in plastic for over six years prior to the invention. The patentee's invention solved the problem of damaged components by insulating semiconductors in plastic. *Id.*

14.3.5.3.4.2 Awards and Praise

Awards or praise for an invention may suggest that it represents a significant advance. For example, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), the Federal Circuit noted the industry's characterization of Gore-Tex as "magical" and "a remarkable new material," along with other secondary indicia (commercial success, long-felt need), to find the invention nonobvious. When analyzing patent claims that cover a component of a larger system, the only awards or praise that are relevant for § 103 are those specifically relating to the patented component, rather than to the system as a whole.

14.3.5.3.4.3 Skepticism, "Teaching Away," and Unexpected Results

If the literature in the relevant field suggested prior to the relevant time for evaluating obviousness that the claimed solution was impossible, that suggests that the invention was nonobvious. *See, e.g.*, *United States v. Adams*, 383 U.S. 39, 51–52 (1966). In *Adams*, the prior art discouraged experimenting with the combination that led to the patented invention as risky and unlikely to be successful.[29] *Id.* The Court relied on this background evidence to find that a person having ordinary skill in the art would have found it nonobvious. *Id.* The record in *Adams* also showed that many experts disbelieved Adams's results, only to later apply for patents on improvements on Adams's invention. *Id.* at 52.

Unexpected results that contradict long-held industry assumptions or beliefs can also demonstrate that the claimed invention was nonobvious at the relevant time. In *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350 (Fed. Cir. 1984), the patentee demonstrated that a thin coating of chemicals could produce stronger safety glass than a thick coating, which was contrary to accepted beliefs in the industry at the time.

29. This discouragement is referred to as "teaching away" from the invention.

14.3.5.3.4.4 Licensing Activity

Extensive licensing may suggest that industry actors consider the patented invention nonobvious. *See, e.g.*, *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 53–56 (1923). However, patent holders routinely cross-license portfolios of patents without considering individual claims. Accordingly, a court should examine whether a nexus exists between the decision to license and the claimed invention.

14.3.5.3.4.5 Copying

Copying by others may give rise to an inference that an invention is nonobvious. *See, e.g.*, *Diamond Rubber Co. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 440–41 (1911). Courts should exercise caution in evaluating this factor because patentees routinely accuse alleged infringers of "copying" their invention. In addition, some alleged infringers may copy the invention believing that the patent is invalid; accordingly, the mere fact of copying should not defeat alternative arguments of obviousness.

14.3.5.3.4.6 Commercial Success

If a claimed invention is successful in the marketplace because of its patented features, the invention may be nonobvious. *See, e.g.*, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). When looking at commercial success as an indication of nonobviousness, courts should carefully assess the nexus between the success and the patent claim. This is particularly important when the patented technology is but one component in a larger system. Consider a patented air bag that an automaker installs on all of its new vehicles. The automaker cannot point to its overall car sales as evidence of nonobviousness unless it can show that the improved airbag is a key factor in car sales. It is likely, however, that consumers are basing their purchasing decisions on a wide variety of factors, such as engine performance, fuel economy, and body design. If, on the other hand, the automaker can demonstrate that safety-conscious buyers bought its cars in large numbers because of the new airbag technology, that evidence would favor a finding that the claimed invention is nonobvious.

14.3.5.3.5 The Ultimate Conclusion and Combining References

With these factual predicates—the level of ordinary skill in the art, the analogous prior art, the differences between the invention and the prior art, and the pertinent secondary considerations—the court then determines as a question of law whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the art as of the relevant time. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007); *Graham*, 383 U.S. at 17–18; *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007); *see generally* § 7.3.4.4. The person having ordinary skill in the art is presumed to know all analogous prior art.

Many cases raising nonobviousness will involve a claimed invention that is a combination of preexisting elements or components. Where all of the limitations were known in the prior art, the question becomes whether it was obvious for a person having ordinary skill in the art to combine those features to address a known problem. Prior to *KSR*, the Federal Circuit applied a doctrine referred to as the "teaching, suggestion, or motivation" or "TSM" test which required evidence of an explicit cross-reference linking the preexisting restrictions from disparate references and that a person having ordinary skill in the art would not have to engage in undue experimentation to create the combination. The *KSR* Court rejected this "rigid formulation." 550 U.S. at 415. Instead, the Court suggested that in many fields "market demand" may compel an inventor to combine prior art elements. *Id*. at 419. The *KSR* Court stressed that nonobviousness cannot be reduced to a single inquiry. Instead, the inquiry is expansive, flexible, and functional. For example, the Court suggested that, "[o]ne of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the [relevant time] a known problem for which there was an obvious solution encompassed by the patent's claims." *Id.* at 1742.

Since *KSR*, the Federal Circuit has held that merely replacing known mechanical components of an invention with electronic parts is likely to be obvious. *See Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007). Often, advances in collateral technologies—such as advances in digital technology or the development of the Internet—or the emergence of market demand (as occurred in *KSR*) will enable persons having ordinary skill in the art to apply known technologies or skills in new but obvious ways that have tremendous value. Section 103 bars patents on such techniques.

The flexible, broad, and open-ended nonobviousness inquiry adopted by the Federal Circuit in its post-*KSR* decisions has been synthesized by the USPTO in a set of examination guidelines for its patent examiners. Examination Guidelines Update: Developments in the Obviousness Inquiry after *KSR v. Teleflex*, 75 Fed. Reg. 53643 (2010). Table 14.5–14.8 summarize those guidelines:

Table 14.5
Combining Prior Art Elements

Case	Teaching Point
In re Omeprazole Patent Litig., 536 F.3d 1361 (Fed. Cir. 2008)	Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.
Crocs, Inc. v. U.S. Int'l Trade Comm'n., 598 F.3d 1294 (Fed. Cir. 2010)	A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.

Case	Teaching Point
Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356 (Fed. Cir. 2008)	A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.
Ecolab, Inc. v. FMC Corp., 569 F.3d 1335 (Fed. Cir. 2009)	A combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.
Wyers v. Master Lock Co., 616 F.3d 1231 (Fed. Cir. 2010)	The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.
DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314 (Fed. Cir. 2009)	Predictability as discussed in *KSR* encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

Table 14.6
Substituting One Known Element for Another

Case	Teaching Point
In re ICON Health & Fitness, Inc., 496 F.3d 1374 (Fed. Cir. 2007)	When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (i.e., is analogous), it is necessary to consider the problem to be solved.
Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337 (Fed. Cir. 2008)	Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose.
Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008)	Because Internet and web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.

Case	Teaching Point
Aventis Pharma Deutschland v. Lupin, Ltd., 499 F.3d 1293 (Fed. Cir. 2007)	A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.
Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008)	A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.
Procter & Gamble Co. v. Teva Pharm. USA, Inc., 566 F.3d 989 (Fed. Cir. 2009)	It is not necessary to select a single compound as a "lead compound" in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.
Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999 (Fed. Cir. 2009)	Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.

Table 14.7
The Obvious-to-Try Rationale[30]

Case	Teaching Point
In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009)	A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. *KSR* applies to all technologies, rather than just the "predictable" arts.
Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)	A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.
Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc., 520 F.3d 1358 (Fed. Cir. 2008)	Where the claimed anticonvulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new antidiabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.
Bayer Schering Pharma A.G. v. Barr Labs., Inc., 575 F.3d 1341 (Fed. Cir. 2009)	A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.
Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075 (Fed. Cir. 2008)	A claimed, isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.

30. Prior to *KSR*, the Federal Circuit had consistently ruled that "obvious-to-try" was not a legitimate test of patentability. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). *KSR* held that the Federal Circuit had been too rigid for precluding "obvious-to-try" considerations. *KSR*, 550 U.S. at 402.

Case	Teaching Point
Rolls-Royce, PLC v. United Techs. Corp., 603 F.3d 1325 (Fed. Cir. 2010)	An obvious-to-try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious-to-try rationale cannot be used to support a conclusion of obviousness.
Perfect Web Techs., Inc. v. InfoUSA, Inc., 587 F.3d 1324 (Fed. Cir. 2009)	Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious-to-try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.

Table 14.8
Consideration of Evidence

Case	Teaching Point
PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342 (Fed. Cir. 2007)	Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.
In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007)	All evidence, including evidence rebutting a prima facie case of obviousness, must be considered when properly presented.
Hearing Components, Inc. v. Shure Inc., 600 F.3d 1357 (Fed. Cir. 2010)	Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.
Asyst Techs., Inc. v. Emtrak, Inc., 544 F.3d 1310 (Fed. Cir. 2008)	Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a prima facie case of obviousness if the prima facie case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.

14.3.6 Inventorship

The Patent Act requires that the patent application list all of the inventors. This section discusses who qualifies as an "inventor," the legal effect of that determination, and how the question arises in litigation.

14.3.6.1 Inventive Entities

Section 116 requires each inventor to apply jointly for a patent on their invention. The statute does not define inventor. Instead, it suggests that multiple people can be joint inventors even if (1) they did not work together in the same space or at the same time, (2) they made unequal contributions to the invention, or (3) they did not contribute to all of the claims of the patent.

For a person to be a joint inventor, they have to contribute to the "conception" of the invention. Testing the invention to make sure it works is not sufficient. *See Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994). Although § 116 does not require that all coinventors work at the same time or in the same place, there must be some collaborative effort. *See Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co.*, 973 F.2d 911 (Fed. Cir. 1992).

An "inventive entity" is the group of inventors behind any given patent. An inventive entity can be a lone inventor A, or it can be a group, for example, A, B, and C. The inventive entity in these two situations is different, despite sharing an inventor. The significance of this difference requires understanding the various statutory rules governing patent validity. Some rules, like § 102(a)'s novelty bar and § 103's nonobviousness requirement, only invalidate a claim based on prior art attributable to other inventive entities. This seems logical when the other inventive entity is a competitor or stranger, but note that the solo work of inventive entity A is distinct from the work of inventive entity A, B, and C. For an application of this principle, *see In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988).

14.3.6.2 Default Rights of Owners

The question of inventorship often arises because inventors receive a potentially powerful and valuable set of rights in their patents. Each inventor is a co-owner of the patent and may freely grant nonexclusive licenses. Alleged infringers have exploited this technicality by searching for an unlisted coinventor of any of the claims of the patent and obtaining a license from them. *See, e.g.*, *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998). Additionally, each joint inventor may freely practice the invention without accounting to the other inventors. *See* § 262.

In general, companies avoid "rogue" inventor problems by obtaining assignment agreements from everyone they employ. The construction and validity of these assignment agreements depend on state contract law, introducing a choice-of-law wrinkle to patent litigation. Some research institutions are more lax in binding researchers and may not have comprehensive assignment agreements. Such contexts, like a university research setting or a collaborative industry meeting, can give rise to knotty inventorship disputes.

14.3.6.3 Correction of Inventorship

The district court can order corrections to address errors in inventorship. § 256. The Federal Circuit has interpreted this provision broadly, allowing for wide-ranging correction of inventorship. *See Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551 (Fed. Cir. 1997). The Federal Circuit was careful to note, however, that any

"mistakes" in inventorship designed to avoid the problems created by misaligned inventive entities discussed above could support a finding of "inequitable conduct" and render the patent unenforceable.

14.4 Enforcement: Infringement, Defenses, and Remedies

The second major aspect of most patent litigations relates to the determination of whether infringement has occurred or will occur. Unlike the validity determination—in which the alleged infringer bears the burden of proof (as a result of the presumption of validity)—the patentee bears the burden of proving infringement by a preponderance of the evidence. The alleged infringer then has the opportunity to assert a broad range of legal and equitable defenses. The final aspect of most patent litigations concerns remedies—injunctive relief, damages (including the possibility of enhanced damages), and attorneys' fees.

14.4.1 Infringement

14.4.1.1 Section 271

Section 271 defines patent liability to include both direct and indirect infringement. Direct infringement exists where an individual violates one of the exclusive rights granted to the patentee under § 271(a). Indirect infringement occurs where a person induces infringement under § 271(b) or contributes to infringement under § 271(c). In either case, the patent holder bears the burden of proving infringement by a preponderance of the evidence. *See Centricut, LLC v. Esab Grp., Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004).

14.4.1.2 Direct Infringement

A person is liable for direct infringement if he "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore." § 271(a). An accused infringer's intent is immaterial, as patent infringement is a strict liability offense.

14.4.1.3 Indirect Infringement

Indirect infringement covers conduct by a person who assists or supports another's direct infringement of a patented invention. Direct infringement must be established as a predicate for each act of indirect infringement. *See Dynacore Holding Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004) ("Indirect infringement . . . can only arise in the presence of direct infringement, though the direct infringer is typically someone other than the defendant accused of indirect infringement."). Both the direct infringer and indirect infringer are jointly and severally liable for the infringement.

The Patent Act recognizes both inducement (§ 271(b)) and contributory infringement (§ 271(c)). A third theory of indirect infringement, whereby multiple parties are conjoined in order to prove that all of the steps of a patented process were practiced, was rejected by the Supreme Court in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 134 S. Ct. 2111 (2014).

14.4.1.3.1 Inducement

Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." A finding of inducement requires that a patent owner establish evidence of culpable conduct directed toward encouraging another's infringement. "[I]nduced infringement under § 271(b) requires knowledge [by the inducer] that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011). Thus, the inducer must have "actively and knowingly aid[ed] and abet[ted] another's direct infringement." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis in original) (noting that "[a]lthough section 271(b) does not use the word 'knowing,' the case law and legislative history uniformly assert such a requirement").

To satisfy the knowledge requirement, the patentee must show that the inducer had actual or constructive knowledge of the patent, *see Insituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998), or acted with "willful blindness." *Global-Tech*, 131 S. Ct. at 2070–71. Under the doctrine of "willful blindness," the inducer must have: (1) subjectively believed that there was a high probability of infringement; and (2) taken deliberate actions to avoid learning of that fact. *Id.* at 2070.

Regarding requisite specific intent, the Federal Circuit commented that "it is clear that a good-faith belief of noninfringement is relevant evidence that tends to show that an accused inducer lacked the intent required to be held liable for induced infringement." *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367–68 (Fed. Cir. 2013). The same standard does not, however, apply to a good-faith belief that a patent is invalid. In *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920 (2015), the Supreme Court ruled that because induced infringement and validity are separate issues and have separate defenses under the Patent Act, belief regarding validity cannot negate § 271(b)'s scienter requirement of "actively induce[d] infringement."

Inducement liability often arises from supplier/customer relationships. A finding that a single party is responsible for direct infringement under § 271(a) is required before any party can liable for inducement under § 271(b). Thus, a single party must either have performed every step of the patent, or directed or controlled others who performed them. *See Limelight Networks, Inc. v. Akamai Techs. Inc.*, 134 S. Ct. 2111 (2014).

Section 298, added by the AIA, provides that an accused infringer's failure to obtain or present advice of counsel may not be used to prove that the accused infringer intended to induce infringement. AIA § 17. Section 298 is applicable to patents issued on or after September 16, 2012.

14.4.1.3.2 Contributory Infringement

Section 271(c) imposes liability under the following circumstances:[31]

> [1] 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, [2] constituting a material part of the invention, [3] knowing the same to be especially made or especially adapted for use in an infringement of such patent, [4] and not a staple article or commodity of commerce suitable for substantial noninfringing use, [5] shall be liable as a contributory infringer.

The alleged contributory infringer must have knowledge of the patent. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964). Element [4] serves as an important defense, immunizing the sale of staple articles of commerce, that is, products that have substantial noninfringing uses. Thus, absent evidence of inducing conduct, sellers of nonpatented goods are shielded from liability unless the good "has no commercial use except in connection with . . . [the] patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 184 (1980).

14.4.1.3.3 Joint Infringement

Patent law has struggled to deal with scenarios in which multiple parties carry out the steps of a claimed method or the elements of a claimed system. The traditional rule in patent law has been that an infringer must practice every limitation of a claim to infringe it. If no single entity practices each step or element, there can be no infringement. Nonetheless, liability can be found where one party controlled or directed each step in a patented process. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 134 S. Ct. 2111, 2117 (2014) (holding that "a method's steps have not all been performed as claimed by the patent unless they are all attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them"); *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l*, 631 F.3d 1279, 1284 (Fed. Cir. 2011) (holding that direct infringement for "use" of the claimed system is possible where a single party does not physically possess or own some elements of the system, if that party "put[s] the invention into service, i.e., control[s] the system as a whole and obtain[s] benefit from it").

The Federal Circuit has expanded the scope of direct infringement under § 271(a) in situations to encompass circumstances where

> an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance. *Cf. Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005) (stating that an actor 'infringes vicariously by profiting from direct infringement' if that actor has the right and ability to stop or limit the infringement). In those instances, the third party's actions are attributed to the alleged infring-

31. The section is reproduced in subdivided form to highlight its essential elements.

> er such that the alleged infringer becomes the single actor chargeable with direct infringement.
>
> Whether a single actor directed or controlled the acts of one or more third parties is a question of fact, reviewable on appeal for substantial evidence, when tried to a jury.

Akamai Techs., Inc. v. Limelight Networks, Inc., 797 F.3d 1020, 1023 (Fed. Cir. 2015) (en banc) (following remand). In addition, the Federal Circuit held that participants in a joint enterprise can be charged with the acts of the other for purposes of direct infringement. *Id.* at 1023 (citing Restatement (Second) of Torts § 491 cmt. b ("The law . . . considers that each is the agent or servant of the others, and that the act of any one within the scope of the enterprise is to be charged vicariously against the rest.").

A joint enterprise requires proof of four elements: "(1) an agreement, express or implied, among the members of the group; (2) a common purpose to be carried out by the group; (3) a community of pecuniary interest in that purpose, among the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control." Restatement (Second) of Torts § 491 cmt. c. As with direction or control, whether actors entered into a joint enterprise is a question of fact, reviewable on appeal for substantial evidence. 797 F.3d at 1023 (citing Restatement (Second) of Torts § 491 cmt. c).

14.4.1.4 Infringement Analysis

Infringement analysis involves two steps: (1) claim construction and (2) comparison of properly construed claims with the accused product or process. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The first step, interpreting the claims, was covered in Chapter 5. We now turn to the second step.

14.4.1.4.1 Literal Infringement

Literal infringement exists when the accused product or process contains each and every limitation recited in a claim, "*i.e.* when the properly construed claim reads on the accused device exactly." *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996). Accordingly, there can be no literal infringement if the accused product or process lacks any claim limitation. The standards for anticipation under § 102 and literal infringement are identical. As the Federal Circuit has observed, "that which would literally infringe if later anticipates if earlier." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001).

One special category of literal claim interpretation relates to so-called means plus function or functional claim formats.

14.4.1.4.1.1 Interpreting the Literal Scope of Means-Plus-Function Claims (§ 112(f))

In *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), the patentee had claimed an apparatus for measuring the depth of oil wells using functional claim

limitations: "means communicating with said well for creating a pressure pulse" and "echo receiving means." *Id.* at 9 n.7. The patentee did not want to limit itself to a specific means, and instead sought to define the claim through the functions sought. Such claiming formats were relatively common in patent practice. Nonetheless, the Supreme Court invalidated the claims for failing to reveal specific structures. *Id.* at 11–14. The Court believed that such claims were overbroad, indefinite, and could discourage experimentation by others.

The patent bar promptly persuaded Congress to remove the cloud over the many functional claims in issued and pending patents the Halliburton decision created. The provision, which is now codified in § 112(f), authorizes the use of the means-plus-function claim format while limiting the scope of such claims to all embodiments set forth in the specification "and equivalents thereof." The determination of "equivalents thereof" is based on the state of technology as of the date that the patent issues. This characterization of "equivalents" differs from the meaning under the "doctrine of equivalents." *See* § 14.4.1.4.2.

14.4.1.4.1.1.1 Determining Whether a Claim Limitation Is Governed by § 112(f)

The use of the term "means" in a claim limitation typically implies that the inventor used the "means-plus-function" claim format, which invokes the associated statutory limits on the literal scope of that claim limitation. *See Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996); *cf. Williamson v. Citrix Online LLC*, 2015 U.S. App. LEXIS 10082, 2015 WL 3687459 at *7 (Fed. Cir. 2015) (en banc) (revoking prior cases holding that there is a strong, but rebuttable, presumption that a term lacking the word "means" does not invoke § 112(f)); § 5.2.3.5.1. Nonetheless, this implication does not apply where the claim language itself provides the structure that performs the recited function. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) (finding that a claim limitation stating "means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles" provides the relevant structure ("internal steel baffles") and hence is not limited to the embodiments in the specification and equivalents thereof); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996) (finding that use of the phrase "perforation means" does not invoke § 112(f)).

Conversely, merely because a claim does not include the word "means" does not prevent a claim limitation from being construed as a means-plus-function limitation. The *Williamson* decision holds that

> [t]he standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Greenberg*, 91 F.3d at 1583. When a claim term lacks the word "means," the presumption can be overcome and § 112[(f)] will apply if the challenger demonstrates that the claim term fails to "recite sufficiently definite structure" or else recites "function without reciting sufficient structure for performing that function." *Watts*, 232 F.3d at 880. The converse presumption remains unaffected: "use of the word 'means' creates a presumption that § 112[(f)] applies." *Personalized Media*, 161 F.3d at 703.

Williamson v. Citrix Online LLC, 792 F.3d. 1339, 1349 (2015). The focus is on the claim language as a whole, not just the isolated term that is akin to "means." *Id.* at *8. Generic terms such as "mechanism," "element," "device" and other such terms that do not connote sufficiently definite structure in the context of the overall claim are tantamount to stating "means," and therefore may be construed pursuant to 112(f) if nothing else in the claim provides sufficient structure. *Id.* at *8. Whether a claim invokes § 112(f) is decided on a limitation-by-limitation basis looking to the patent and the prosecution history. *See Cole*, 102 F.3d at 531.

14.4.1.4.2 Nonliteral Infringement—The Doctrine of Equivalents

The doctrine of equivalents allows for a finding of infringement where the accused product or process is close to the patented invention, but does not literally infringe. The doctrine of equivalents evolved in response to the concern that an "unscrupulous copyist" could avoid literal infringement of a patented invention by making insubstantial changes to the invention. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607–08 (1950). The doctrine is judge-made and has long served to provide courts some leeway to ensure that insubstantial variations do not destroy the value of patents. The doctrine of equivalents has increasingly come under scrutiny on the grounds that it introduces tremendous uncertainty into the scope of patents and makes it difficult for competitors to determine where they can legitimately tread. As a result, the Supreme Court and the Federal Circuit have revisited the contours of this doctrine frequently over the past decade. The process of judicial tinkering appears to have come to rest.

There are two tests for determining equivalence: (1) the function-way-result test and (2) the insubstantial differences test. The use of either test is case-dependent. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Under the function-way-result test, an accused element is equivalent to a claim limitation "if it performs substantially the same function in substantially the same way to obtain the same result." *Graver Tank*, 339 U.S. at 608 (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)). Under this test, a finding of equivalence requires that all three prongs be satisfied. Under the insubstantial differences test, equivalence exists where the differences between the element in the accused product or process and the claim limitation are insubstantial. *See* Kenneth D. Bassinger, *Unsettled Expectations in Patent Law:* Festo *and the Moving Target of Claim Equivalence*, 48 How. L.J. 685, 695 (2005). Under either test, nonliteral infringement is a question of fact for the jury to decide. *See Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006). The doctrine of equivalents determination is judged on the state of technology as of the time of the infringement, not (as in the case of means-plus-function claims) as of the time the patent issued.

14.4.1.4.2.1 Limiting Principles

While the doctrine of equivalents is a question of fact, the courts have developed various legal doctrines that limit its applicability: (1) the all-elements rule, along with

the claim vitiation corollary; (2) prosecution history estoppel, along with the specific exclusion corollary; (3) the prior art rule; and (4) the public dedication rule. These limiting doctrines are not mutually exclusive—the patentee must satisfy all of them to establish infringement under the doctrine of equivalents.

14.4.1.4.2.1.1 The All-Elements (All-Limitations) Rule

The all-elements rule[32] provides that the test for equivalence under the doctrine of equivalents must be applied on an element-by-element (or limitation-by-limitation) basis. A finding of infringement therefore requires that the accused product or process contain each claim limitation or its equivalent. Under the all-elements rule, the trier of fact performs an equivalence analysis to determine whether each claim limitation exists in the accused product or process either literally or as an equivalent. However, if no reasonable jury could find an equivalent element in the accused product or process to the claim limitation, the court must grant summary judgment as to noninfringement. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

14.4.1.4.2.1.1.1 Claim Vitiation

The claim vitiation doctrine is a corollary of the all-elements rule: an accused device cannot be infringing if it would effectively vitiate (or eliminate) any claim limitation. *See Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). The Federal Circuit has applied the claim vitiation rule in varying ways, leading to somewhat unpredictable results. *See* Daniel H. Shulman & Donald W. Rupert, *"Vitiating" the Doctrine of Equivalents: A New Patent Law Doctrine*, 12 Fed. Cir. B.J. 457 (2003). In *Cadence Pharmaceuticals Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015), the Federal Circuit clarified that "'vitiation' is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted." The court explained that equivalence should not depend on "labels like 'vitiation' . . . but on the proper assessment of the language of the claimed limitation and the substantiality of whatever relevant differences may exist in the accused structure."

14.4.1.4.2.1.2 Prosecution History Estoppel

Prosecution history estoppel can preclude a patent holder from using the doctrine of equivalents to reclaim subject matter relinquished expressly or by operation of law during patent prosecution. *See Eagle Comtronics, Inc. v. Arrow Commc'n*

32. The Federal Circuit prefers to use "limitation" when referring to claim language and "element" when referring to the accused product. *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 234 F.3d 558, 563 n.1 (Fed. Cir. 2000). Along those lines, the all-elements rule is also known as the all-limitations rule. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1317 n.1 (Fed. Cir. 1998).

Labs., Inc., 305 F.3d 1303, 1315 (Fed. Cir. 2002). Prosecution history estoppel is most often applied where a patent applicant amended or canceled a claim that the patent examiner rejected as unpatentable in light of prior art. Whether prosecution history estoppel applies in a particular case is a question of law. *See Panduit Corp. v. Hellermanntyton Corp.*, 451 F.3d 819, 826 (Fed. Cir. 2006).

In *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 535 U.S. 722 (2002), the Supreme Court adopted a rebuttable presumption that amendments made to narrow a claim limitation foreclose later stretching of that limitation to reach an accused technology under the doctrine of equivalents. The patentee can rebut this presumption under three scenarios: (1) the equivalent was unforeseeable to a person having ordinary skill in the art at the time of the amendment; (2) the rationale for the amendment was no more than tangentially related to the equivalent at issue; or (3) another reason suggesting that the patentee could not reasonably be expected to have described the alleged equivalent. *Id.* at 740–41. Table 14.9 summarizes guidelines outlined by the Federal Circuit for applying the three rebuttal criteria. *See Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 344 F.3d 1359, 1368–70 (Fed. Cir. 2003) (en banc).

Table 14.9
Rebuttal Criteria for Presumptive *Festo* Bar

Rebuttal Criteria	Application	Focus of Inquiry	Evidence the Court May Consider
The equivalent was unforeseeable at the time of the application.	Unforeseeable equivalent: later-developed technologies or technology unknown in the relevant art. Foreseeable equivalent: old technology or equivalent was known in the prior art in the relevant field of the invention.	Underlying factual issues such as the state of the art and understanding of one skilled in the art at the time of the amendment.	Expert testimony and other extrinsic evidence relating to relevant factual inquiries.
The rationale for the amendment was no more than tangentially related to the equivalent at issue.	Tangential means peripheral or not directly relevant Not tangential: amendment made to avoid prior art containing the alleged equivalent.	Patentee's objective apparent reason for the narrowing amendment, including the context in which the amendment was made.	Prosecution history record and no additional evidence except when expert testimony is necessary for interpretation of that record.

Rebuttal Criteria	Application	Focus of Inquiry	Evidence the Court May Consider
Another reason suggesting that the patentee could not reasonably be expected to have described the alleged equivalent.	Another reason: shortcomings in language.	[No cases yet on point.]	Should be limited to prosecution history record.

14.4.1.4.2.1.2.1 Specific Exclusion

The specific exclusion principle is a corollary to the doctrine of prosecution history estoppel. It provides that a patentee cannot use the doctrine of equivalents to reclaim subject matter which he clearly excluded. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1347 (Fed. Cir. 2001). A patent may specifically exclude a proposed equivalent from the scope of the claimed invention either implicitly or explicitly. The rule ensures that the public may rely on clear disclaimers in the patent to conclude that the patentee did not seek patent rights for this excluded subject matter.

The specific exclusion doctrine applies where the patentee clearly disclaims subject matter from the scope of the claimed invention in the specification or the claims. Cases involving specific exclusion in the specification focus on explicit disclaimers, such as where the patentee criticizes the equivalent or requires that the invention contain the specific element claimed. *See Gaus v. Conair Corp.*, 363 F.3d 1284, 1291 (Fed. Cir. 2004); *SciMed*, 242 F.3d at 1345. Specific exclusion is rarely applied on the basis of a claim, but where the patentee claims one option in a binary choice setting, specific exclusion precludes the patent holder's assertion that the other option is equivalent. *See Senior Techs., Inc. v. R.F. Techs. Inc.*, 76 F. App'x 318, 321 (Fed. Cir. 2003). The binary choice setting does not simply involve the negation of a claim limitation (i.e., "suede" versus "not suede" or "blue" versus "not blue"), but requires that the claim limitation be one of only two options.

14.4.1.4.2.1.3 Prior Art Rule

A third limiting principle of nonliteral infringement analysis, the prior art rule, provides that a patentee may not use the doctrine of equivalents to obtain coverage of subject matter in the prior art, that is, "coverage which he could not lawfully have obtained from the USPTO by literal claims." *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683–84 (Fed. Cir. 1990). Accordingly, an accused infringer who merely practices the prior art cannot infringe under the doctrine of equivalents. This principle is applied by constructing a hypothetical claim based on the accused technology. *See id.* at 684. If the USPTO could have allowed the hypothetical claim over the prior art (i.e., if the prior art did not anticipate or render the hypothetical claim obvious, *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1105–06 (Fed. Cir. 2002)), the prior art does not preclude infringement under the doctrine of

equivalents. The patent holder bears the burden of proving that the range of equivalents sought does not cover the prior art. *See Wilson Sporting Goods*, 904 F.2d at 685. This determination is a question of law. *See id.* at 683.

14.4.1.4.2.1.4 The Public Dedication Rule

The public dedication rule (or disclosure-dedication rule) provides that a patent holder cannot invoke the doctrine of equivalents to recapture subject matter disclosed but not claimed in a patent. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) (per curiam). The Federal Circuit stated that to hold otherwise would "conflict with the primacy of the claims in defining the scope of the patentee's exclusive right." *Id.* (quoting *Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997)). The public dedication rule derives from and promotes the patent system's notice function. The test for determining whether a disclosure has been dedicated to the public is whether "one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description." *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). Like prosecution history estoppel, the public dedication rule is a question of law. *See Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004). Patentees are free to broaden the scope of their patent under the broadening reissue provision, § 251, for up to two years following issuance. *See* § 14.2.5.4.2.

14.4.1.4.2.2 Interpreting the Nonliteral Scope of Means-Plus-Function Claims

The question arises whether means-plus-function claims are entitled to one or two stretches for "equivalents"—one as a part of literal infringement analysis under § 112(f) (to reach "equivalents thereof" relating to embodiments set forth in the specification) and a second under the doctrine of equivalents. Since the § 112(f) literal "equivalents" analysis is based on the state of technology as of the time the patent issues, the doctrine of equivalents provides a second stretch to the extent that the accused device employs "after-arising" technology—means that were not known in the art at the time that the patent issued. *See Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1320 (Fed. Cir. 1999).

Even with regard to technology that was known as of the time that the patent issued, the patentee is entitled to additional scope under the doctrine of equivalents to the extent that the function of the accused device is substantially the same as the function of the claimed invention. *See id.* at 1320–21; *see also WMS Gaming v. Int'l Game Tech.*, 184 F.3d 1339, 1353 (Fed. Cir. 1999). This is because § 112(f) requires that the function of the accused element be identical to the function of the claim limitation, whereas the doctrine of equivalents is broader—allowing substantially similar function.

Nonetheless, the patentee cannot invoke the doctrine of equivalents to reach a substantially similar "structure, material, or act" that did not fall within the scope of the § 112(f) "equivalents thereof" with regard to technology that was known as of the

time that the patent issued. The Patent Act will not permit an "equivalent of an equivalent" by applying both § 112(f) and the doctrine of equivalents to the structure of a given claim element with regard to technology that the patent draftsperson was fully capable of capturing when preparing the application. *Al-Site*, 174 F.3d at 1320 n.2; *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1310–11 (Fed. Cir. 1998).

14.4.1.4.3 The Reverse Doctrine of Equivalents

The reverse doctrine of equivalents is an equitable doctrine designed "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991). More than a century ago, the Supreme Court recognized that there may be circumstances in which an accused device that literally infringes a patent should nonetheless be excused from liability because it substantially differs in operative principle and results. Although the so-called reverse doctrine of equivalents has rarely been found, it nonetheless continues to be raised. In *Boyden Power-Brake Co. v. Westinghouse*, 170 U.S. 537 (1898), George Westinghouse had invented a train brake that used a central reservoir of compressed air for stopping power in 1869. *Id.* at 545–46. Further advances in his design, primarily the addition of an air reservoir in each brake cylinder, resulted in a brake that was patented in 1887. *Id.* at 558–60. An improvement on this 1887 brake, invented by George Boyden, added an ingenious mechanism for pushing compressed air into the brake piston from both the central reservoir and a local reservoir in each brake cylinder. (Westinghouse's brake required a complicated series of passageways to supply air from the two sources.) With the added stopping power of the Boyden brake, engineers could safely operate the increasingly long trains of the late nineteenth century.

The Westinghouse patent included a claim for "the combination of a main air-pipe, an auxiliary reservoir, a brake-cylinder, a triple valve [the device that coordinated the airflows from the main reservoir and the individual brake reservoir] and an auxiliary-valve device, actuated by the piston of the triple-valve . . . for admitting air in the application of the brake." *Id.* at 553–54. The Court noted that the literal wording of the Westinghouse patent could be read to cover Boyden's brake since it included a "triple valve." But it refused to find infringement on the ground that Boyden's device was a significant contribution that took the invention outside the equitable bounds of the patent, explaining:

> a charge of infringement is sometimes made out, though the letter of the claims be avoided . . . [t]he converse is equally true. The patentee may bring the defendant within the letter of his claims, but if the latter has so far changed the principle of the device that the claims of the patent, literally construed, have ceased to represent his actual invention, he is as little subject to be adjudged an infringer as one who has violated the letter of a statute has to be convicted, when he has done nothing in conflict with its spirit and intent.

Id. at 562.

The reverse doctrine of equivalents was recognized—but not applied—once again by the Supreme Court in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608–609 (1950). But since 1898, no case has squarely applied the doctrine to excuse infringement. According to the Federal Circuit, "because products on which patent claims are readable word for word often are in fact the same, perform the same function in the same way, and achieve the same result, as the claimed invention, a defense based on the reverse doctrine of equivalents is rarely offered." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1123 n.19 (Fed. Cir. 1985); *See Monsanto Co. v. Mycogen Plant Sci., Inc.*, 61 F. Supp. 2d 133, 187–88 (D. Del. 1999) (granting JMOL overturning jury's exoneration of accused infringer under reverse doctrine of equivalents). Indeed, the Federal Circuit has observed that "[t]he reverse doctrine of equivalents is rarely applied, and this court has never affirmed a finding of noninfringement under the reverse doctrine of equivalents." *See Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1378 (Fed. Cir. 2008) (*citing Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357 (Fed. Cir. 2002)).

14.4.1.5 Extraterritorial Infringement

14.4.1.5.1 Manufacturing Components Within the United States for Assembly Abroad—§ 271(f)

The rights conferred under patent law generally apply only to inventions made, used, sold, or imported into the United States. § 271(a). After the Supreme Court held that there could be no liability for shipping the components of a patented device outside of the United States for purposes of assembly abroad, *see Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), Congress added § 271(f) to extend liability for supplying unassembled "components" from the United States for "combination" outside the United States, where the same combination would infringe a patent if it occurred within the United States. The two prongs of infringement under § 271(f) are similar to active inducement and contributory infringement found in § 271(b) and (c).

Applying § 271(f) poses several challenges in the digital age. One particularly thorny issue has been the meaning of "component." For example, a "component" does not include the supply of blueprints, plans, or instructions. *Pellegrini v. Analog Devices, Inc.*, 275 F.3d 1113 (Fed. Cir. 2004). Nor does it include software; instead only a tangible, computer-readable medium like a CD can be a "component." *See Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). The term "supply" has also been controversial. In *Microsoft*, the Court held that to "supply" a component from the United States means to ship it from the United States; making copies abroad does not constitute "supplying." *Id.* at 452–53.

Notably, § 271(f) is inapplicable to method claims. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1364 (Fed. Cir. 2009) (en banc in relevant part) ("[B]ecause one cannot supply the step of a method, Section 271(f) cannot apply to method or process patents."). Accordingly, "Section 271(f) does not encompass devices that may be used to practice a patented method." *Id.* at 1366.

14.4.1.5.2 Importing Products Made Using Patented Processes—§ 271(g)

Section 271(g) was also added in the 1980s to close a loophole pertaining to products imported into the United States made using patented processes. It establishes liability for importing, making, using, or selling within the United States a nonpatented product made abroad using a process that is patented in the United States. A "product" under subsection (g) must be a manufactured physical article; it does not include intangible information produced or transmitted by a patented process. *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005). Furthermore, there is no liability if the product is "materially changed by subsequent processes." § 271(g)(1). The Federal Circuit has held that "in the chemical context a 'material' change . . . is a significant change in the compound's structure and properties." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1573 (Fed. Cir. 1996).

14.4.2 Defenses

Section 282 of the Patent Act provides for the following defenses:

(1) Noninfringement, absence of liability for infringement or unenforceability;

(2) Invalidity of the patent or any claim in suit on any ground specified in part II [of the Patent Act] as a condition for patentability;

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 [of the Patent Act];

(4) Any other fact or act made a defense by [the Patent Act].

14.4.2.1 Noninfringement

An accused infringer may contend that he does not infringe the asserted patent either literally or under the doctrine of equivalents. Noninfringement exists where the patent holder does not meet the burden of proving infringement by a preponderance of the evidence.

14.4.2.2 Absence of Liability

Even if the accused technology is found to read on the claimed invention, the defendant can prevail by establishing consent, experimental use, or several other legal and equitable defenses.

14.4.2.2.1 Consent or License

An alleged infringer can defend on the ground that the patentee has consented to their use of the technology by, for example, granting a license. A patent license is an agreement or covenant between the patent holder and the licensee stipulating that the patent holder will not sue the licensee for otherwise infringing acts. If such an agreement covers the acts in question, the accused infringer cannot be liable for in-

fringement because his or her acts were not "without authority" as required by § 271(a).

Patent licenses can be express or implied. An implied license arises by acquiescence, conduct, equitable estoppel, or legal estoppel. *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997). Such licenses are generally revocable. The existence and scope of licenses are generally governed by state contract law.

14.4.2.2.1.1 First-Sale Doctrine/Exhaustion Principle

Under the first-sale doctrine (sometimes referred to as the exhaustion principle), a form of implied license by operation of law, the first unrestricted sale of a patented product exhausts the patentee's control over that product, and it can be resold and repaired without implicating the patent owner's rights. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964) (stating that "it is fundamental that sale of a patented article by the patentee . . . carries with it an 'implied license to use.'"). The line between permitted repair and impermissible reconstruction is not easily determined, resulting in rather vague, context-specific rulings. *See, e.g.*, *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Co.*, 123 F.3d 1445 (Fed. Cir. 1997). Such issues frequently arise in the context of contributory infringement claims, where the alleged infringer is providing specialized replacement parts.

Contractual restrictions on resale or reuse can provoke patent misuse allegations and antitrust counterclaims. *See Lexmark International, Inc. v. Impression Prods., Inc.*, — F.3d —, 2016 WL 559042 (Fed. Cir. 2016); *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992); *see also* § 14.4.2.3.2. Unlike other forms of implied licenses, patent exhaustion cannot be disclaimed. Nonetheless, patent exhaustion does not prevent the owner of a patent on a self-replicating product from using contractual restrictions to bar use of self-replicated progeny. Patent exhaustion only applies to "the particular item sold, and not to reproductions" made within the purchaser's control. *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1768 (2013).

Exhaustion is determined on a patent-by-patent, as opposed to a claim-by-claim, basis. *See Keurig, Inc. v. Sturm Foods, Inc.*, 732 F.3d 1370 (Fed. Cir. 2013); *but see id.* at 1375 (O'Malley, J., concurring in the result) (noting that because each patent claim represents a separate invention, patent exhaustion should apply on a claim-by-claim basis).

The doctrine of patent exhaustion applies to method claims and the method patent is exhausted by sale of the item that embodies the method. *See Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008). Although repair of a patented product that has been sold is permissible, reconstruction of the patented technology crosses the line into the patentee's "make" right. Furthermore, sale of a component that does not completely practice or embody a patent claim can still exhaust the patent if the product has no substantial noninfringing use or if the component substantially embodies the claim. *See id.*

The Federal Circuit held in *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), that where a licensee sells a product outside the U.S.,

such sale does not exhaust the licensor's U.S. patents if that product is subsequently imported and sold in the U.S. The Federal Circuit reaffirmed the *Jazz Photo* rule in *Lexmark International, Inc. v. Impression Products, Inc.*, — F.3d —, 2016 WL 559042 (Fed. Cir. 2016) (en banc) (distinguishing the Supreme Court's holding in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct 1351 (2013), holding that international exhaustion applies under the Copyright Act notwithstanding the importation right).

14.4.2.2.1.2 Shop Right

Based on state law, a "shop right" entitles an employer to use patented technology developed by an employee in the employer's "shop." *See McElmurry v. Ark. Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993). An employer has a shop right where it has provided wages, materials, tools, and workspace to finance its employee's invention. An employee's consent, acquiescence, inducement, or assistance to the employer in using the invention without seeking payment or restricting its use also creates a shop right. *Id.* at 1582. The defense is an equitable doctrine. *Schroeder v. Tracor, Inc.*, No. 99-1281, 1999 U.S. App. LEXIS 30386, at *4–5, 1999 WL 1021055 (Fed. Cir. Nov. 5, 1999). To determine whether an employer has a shop right to an invention, courts "look to the totality of the circumstances on a case by case basis and determine whether the facts of a particular case demand, under principles of equity and fairness, a finding that a 'shop right' exists." *McElmurry*, 995 F.2d at 1581–82. A shop right is personal to an employer and cannot be assigned or transferred. *See Francklyn v. Guilford Packing Co.*, 695 F.2d 1158, 1163 (9th Cir. 1983). However, a shop right will pass to the purchaser of the employer's entire business. *See Cal. E. Labs., Inc. v. Gould*, 896 F.2d 400, 402 (9th Cir. 1990).

14.4.2.2.2 Experimental Use Defense

Courts have long recognized a common-law defense of experimental use. The Federal Circuit has, however, interpreted this doctrine quite narrowly, limiting it to uses "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *See Madey v. Duke Univ.*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002). If the use has the "slightest commercial implication," the experimental use defense does not apply. *Id.* at 1362. Additionally, conduct in keeping with the legitimate business of the accused infringer does not qualify for the defense, regardless of the commercial implications. *Id.* Furthermore, whether a user is a profit or nonprofit entity is not determinative. *Id.*

In addition to the common-law doctrine of experimental use, § 271(e) creates a limited experimental use exception for submitting information for regulatory purposes. Adopted in 1984 as part of the Drug Price Competition Act (also known as the Hatch-Waxman Act), § 271(e)(1) provides a safe harbor for using a patented drug in testing before the end of the patent term "solely for uses reasonably related to the development and submission" of regulatory information. Without this safe harbor, a competitor seeking to get advance approval of a generic version of a particular drug would infringe if they tested their alternative before the patent term expired, which would effectively lengthen the patent term by the amount of time nec-

essary to test the generic drug for FDA approval. *See Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984). While the safe harbor is not so expansive as to include "basic scientific research . . . performed without the intent to develop a particular drug," its scope has been interpreted broadly to cover drug testing, human clinical trials, and preclinical laboratory testing, or any reasonable research that might be "appropriate to include in a submission to the FDA." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205–06 (2005); *see also Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334 (Fed. Cir. 2007). In addition to pharmaceuticals, § 271(e)(1) covers experimental testing of medical devices. *See Eli Lilly & Co. v. Medtronic Inc.*, 872 F.2d 402 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

14.4.2.2.3 Prior-Use Right

Section 273 of the Patent Act, added by the First Inventor Defense Act of 1999, provides an infringement defense for an earlier inventor of a business method which was subsequently patented by another. This defense is available if the accused infringer "had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent." § 273(b)(1). The party asserting a prior-use defense need not prove that it invented the business method before the patentee in accordance with § 102(g). Section 273(e) limits the transfer of the prior-use right except as "an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates."

Effective September 16, 2011, to patents issued on or after that date, the AIA expands the scope of prior-use rights to also include "subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process." AIA § 5. For this defense to apply, the prior use must have been a prior commercial use in the U.S. by the party asserting the defense. In addition, the prior use must have occurred at least one year before the earlier of either: (1) the effective filing date, or (2) the date of the first public disclosure of the claimed invention. The prior-use defense must be established by clear and convincing evidence. In certain cases, this defense does not apply to patents held by universities.

14.4.2.2.4 Bar Against Remedies for Infringement of Medical Procedure Patents by Doctors and Hospitals

Following a lawsuit against a doctor to enforce a patent on a cataract surgery procedure in 1993, the American Medical Association lobbied Congress to exclude medical procedure patents from the scope of patentable subject matter. While declining to curtail the scope of § 101, Congress enacted § 287(c) which bars the enforcement of medical procedure patents against medical practitioners or related health-care entities. This provision does not, however, insulate sellers of medical devices from indirect (inducement or contributory) infringement of medical procedure patents.

14.4.2.2.5 Sovereign Immunity

During the 1980s, intellectual property owners became concerned that states and state agencies, including public universities, might escape or at least frustrate enforcement of federal intellectual property rights by invoking state sovereign immunity under the Eleventh Amendment of the U.S. Constitution. In the early 1990s, Congress enacted a series of laws expressly abrogating state sovereign immunity for intellectual property infringement, including patent violations. The Supreme Court struck down one such act, the Patent and Plant Variety Remedy Clarification Act, on the grounds that Congress cannot abrogate state sovereign immunity on the basis of its Article I powers under the Constitution and that Congress had not established an adequate basis for abrogation of state sovereign immunity pursuant to the Fourteenth Amendment. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999). As a result, states and state instrumentalities cannot be sued in federal court for patent infringement without their consent.

14.4.2.3 Unenforceability

A finding that a patent is unenforceable renders each and every claim of that patent unenforceable. By contrast, a finding of invalidity is assessed on a claim-by-claim basis, the result of which may be that some claims are held invalid whereas others are sustained and may continue to be enforceable.

14.4.2.3.1 Inequitable Conduct

Where a patent applicant breaches the duty to prosecute a patent application in good faith and candor, it may result in a finding of inequitable conduct. *See* 37 C.F.R. § 1.56 (2013); *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 410 F.3d 690, 695 (Fed. Cir. 2005). Inequitable conduct may "arise from an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the USPTO." *Id.* A determination that inequitable conduct occurred in relation to one or more claims will render the entire patent unenforceable. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc in relevant part). Furthermore, inequitable conduct is not limited to the patent-in-suit; it may also render related patents unenforceable where the inequitable conduct had an "immediate and necessary relation" to other patents. *See Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 810–12 (Fed. Cir. 1990) (*quoting Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933)).

Inequitable conduct claims must be pled with particularity under Federal Rule of Civil Procedure 9(b), and "requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the USPTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). The accused infringer must prove both materiality and intent by clear and convincing evidence. *See Purdue Pharma*, 410 F.3d at 695. Once these threshold findings are established, the court "must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred." *Id.* at 696. "Intent and

materiality are separate requirements. A district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality and vice versa." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) (internal citation omitted).

The level of materiality required to establish inequitable conduct is "but-for" materiality. *Id.* at 1291. "[P]rior art is but-for material if the USPTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 1291–92. To determine whether the USPTO would have allowed the claim, "the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.* (citing Manual of Patent Examining Procedure (MPEP) §§ 706, 2111 (8th ed. Rev. 8, July 2010)). Even if the withheld prior art does not invalidate a claim under the clear-and-convincing standard, it may be "but-for" material if it would have blocked patent issuance under the USPTO's evidentiary standards. *Id.* at 1292 (citing MPEP §§ 706 (preponderance of the evidence), 2111 (broadest reasonable construction)). In addition, "[a]lthough but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, [the Federal Circuit] recognizes an exception in cases of affirmative egregious misconduct," such as the filing of an unmistakably false affidavit. *Id.*

Intent to mislead or deceive the USPTO may be shown by direct evidence or inferred from clear and convincing evidence of the surrounding circumstances. *See Purdue Pharma*, 410 F.3d at 700. A court may not infer intent solely from materiality. *Therasense*, 649 F.3d at 1290. Rather, it must weigh the evidence of intent independent of its analysis of materiality. *Id.* "[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id.* (quoting *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). Otherwise, if multiple reasonable inferences may be drawn, intent to deceive cannot be found. *Id.* at 1290–91.

14.4.2.3.2 Patent Misuse

The affirmative defense of patent misuse exists to prevent harm to the market caused by a patentee extending a patent's right to exclude beyond its legal scope. The underlying principle of misuse is that an alleged infringer must prove by clear and convincing evidence that a patentee has both "impermissibly broadened the physical or temporal scope of the patent grant" and caused some "anticompetitive effect." *See Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860 (Fed. Cir. 1997). Where the patentee's behavior remains within the grant of the patent right to exclude, however, there can never be patent misuse. *See Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004). In response to concern that this judge-made doctrine was vague, unpredictable, and overbroad, Congress exempted several specific behaviors from the doctrine by adding § 271(d). For example, enforcing a patent or refusing to license cannot constitute patent misuse. *See* §§ 271(d)(3)–(4). Courts scrutinize other behavior under antitrust's familiar levels of review: per se and rule of reason.

Many behaviors can theoretically constitute patent misuse. Tying sales of a patented good and an unpatented good, package licenses, extending royalties beyond

the patent term, grantback clauses, field-of-use restrictions, horizontal arrangements like patent pools, price discrimination, and market division can all constitute patent misuse if they improperly expand a patent right to anticompetitive effect. A detailed discussion of this doctrine can be found in 1 Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP and Antitrust § 3.3 (2006).

14.4.2.3.2.1 Postexpiration Royalties

The Supreme Court held in *Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964), that license agreements providing for payment of patent royalties beyond the expiration of a patent are per se patent unlawful. The Supreme Court reaffirmed that decision in *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401 (2015).

14.4.2.3.3 Equitable Estoppel

Equitable estoppel arises where a patentee misleads an alleged infringer into believing that he or she would not be sued for using the patented technology. The defense may bar all relief on an infringement claim. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (en banc). Three elements must be established to prove equitable estoppel:

> (1) The actor, who usually must have knowledge of the true facts, communicates something in a misleading way, either by words, conduct or silence.
>
> (2) The other relies upon that communication.
>
> (3) And the other would be harmed materially if the actor is later permitted to assert any claim inconsistent with his earlier conduct.

Id. (quoting D.B. Dobbs, Handbook on the Law of Remedies § 2.3, at 42 (1973)). In the patent infringement context, the "something" communicated is that the plaintiff will not bring an infringement claim against the accused infringer. *See id.* at 1042. Accordingly, the defendant must not only be aware of the patentee and/or his patent but also know or reasonably be able to infer that the patentee has been aware of the accused infringer's acts for some time. A plaintiff's inaction may give rise to the inference that he abandoned his infringement claim when combined with other facts regarding the parties' relationship or contracts with each other. Regarding the third factor, material harm may include a change of economic position or loss of evidence. *See id.* at 1043.

Even where the defendant proves all three elements of the estoppel defense, the court must consider "any other evidence and facts respecting the equities of the parties in exercising its discretion and deciding whether to allow the defense of equitable estoppel to bar the suit." *Id.* The defense does not require an unreasonable delay in filing suit, as is necessary for laches. *See id.* at 1041–42. However, such a delay may be evidence relevant to determining whether the plaintiff's conduct was misleading.

14.4.2.3.4 Laches

The equitable defense of laches may be available where the plaintiff unreasonably delayed filing his or her infringement suit. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1032 (Fed. Cir. 1992) (holding that Congress codified a laches defense in § 282(b)(1)); *see also SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 807 F.3d 1311 (Fed. Cir. 2015) (en banc) (holding that *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962 (2014) does not disturb the patent laches doctrine articulated in *A.C. Aukerman Co.*). The defense is applicable where the accused infringer proves two factors:

> (1) the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant, and
>
> (2) the delay operated to the prejudice or injury of the defendant.

A.C. Aukerman Co., 960 F.2d at 1028. The period of delay is defined as the time from when the plaintiff knew or reasonably should have known of the defendant's alleged infringing acts until the date of suit. *Id.* This period may not begin until after the patent issues. *Id.* Regarding the second factor, prejudice to the defendant may be either economic or evidentiary. *See id.* at 1033. A laches defense may be defeated where the infringer "has engaged in particularly egregious conduct which would change the equities significantly in plaintiff's favor." *Id.* (quoting *TWM Mfg. Co. v. Dura Corp.*, 592 F.2d 346, 349 (6th Cir. 1979)). Laches only bars damages accrued prior to suit. *See id.* at 1041.

A rebuttable presumption of laches exists where the accused infringer proves that the plaintiff delayed filing suit for more than six years after actual or constructive knowledge of the defendant's alleged infringing acts. *See id.* at 1035–36, 1038. The defendant's burden of persuasion does not shift as a result of the plaintiff's six-year delay. *See id.* at 1039.

14.4.2.3.4.1 Prosecution Laches

A special form of laches—prosecution laches—renders a patent unenforceable where the patentee unreasonably delayed in prosecuting the patent, and the accused infringer or others suffered prejudice by the delay. *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010). "[T]o establish prejudice[,] an accused infringer must show evidence of intervening rights, *i.e.*, that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." *Id.* The Federal Circuit reviews a determination of prosecution laches for abuse of discretion. *Id.* at 728–29. The Federal Circuit has left the threshold for applying prosecution laches somewhat vague, but stressed that it should only be invoked in "egregious cases of misuse of the statutory patent system." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., L.P.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) (affirming judgment of unenforceability due to prosecution laches where patent applications were pending between eighteen to thirty-nine years, the

applicant had engaged in "culpable neglect" in allowing them to linger, and intervening rights had developed).

14.4.2.4 Invalidity

The invalidity defense may be asserted where the patent fails to comply with any of the statutory requirements provided in §§ 101, 102, 103, and 112. Under § 282, a patent is presumed to be valid. "The presumption of validity is based on the presumption of administrative correctness of actions of the agency charged with examination of patentability." *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996). Accordingly, the burden of proving invalidity of a claim rests on the accused infringer, who must prove invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011).

Once a claim is declared invalid, patentees are collaterally estopped from asserting the claim unless they can show that they did not have "a fair opportunity procedurally, substantively and evidentially to pursue [their] claim the first time." *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 332–33, 350 (1971).

14.4.2.4.1 Double Patenting

Courts have interpreted patent law to forbid a second patent from covering the same invention or an obvious variation of it so as to prevent patentees from extending the duration of their patents by patenting the same subject matter more than once. The cases distinguish between two forms of double patenting: (1) so-called statutory or same-invention double patenting; and (2) obviousness-type or nonstatutory double patenting. The former draws upon the language of § 101 stating that "[w]hoever invents or discovers any new and useful [invention] may obtain a patent therefore . . . ." Use of the singular implies that inventors are entitled to only one patent per invention. The latter is a judicial doctrine intended to prevent prolongation of the patent term through the assertion of claims that were made obvious by a prior patent of the same inventor. A patent which merely discloses a prior invention does not double patent—only the claims matter.

14.4.2.4.1.1 Statutory, or Same-Invention

Statutory double patenting occurs when the claims of a later patent would infringe an earlier-issued patent by the same inventor. This can happen where multiple patents derive from a common application. The courts have interpreted § 121 (relating to divisional applications, *see* § 14.2.2.3) as shielding applicants subject to a restriction requirement from the double-patenting doctrine. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (holding that a species patent that issues before an earlier-filed genus patent is not a double patent if the order of issue was due solely to USPTO delay); *Gerber Garment Tech., Inc. v. Letra Sys.*, 916 F.2d 683 (Fed. Cir. 1990) (holding that divisional application from a USPTO restriction requirement is not a double patent as long as divisional claims have not materially changed).

14.4.2.4.1.2 Nonstatutory or Obviousness-Type

Obviousness-type double patenting occurs when a later patent is made obvious by an earlier patent of the same inventor. Thus, where a prior patent for "pork" packing exists, a later patent which claims technology for "meat" packing is an obviousness-type double patent, but not a same-invention double patent. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967–72 (Fed. Cir. 2001); *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970). Where double patenting allegations arise, patentees often elect to shorten the term of their second patent so that it expires with the first, precluding concern over double patenting as long as each subsequent patent remains commonly owned. *See* § 253; 37 C.F.R. § 1.321(c)(3); § 14.2.5.1 (terminal disclaimer).

In addition, "a later-issued, but earlier-expiring patent could qualify as a double patenting reference, and thus invalidate an earlier-issued but later-expiring patent." *AbbVie Inc. v. Kennedy Inst. of Rheumatology*, 764 F.3d 1366, 1374 (Fed. Cir. 2014) (citing *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014)).

14.4.2.4.2 Estoppel by Transfer of Ownership

Although patent validity may generally be challenged by third parties, courts have developed doctrines affecting whether patent invalidity may be asserted by those in privity with the patent owner. These doctrines derived from principles holding that parties to contracts relating to property ought not to be permitted to question the consideration on which the deeds or other property conveyances were based. These doctrines have been reassessed in light of patent-law policies.

14.4.2.4.2.1 Assignor Estoppel

Under the doctrine of assignor estoppel, a seller of a patent or patent application may not, absent exceptional circumstances, attack the validity of that patent in a subsequent patent-infringement litigation. *See Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 150 F.3d 1374, 1378 (Fed. Cir. 1998); *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1223 (Fed. Cir. 1988). The doctrine derives from legal estoppel (or estoppel by deed), which prohibits a grantor of property from challenging the validity of the grant. *See Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co.*, 266 U.S. 342, 348–49 (1924). Notwithstanding dicta in *Lear, Inc. v. Adkins*, 395 U.S. 653, 670–71 (1969) ("Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain."), *see* § 14.4.2.4.2.2 (discussing rejection of licensee estoppel); *see e.g.*, *Coastal Dynamics Corp. v. Symbolic Displays, Inc.*, 469 F.2d 79 (9th Cir. 1972) (per curiam) (holding that dicta in *Lear* indicates that the assignor estoppel doctrine is no longer valid), the Federal Circuit continues to uphold the assignor estoppel doctrine. *See Diamond Scientific*, 848 F.2d at 1223 (Fed. Cir. 1988) ("Beyond the questioning dicta in *Lear*, the Court has left assignment estoppel untouched . . ."). The considerations supporting the assignor estoppel doctrine (encouraging fair dealing) differ from those motivating the licensee estoppel doctrine (fostering free competition). *Cf. id.* at 1224 ("Unlike the licensee, who, without *Lear* might be forced to continue to pay for

a potentially invalid patent, the assignor who would challenge the patent has already been fully paid for the patent rights.").

The doctrine of assignor estoppel is not absolute and courts have allowed assignors to challenge patent validity in exceptional circumstances. "A determination whether assignor estoppel applies in a particular case requires a balancing of the equities between the parties." *See Carroll Touch, Inc. v. Electro Mechanical Systems, Inc.*, 15 F.3d 1573, 1579 (Fed. Cir. 1993). Such balancing is a matter committed to the discretion of the trial court. *See id*. (analogizing to laches defense; nonetheless overturning the determination that assignor estoppel did not apply where the trial court's findings—that the controlling owner of defendant, a named inventor and former employee of the firm that assigned the patent, played only a minimal role in the invention and was misled as to the scope of the patent at issue—were not adequately supported by the entire record).

Exceptional circumstances disfavoring application of the assignor estoppel doctrine include: an express reservation by the assignor of the right to challenge the validity of the patent or an express waiver by the assignee of the right to assert assignor estoppel, *cf. Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 150 F.3d 1374, 1378 (Fed. Cir. 1998); where the assignor's participation was under duress, *cf. Shamrock Technologies, Inc. v. Medical Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990); or where the rights were assigned prior to the invention being completed (and hence it might not be reasonable to presume the assignor's representation that the patent was valid).

14.4.2.4.2.2 No Licensee Estoppel

Under traditional contract and property principles, "one receiving bargained-for benefits under a contract may not question the consideration he has received." *See* Robert B. Orr, Note, *The Doctrine of Licensee Repudiation in Patent Law*, 63 Yale L.J. 125 (1953). Courts applied this doctrine to bar patent licensees from challenging the validity of the patents supporting their bargain since the mid-nineteenth century. *See Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 836 (1950); *United States v. Harvey Steel Co.*, 196 U.S. 310, 317 (1905); 3 William C. Robinson, A Treatise on the Law of Patents for Useful Inventions § 1252 (1890) ("The licensee, in his defense, cannot attack the patent or the title of his licensor."); *but cf. Lear, Inc. v. Adkins*, 395 U.S. 653, 663–64 (1969) (observing that "[l]ong before *Hazeltine* was decided, the estoppel doctrine had been so eroded that it could no longer be considered the 'general rule,' but was only to be invoked in an ever narrowing set of circumstances"). The applicability of this doctrine to patents came under scrutiny for failing to account for the larger public-policy considerations surrounding patents. *See* James M. Treece, *Licensee Estoppel in Patent and Trademark Cases*, 53 Iowa L. Rev. 525, 542 (1967); *cf. Sears, Roebuck & Company v. Stiffel Company*, 376 U.S. 225, 229–31 (1964) (emphasizing the public interest in a robust public domain); *Compco Corporation v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964) (same); *cf. Brulotte v. Thys Company*, 379 U.S. 29 (1964) (declaring as per se unlawful a patentee's agreement projecting royalty payments beyond the patent's expiration); *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401 (2015) (reaffirming *Brulotte*).

The Supreme Court looked to "the strong federal policy favoring free competition in ideas which do not merit patent protection" reflected in these cases in overturning more than a century of jurisprudence and rejecting the doctrine of licensee estoppel. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670–71 (1969). The Court emphasized:

> Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued.

Id.

14.4.2.4.2.3 Assignee Estoppel

Although the basic rationale of *Lear v. Adkins* (*see* § 14.4.2.4.2.2) would appear to apply to assignees (*see* 6 Moy's Walker on Patents § 17:42 (4th ed.)), a few courts have declined to extend the doctrine. *See, e.g.*, *Coast Metals, Inc. v. Cape*, 205 U.S.P.Q. 154 (D.N.J. 1979); *Baladevon, Inc. v. Abbott Laboratories, Inc.*, 871 F. Supp. 89, 95 (D. Mass. 1994) ("Outside of licensee estoppel, which is commonly understood to have been abolished by *Lear*, the status of estoppel doctrines in patent law has not been definitively settled. The weight of authority holds that the doctrine of assignee estoppel survived *Lear*."); *see also Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224–25 (Fed. Cir. 1988) (citing two decisions holding that an assignee may be estopped from challenging the validity of the assigned patent: *Roberts v. Sears, Roebuck & Co.*, 573 F.2d 976 (7th Cir. 1978), and *Coast Metals, Inc. v. Cape*, 205 U.S.P.Q. 154 (D.N.J. 1979)).

14.4.2.5 Antitrust Counterclaims

While not technically a defense, antitrust counterclaims frequently arise in patent cases. *See* 1 Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP and Antitrust § 13.1, 11–12 (2006) (observing that between 1993 and 2000, there were more than 100 reported decisions regarding counterclaims alleging the original suit was anticompetitive behavior in violation of the antitrust laws). Patent litigation can constitute an attempt to monopolize in violation of § 2 of the Sherman Act in two contexts: (1) where the counterclaimant can show that the patentee obtained the patent through fraud on the Patent Office, *see, e.g.*, *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965); and (2) where the counterclaimant can establish that the litigation is a "mere sham," which requires proving that the initial suit is objectively baseless and motivated by a desire to impose harm. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998); *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979).

Most antitrust counterclaims ultimately fail. *See* David R. Steinman & Danielle S. Fitzpatrick, *Antitrust Counterclaims in Patent Infringement Cases: A Guide to* Walker

Process *and Sham-Litigation Claims*, 10 Tex. Intell. Prop. L.J. 95, 99 & n.22 (2001). Because of the Federal Circuit's strict requirements for stating a Sherman Act § 2 claim, and the Supreme Court's concern about the scope of discovery in antitrust cases, these counterclaims can potentially be dismissed on the pleadings or on summary judgment. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

14.4.3 Remedies

Patent law provides a potent arsenal of remedies, including injunctive relief, damages (which can be enhanced based on an infringer's conduct), costs, prejudgment interest, and attorneys' fees.

14.4.3.1 Injunctive Relief

Section 283 of the Patent Act provides that courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." Injunctive relief serves to protect and uphold the right to exclude granted by a patent. *Smith Int'l v. Hughes Tool Co.*, 718 F.2d 1573, 1577–78 (Fed. Cir. 1983). The law permits both preliminary and permanent injunctions.

14.4.3.1.1 Preliminary Injunction

In assessing whether to grant a preliminary injunction, the court must consider four factors, with the burden of proof on the moving party:

(1) the likelihood of the movant's success on the merits (validity, enforceability, and infringement),

(2) the irreparability of harm to the movant without an injunction,

(3) the balance of hardships between the parties, and

(4) the demands of the public interest.

AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042 (Fed. Cir. 2010); *see generally* Chapter 3. The court must balance these factors in the interests of equity. No one factor is dispositive. *FMC Corp. v. United States*, 3 F.3d 424, 427 (Fed. Cir. 1993). Prior to the establishment of the Federal Circuit in 1982, courts rarely granted preliminary injunctive relief in patent cases on the grounds that likelihood of success on the merits typically required prior judicial determination of validity and the difficulty of establishing irreparable harm due to the availability of compensatory damages after trial. The Federal Circuit substantially eased these requirements soon after its creation by emphasizing the role of equity to protect the right to exclude and erecting a rebuttable presumption of irreparable harm once validity and continuing infringement were established. *See Smith Int'l v. Hughes Tool Co.*, 718 F.2d 1573 (Fed. Cir. 1983). A decade later, the Federal Circuit shifted toward a higher burden on movants, noting that a preliminary injunction "is a drastic and extraordinary remedy . . . not to be routinely granted." *See Intel v. ULSI*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). The Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), discussed

in § 14.4.3.1.2, provides the most authoritative word on the exercise of discretion in assessing injunctive relief in patent cases. Although the case involved the granting of permanent injunctive relief, its analysis applies with extra force in the context of preliminary injunctions—where caution in granting relief is especially important.

The Federal Circuit has since further restricted the grant of preliminary and permanent injunctions on multifeatured products by introducing a "causal nexus" requirement to inform the irreparable harm inquiry. A patentee must show a "casual nexus" between its alleged harm and the defendant's infringement before a court can issue an injunction on a multifeature product. *See Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012); *Apple Inc. v. Samsung Elecs. Co. (Apple III)*, 735 F.3d 1352 (Fed. Cir. 2013) (extending the "causal nexus" requirement to permanent injunctions). To satisfy the "causal nexus" inquiry, the patentee must prove that the infringing feature drove demand for the entire product. *See Apple, Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374–75 (Fed. Cir. 2012); *see also* § 3.2.2.2.4.

The patent holder has the burden of proof to demonstrate the predicates for a preliminary injunction. *See Abbott Labs. v. Andrx Pharm., Inc.,* 452 F.3d 1331, 1334 (Fed. Cir. 2006). This includes the burden of showing that the asserted patents likely are infringed and the absence of any substantial question that the asserted patent claims are valid (*Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1166–67 (Fed. Cir. 2014)) or that the patent is enforceable (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). On the other hand, an accused infringer challenging a preliminary injunction can be successful on evidence that would not suffice to support an invalidity judgment at trial, but merely raises a substantial question concerning either infringement or validity. *Id.* The showing of a substantial question as to invalidity requires less proof than a clear and convincing showing necessary to establish invalidity itself. *Id.* "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Id.*

14.4.3.1.2 Permanent Injunction

A court may enter a permanent injunction after a final judgment of infringement in accord with principles of equity. § 283. To obtain a permanent injunction, the plaintiff must satisfy a four-factor test, similar to the test used for preliminary injunctions. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). The plaintiff must show:

(1) That it has suffered an irreparable injury;

(2) That remedies available at law, such as monetary damages, are inadequate to compensate for that injury;

(3) That, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and

(4) That the public interest would not be disserved by a permanent injunction.

In the past, courts routinely issued permanent injunctions once infringement had been found. *See id.* at 393–94 ("The [Federal Circuit] articulated a 'general rule,' unique to patent disputes, 'that a permanent injunction will issue once infringement

and validity have been adjudged.'"). However, in *eBay*, the Supreme Court explicitly overruled such categorical granting of injunctive relief. *See id.* at 394. Accordingly, courts must carefully apply the four-factor test in determining whether to grant a permanent injunction. As with all injunctions, the district court's order is reviewed for abuse of discretion.

eBay eliminates any presumption of irreparable injury to a patent holder after a judgment of infringement and no invalidity. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (2011). The Federal Circuit also has also held that there must be a "causal nexus" between any such irreparable injury and patent infringement. *Apple III,* 735 F.3d at 1360. In a case in which the harm stems from lost sales owing to a competitor's infringement, this requires proof that "the patented features impact consumers' decisions to purchase the accused devices" even if they are not "the exclusive or predominant reason why consumers bought … [the infringing] products." *Apple Inc. v. Samsung Elecs. Co.*, 801 F.3d 1352, 1360 (Fed. Cir. 2015).

14.4.3.2 Damages

Section 284 of the Patent Act provides:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.
>
> When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.
>
> The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

Section 286 establishes a six-year statute of limitations, barring patentees from recovering damages for any infringing acts committed more than six years prior to the filing of the complaint or counterclaim for infringement.

14.4.3.2.1 Compensatory Damages

Courts apply several approaches for measuring damages "adequate to compensate" for a defendant's infringement.

14.4.3.2.1.1 Lost Profits

To recover lost-profits damages, the patentee must prove a causal relation between the infringement and its lost profits. *See Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1354 (Fed. Cir. 2001). Accordingly, the patentee must show "a reasonable probability that 'but for' the infringing activity, the patentee would have made the infringer's sales." *Id.* An accepted, "but non-exclusive" method for establishing "but-for" causation is the four-factor "DAMP" test, under which the patentee must prove:

(1) Demand for the patented product;

(2) Absence of acceptable noninfringing substitutes;

(3) Manufacturing and marketing capability to exploit the demand; and

(4) Profit he would have made.

Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (citing *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978)). Additionally, the patentee is required to show that the damages were or should have been reasonably foreseeable by an infringing competitor in the relevant market. *See id.* at 1546.

14.4.3.2.1.2 Convoyed Sales

"A 'convoyed sale' refers to the relationship between the sale of a patented product and a functionally associated nonpatented product. A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products 'together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.'" *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (citing *Rite-Hite*, 56 F.3d at 1550). "A functional relationship does not exist when independently operating patented and unpatented products are purchased as a package solely because of customer demand." *Id.*

14.4.3.2.1.3 Price Erosion

The patentee may also recover additional lost profits damages under a price-erosion theory. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1357 (Fed. Cir. 2001). To recover for price-erosion damages, patentees are required to prove that "but for" the infringement, they would have sold their patented invention at a higher price. *Id.* Furthermore, patentees must prove the number of products they would have sold at this price. *Id.* Accordingly, "the patentee's price erosion theory must account for the nature, or definition, of the market, similarities between any benchmark market and the market in which price erosion is alleged, and the effect of the hypothetically increased price on the likely number of sales at that price in that market." *Id.*

Because lost sales and price erosion are "inextricably linked," patentees must show how a price increase would have affected their profits due to lost sales. *See id.* at 1360. Consequently, the court should not independently analyze lost profits and price-erosion damages. *See id.*

14.4.3.2.1.4 Reasonable Royalty

Under § 284, the patentee may recover no less than a reasonable royalty on the infringer's sales for which the patentee has not shown entitlement to lost profits. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) (en banc). A reasonable royalty may be derived from an established royalty (if one exists) or, more

commonly, from a hypothetical negotiation between the patentee and the infringer when the infringement began. *Id.*

The hypothetical negotiation (during which the asserted patent claims are assumed to be valid and infringed) tries "to recreate the *ex ante* licensing negotiation scenario and to describe the resulting agreement." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009). Evidence relevant to calculating the reasonable royalty may include not only factual developments before the date of the hypothetical negotiation, but also events occurring after that date. *Id.* at 1333–34.

Determining the reasonable royalty based on the hypothetical negotiation commonly involves an analysis of the factors set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970):

(1) The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.

(2) The rates paid by the licensee for the use of other patents comparable to the patent in suit.

(3) The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.

(4) The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.

(5) The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.

(6) The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.

(7) The duration of the patent and the term of the license.

(8) The established profitability of the product made under the patent; its commercial success; and its current popularity.

(9) The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.

(10) The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the

licensor; and the benefits to those who have used the invention.

(11) The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.

(12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

(13) The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

(14) The opinion testimony of qualified experts.

(15) The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

Id. at 1120. The *Georgia-Pacific* factors are unprioritized, and some factors may overlap. *See ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010).

14.4.3.2.1.4.1 Damages Theories

A reasonable royalty calculation will typically require determining the royalty base and the royalty rate. The determination is relatively straightforward where the demand for a final product comprises a single patented technology, such as a drug with a patented active ingredient. The most sensible royalty base would typically be total sales revenue for the final product, what is often referred to as the entire market value. *See Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1552 (Fed. Cir. 1997) (citing *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549 (Fed. Cir. 1995) (en banc)). The royalty rate would account for alternative treatments (of which there may be few), marketing costs, and manufacturing costs.

Patent law has long struggled to deal with apportioning patent value where a patent covers only one component of a larger product. *See Cincinnati Car Co. v. New York Rapid Transit Corp.*, 66 F.2d 592, 593 (2d Cir. 1933) (Learned Hand, J.) (observing that the allocation of profits among multiple components "is in its nature unanswerable"). The problem has become particularly acute in modern patent litigation as a result of the growing use of juries called upon to apportion value based on complex and often widely divergent economic expert analyses.

In theory, a wide range of royalty bases can be appropriate with an appropriately calibrated royalty rate to account for the myriad factors affecting consumer demand. In practice, however, the open-ended nature of the *Georgia-Pacific* framework can lead to wildly divergent royalty calculations by expert economists. Especially in a jury trial, such testimony can produce outsize damage awards. As the Supreme Court recognized long ago, it would be "very grave error to instruct a jury 'that as to the measure of damages the same rule is to govern, whether the patent covers an entire machine or an improvement on a machine.'" *Seymore v. McCormick*, 57 U.S. 480, 491 (1853); *see also Westinghouse Elec. & Mfg. Co. v. Wagner Co.*, 225 U.S. 604, 614–15 (1912) ("[The] invention may have been used in combination with valuable improvements made, or other patents appropriated by the infringer, and each may have jointly, but unequally contributed to the profits. In such case, if plaintiff's patent only created a part of the profits, he is only entitled to recover that part of the net gains."); *Garretson v. Clark*, 111 U.S. 120, 121 (1884) ("When a patent is for an improvement, and not for an entirely new machine or contrivance, the patentee must show in what particulars his improvement has added to the usefulness of the machine or contrivance.)

While estimating a reasonable royalty is not an "exact science" in that there may be more than one reliable method, *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1315 (Fed. Cir. 2014), the Federal Circuit has enhanced the judge's gatekeeping role in order to prevent excessive awards. Recent decisions have sought to align the royalty base to the patented component of a product, exclude unreliable damages theories, scrutinize the admissibility of various forms of evidence, and provide limiting jury instructions.

In general, a patent holder seeking a reasonable royalty must provide substantial evidence supporting both its choice of royalty base and royalty rate. "[W]here multicomponent products are involved, the governing rule is that the ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features of the product, and no more." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) (citing *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014)).

As the Federal Circuit has warned, "reliance on the entire market value might mislead the jury, who may be less equipped to understand the extent to which the royalty rate would need to do the work in such instances." *Ericsson*, 773 F.3d at 1227 (citing *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67, 68 (Fed. Cir. 2012) (barring the use of too high a royalty base—even if mathematically offset by a "'low enough royalty rate'"—because such a base "carries a considerable risk" of misleading a jury into overcompensating, stating that such a base "'cannot help but skew the damages horizon for the jury'" and "make a patentee's proffered damages amount appear modest by comparison" (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011)))).

To cabin the risk of outsize awards in multicomponent cases, the Federal Circuit has pushed the royalty base toward the smallest salable patent-practicing unit or "SSPPU." *See Cornell Univ. v. Hewlett-Packard Co.*, 609 F. Supp. 2d 279 (N.D.N.Y. 2009) (Rader, J., sitting by designation). The Federal Circuit embraced the SSPPU

framework in *LaserDynamics Inc. v. Quanta Computer, Inc.*, 694 F.3d 51 (Fed. Cir. 2012), holding that "it is generally required that royalties be based not on the entire product, but instead on the 'smallest salable patent-practicing unit.' . . . The entire market value rule is a narrow exception to this general rule." *Id.* at 67; *see also VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1328–29 (Fed. Cir. 2014); *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 66–70 (Fed. Cir. 2012); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1336 (Fed. Cir. 2009).

Beyond calibrating the royalty base to the scale of the patent-practicing unit, courts seek to ensure that the royalty rate is based on sound economic methodology and grounded in reliable and pertinent evidence. Using the construct of the hypothetical negotiation between a willing licensor and licensee, experts use the *Georgia-Pacific* factors to determine a license rate that would have been agreed upon just before the infringement began (and based on the assumption that the patent was valid, infringed, and enforceable). The proof of an appropriate royalty rate using this method allows for necessary "approximation and uncertainty." *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 771 (Fed. Cir. 2014). Nevertheless, it must be supported by substantial evidence, which usually will be based on the application of the relevant, but not necessarily the complete list of fifteen, *Georgia-Pacific* factors. *See WhitServe, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 31–32 (Fed. Cir. 2012).

The open-ended *Georgia-Pacific* framework affords economic experts substantial leeway in determining a royalty rate. The most pertinent evidence usually comprises past licenses to the infringing or comparable technology, the value of comparable features in the marketplace, an estimate of the value of the benefit provided by the infringed features by comparison to noninfringing alternatives, or an estimate of the cost to design around the patent. *See, e.g.*, *Ericsson*, 773 F.3d at 1227 (citing *Monsanto Co. v. McFarling*, 488 F.3d 973, 978 (Fed. Cir. 2007) ("An established royalty is usually the best measure of a 'reasonable' royalty for a given use of an invention . . . ."). However, license agreements that are unrelated to the claimed invention cannot form the basis of a reasonable royalty calculation. *See, e.g.*, *Lucent*, 580 F.3d at 1327; *see also ResQNet*, 594 F.3d at 869 ("Any evidence unrelated to the claimed invention does not support compensation for infringement but punishes beyond the reach of the statute."). The Federal Circuit has observed that licenses arising out of litigation might be reliable in certain circumstances, but has cautioned that "litigation itself can skew the results of the hypothetical negotiation." *ResQNet*, 594 F.3d at 872.

In many cases, the technology either has not been previously licensed or the licenses cover a broader range of technologies than the patented invention and/or multiple product or product components. As an alternative or shortcut to considering the *Georgia-Pacific* factors, some patentees have put forward general royalty theories such as the 25% rule and the Nash Bargaining Solution (50% split of net product value). The Federal Circuit has rejected the application of these generalized "rules of thumb." *See Apple*, 757 F.3d at 1324–25; *VirnetX*, 767 F.3d at 1331–34 (rejecting the Nash Bargaining Solution); *Uniloc*, 632 F.3d at 1312 (rejecting the "25% Rule"); *but cf. Summit 6, LLC v. Samsung Electronics Co., Ltd.*, 802 F.3d 1283 (Fed.

Cir. 2015) (allowing limited use of the Nash Bargaining Solution as part of a multifaceted expert analysis).

Damages experts have begun to deploy consumer surveys to allocate value within multicomponent patented products. *See* Zelin Yang, Note, *Damaging Royalties: An Overview of Reasonable Royalty Damages*, 29 Berkeley Tech. L.J. 647, 664 (2014); S. Christian Platt & Bob Chen, *Recent Trends and Approaches in Calculating Patent Damages: Nash Bargaining Solution and Conjoint Surveys*, 86 Patent, Trademark & Copyright J. (BNA) 909 (Aug. 30, 2013). Marketing researchers have long used "conjoint analysis" to differentiate value within product configurations. *See* Paul E. Green, Abba M. Krieger & Yoram Wind, *Thirty Years of Conjoint Analysis: Reflections and Prospects*, 31 Interfaces 56 (2001); Paul E. Green and V. Srinivasan, *Conjoint Analysis in Marketing: New Developments with Implications for Research and Practice*, 54(4) J. of Marketing 3 (1990).

Conjoint analysis draws upon consumer ranking of products with different features. Researchers use statistical methods to estimate consumers' willingness to pay for particular attributes. While these methods provide a logical framework for differentiating value, the technique can be limited in practice. *See* Patricia Dyck, *Beyond Confusion—Survey Evidence of Consumer Demand and the Entire Market Value Rule*, 4 Hastings Sci. & Tech. L.J. 209, 226 (2012) (noting sensitivity to data collection methods and algorithms and the problem of combinatorial explosion); Lisa Cameron, Michael Cragg & Daniel McFadden, *The Role of Conjoint Surveys in Reasonable Royalty Cases*, Law360 (Oct. 16, 2013), http://www.law360.com/articles/475390/the-role-of-conjoint-surveys-in-reasonable-royalty-cases.

Courts have shown cautious receptivity to conjoint analysis. Recognizing the general admissibility of consumer surveys in *Oracle America, Inc. v. Google, Inc.*, No. C 10-03571 WHA, 2012 WL 850705, at *10 (N.D. Cal. Mar. 13, 2012), Judge Alsup nonetheless rejected some of Oracle's expert's conjoint analysis as unreliable while allowing some of it to be admitted. *Id.* *10–14. In *TV Interactive Data Corp. v. Sony Corp.*, 929 F. Supp. 2d 1006 (N.D. Cal. 2013), Magistrate Judge Joseph Spero held the patentee's expert testimony using conjoint analysis to be admissible. *Id.* at 1019–25.

14.4.3.2.1.4.2 FRAND Licensing of Standard Essential Patents

A growing number of technologies arise within the context of network industries in which standard protocols and interfaces promote technological innovation and greater consumer value. Industry standard-setting organizations such as the Institute of Electrical Electronics Engineers (IEEE) and the International Telecommunication Union (ITU) bring together company representatives to develop industry standards. To ensure that the industry standards reflect the best technologies while avoiding (or at least postponing) licensing disputes, the participants typically commit to license standard-essential patents (SEPs) on "reasonable and non-discriminatory" (RAND) or "fair, reasonable and non-discriminatory" (FRAND) terms. The standard-setting organizations have typically left the parameters for determining FRAND license terms undefined, *see* Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 Cal. L. Rev. 1889, 1906 (2002), leaving courts with the diffi-

cult task of determining licensing rates for highly complex products involving potentially hundreds of patents.

The valuation of SEPs presents distinct problems. Industry standards can encompass hundreds of patented technologies of carrying significance. Not surprisingly, owners of patents within a SEP pool often see their patents as particularly valuable, thereby risking hold-up and undue royalty stacking. The challenge lies in separating the value of the particular technology from the often tremendous value from standardization. Once consumers adopt a product, they become locked into the standard to varying degrees. This could provide the patentee tremendous leverage in a negotiation. With potentially hundreds of SEPs and dozens of patent owners, the problem becomes intractable if patent owners stake out aggressive positions or refuse to propose licensing terms.

In a series of recent cases, courts have surmounted this challenge by interpreting the principal goal of standard-setting agreements to be widespread adoption of the standard by barring FRAND licensors from capturing the coordination and network value of the standard. *See* § 14.4.3.2.1.4.2; *Commonwealth Sci. and Indus. Research Org. (CSIRO) v. Cisco Sys., Inc.*, 809 F.3d 1295 (Fed. Cir. 2015); *Microsoft Corp. v. Motorola, Inc.*, No. C10-1823JLR, 2013 U.S. Dist. LEXIS 60233, 2013 WL 2111217 (W.D. Wash. Apr. 25, 2013); *see also Ericsson*, 773 F.3d at 1229–35; *In re Innovatio IP Ventures LLC Patent Litig.*, No. 11 C 9308, 2013 U.S. Dist. LEXIS 144061, 2013 WL 5593609 (N.D. Ill. Oct. 3, 2013). The courts have adapted the *Georgia-Pacific* factors to serve the standard-setting context.

14.4.3.2.1.5 Marking

The Patent Act encourages patentees and persons who make, sell, or import any patented article to provide notice to the public by marking the article or, if the article cannot be marked, to label the package containing it with "patent" or "pat." and the patent number. *See* § 287(a). To further facilitate marking, § 287 has been amended under the AIA to allow patentees to "virtually mark" a product by providing the address of a webpage containing a list of the patents covering the product. The virtual-marking provision became effective September 16, 2011, and applies to any case pending or filed on or after that date. AIA § 16.

While marking is not required for patent protection, the failure to mark may limit the award of damages unless the infringer was notified of the infringement and subsequently continued to infringe. In such a case, damages may be awarded only for infringing acts performed after such notice (which includes the filing of an infringement action). "Actual notice [under the second prong of § 287(a)] requires the affirmative communication of a specific charge of infringement by a specific accused product or device." *See Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994). Mere notice of the patent itself or its ownership does not constitute sufficient notice for purposes of the actual notice prong of § 287(a). The notice inquiry must focus on the patentee's actions as opposed to the infringer's knowledge.

The marking provision of § 287(a) does not apply to patents claiming only processes or methods. *See Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1538

(Fed. Cir. 1993). Furthermore, the marking provisions do not apply to patents that contain both method and apparatus claims if the plaintiff elects to assert only the method claims in such patents. *See Crown Packaging Tech. v. Reexam Beverage Can, Co.*, 559 F.3d 1308 (Fed. Cir. 2009); *Hanson v. Alpine Valley Ski Area*, 718 F.2d 1082 (Fed. Cir. 1983). The provisions do apply, however, "[w]here the patent contains both apparatus and method claims . . . to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given." *Id.* at 1538–39.

Several district courts have interpreted the marking provision to apply to websites offering or running patented software. In *IMX, Inc. v. Lendingtree, LLC*, 79 U.S.P.Q.2d 1373, 2005 U.S. Dist. LEXIS 33179, 2005 WL 3465555 (D. Del. Dec. 14, 2005), *motion for reconsideration denied*, 2006 U.S. Dist. LEXIS 551, 2006 WL 47066 (D. Del. Jan. 10, 2006), the court held that Internet vendors of downloadable patented software must mark their websites in order to satisfy § 287(a): "[a]lthough IMX did not make or sell the computer components through which its patented system is processed, and although the IMX website itself was not the patented invention, nevertheless . . . the website is intrinsic to the patented system and constitutes a 'tangible item to mark by which notice of the asserted method claims can be given.'" Similarly, the court in *Soverain Software LLC v. Amazon.com, Inc.*, 383 F. Supp. 2d 904 (E.D. Tex. 2005), held that websites were "tangible items," and thus the patentee was required to mark its websites in order to comply with the marking provision and establish entitlement to damages for willful infringement.

14.4.3.2.2 Enhanced Damages

Under § 284, the court may increase damages up to three times the compensatory award. An award of enhanced damages and the extent of the enhancement are within the court's discretion. *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992), abrogated on other grounds; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc). In *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. ___ (2016), the Supreme Court rejected as "unduly rigid" the two-prong test that the Federal Circuit adopted in *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007). *Seagate* had required a patentee to first "show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent," and then "demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." *Id.* at 1371.

The Supreme Court did not adopt a specific test for enhanced damages, but rather gave broad guidelines within which the district court should exercise its discretion. Damages should not be enhanced in "garden-variety" infringement cases. They are "generally … reserved for egregious cases typified by willful misconduct," such as "deliberate or wanton" infringement, "malicious pira[cy]," or objective recklessness. Nonetheless, willfulness is not a per se requirement for enhanced damages and enhanced damages need not follow a finding of egregious misconduct. *Halo*, slip op. at 11, 15. "[C]ourts should continue to take into account the particular circumstances of each case in deciding whether to award damages, and in what amount." *Id*. Willful infringement must be proven by a preponderance of evidence, *id*. at 12, and usually

is based the infringer's knowledge and conduct at the time of infringement, not, for example, the merit of arguments later asserted in litigation, *id*. at 10.

14.4.3.2.3 Prejudgment Interest

Section 284 authorizes the patentee to recover prejudgment interest. The Supreme Court has held that prejudgment interest "should be awarded . . . absent some justification for withholding such an award." *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 657 (1983). The court may award prejudgment interest only on compensatory damages and not on enhanced damages. *See Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983), overruled on other grounds by *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc), and *In re Seagate*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc). Interest is calculated from the time of infringement until the date judgment is rendered. *See General Motors*, 461 U.S. at 656. The district court has substantial discretion to determine both the prejudgment interest rate and the assessment of simple or compound interest to the damages. *See Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 556–57 (Fed. Cir. 1984).

14.4.3.3 Costs

The award of costs under § 284 refers to Federal Rule of Civil Procedure 54(d)(1), which provides that "costs other than attorneys' fees shall be allowed as of course to the prevailing party unless the court otherwise directs." Fed. R. Civ. P. 54(d)(1). Section 1920, title 28 of the U.S. Code, lists the types of costs the prevailing party may recover under Federal Rule of Civil Procedure 54(d)(1), some of which include court reporter fees, docket fees, and compensation for court-appointed experts.

14.4.3.4 Attorneys' Fees

Section 285 provides that the "court in exceptional cases may award reasonable attorney fees to the prevailing party." The Supreme Court has interpreted this standard to afford district judges discretion to award attorneys' fees where it finds that the case "simply . . . stands out from others with respect to the substantive strength of a party's litigating position . . . or the unreasonable manner in which the case was litigated." *Octane Fitness LLC v. Icon Health & Fitness Inc.*, 134 S. Ct. 1749, 1755–76 (2014) (rejecting the Federal Circuit's rule that a defendant may only be awarded fees where it demonstrates that the patentee litigated with subjective bad faith and that the suit was objectively baseless). The Court directed district courts to consider the totality of the circumstances. Such determinations are reviewable for abuse of discretion. *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 1749 (2014).

14.5 Other Patent-Related Causes of Action

This section provides an overview of other patent-related causes of action that do not relate to enforcement, such as false marking and civil actions challenging decisions of the USPTO's Patent Trial and Appeal Board (PTAB).

14.5.1 False Marking

While § 287 encourages the marking of patented products with the patent number, § 292 imposes a civil penalty for false marking. A party asserting false marking must show by a preponderance of the evidence that an unpatented article was marked with intent to deceive the public. *Forest Grp., Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1300 (Fed. Cir. 2009). False marking claims must be pled with particularity under Federal Rule of Civil Procedure 9(b). *In re BP Lubricants USA Inc.*, 637 F.3d 1307, 1309 (Fed. Cir. 2011).

Prior to the enactment of the AIA on September 16, 2011, the false marking statute had been enforceable as a *qui tam* action, in which anyone may bring suit on behalf of the government and retain one-half of the recovery. As a response to the proliferation of false marking suits in recent years, the AIA amended § 292 to eliminate the *qui tam* provision so that only the U.S. government may sue to recover the statutory penalty. AIA § 16. In addition, private parties may bring false marking actions only if they have suffered a "competitive injury" as a result of false marking, and damages are limited to an amount "adequate to compensate for the injury." *Id.* Marking with an expired patent number is no longer deemed a false marking violation. The amendment to § 292 became effective September 16, 2011, and applies to any case pending or filed on or after that date.

14.5.2 Civil Actions Under §§ 145 and 146

In most instances, a party dissatisfied with a PTAB decision files an appeal to the Federal Circuit under § 141. Alternatively, a party may challenge the PTAB decision in a civil action filed against the USPTO in federal district court. *See* §§ 145 (civil action to obtain patent), 146 (civil action for interference/derivation proceedings).

Actions brought under §§ 145 or 146 have a "hybrid" nature of an appeal and a trial de novo: while new evidence may be introduced, issues that were not raised during the USPTO proceedings cannot be raised in the district court action absent compelling circumstances. *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102–03 (Fed. Cir. 1994). If a party introduces new evidence, the district court can make de novo findings with respect to factual issues to which the new evidence relates. *Mazzari v. Rogan*, 323 F.3d 1000, 1005 (Fed. Cir. 2003) ("If the parties choose to present additional evidence . . . the district court would make de novo factual findings if the evidence is conflicting."). However, if no new evidence is introduced, the district court reviews the USPTO's fact findings under the "substantial evidence" standard of review. *Id.* at 1004–05.

In *Hyatt v. Kappos*, the Supreme Court unanimously held that parties may present new evidence in the district court action without regard to whether the evidence could have been presented during the USPTO proceeding. 132 S. Ct. 1690, 1700 (2012). In addition, the district court must make de novo factual findings based on the new evidence and evidentiary record from the USPTO. *Id.*

14.6 Appeals and Parallel Litigation

The blockbuster patent case can unfold before multiple judicial and quasi-judicial bodies. As discussed in §§ 14.2.5.5–6, parties can request the USPTO to reexamine issued patents. The following section discusses the appellate process and its consequences for patent cases as well as the various forms of parallel litigation that can occur.

14.6.1 Appeals to the Federal Circuit

In 1982, Congress created the U.S. Court of Appeals for the Federal Circuit and gave it exclusive jurisdiction over all appeals in patent cases. *See* 28 U.S.C. § 1295 (2000). The Federal Circuit was deemed necessary because patent cases were "inconsistently adjudicated," which led to forum shopping. S. Rep. No. 97-275 at 5 (1981). Congress believed that unpredictability of patent law hampered technological innovation.

14.6.1.1 Appellate Jurisdiction

The Federal Circuit has jurisdiction over any final judgment of a district court if the district court's jurisdiction was based on 28 U.S.C. § 1338. 28 U.S.C. § 1295(a)(1). Section 1338 in turn provides that the district courts have original, exclusive jurisdiction over cases arising under the Patent Act. *See* 28 U.S.C. § 1338(a).

14.6.1.2 Choice of Law

One of the many complications arising from patent cases stems from this "exclusive" subject-matter jurisdiction. Unlike other cases, patent cases involve intercircuit choice-of-law questions because of the Federal Circuit's subject matter, as opposed to regional, appellate jurisdiction. This limited jurisdiction has led the Federal Circuit to create a choice-of-law jurisprudence reminiscent of the *Erie* doctrine.

Where a question of law relates to the Federal Circuit's exclusive patent-law jurisdiction, courts should apply Federal Circuit law. *See Lab. Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1330 (Fed. Cir. 2004) (regarding the interlocutory appealability of an injunction order). If not, courts should apply the regional circuit's law. Hence, substantive matters like claim construction require the district court to follow Federal Circuit precedent. Procedural matters like whether a party waived an issue by not moving for judgment as a matter of law require the district court to apply its regional circuit's precedent. Difficulties arise when courts face a procedural issue that potentially implicates a substantive patent law issue. Federal Circuit law

controls such an issue if "the issue pertains to patent law, if it bears an essential relationship to matters committed to [the Federal Circuit's] exclusive control by statute, or if it clearly implicates the jurisprudential responsibilities of [the Federal Circuit] in a field within its exclusive jurisdiction." *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc in relevant part) (internal quotation marks omitted). The Federal Circuit decides whether an issue pertains to patent law on an issue-by-issue basis. *See Mars Inc. v. Kabushiki-Kaisha Nippon Conlux*, 24 F.3d 1368 (Fed. Cir. 1994).

Table 14.10 presents a sampling of the issues requiring choice-of-law analysis and the Federal Circuit's rationale in deciding which law to apply. In general, if there is a cognizable argument that allowing differences in the procedural law will undermine the uniformity of patent law, the Federal Circuit will hold that its body of precedent controls the outcome.

Table 14.10
Choice of Law

Issue	Does Federal Circuit Law Govern?/Reasoning
Whether the district court had subject-matter jurisdiction to hear a claim of Japanese patent infringement. *Mars Inc. v. Kabushiki-Kaisha Nippon Conlux*, 24 F.3d 1368, 1371 (Fed. Cir. 1994).	Yes: "[The issue] is of importance to the development of the patent law and is clearly a matter that falls within the exclusive subject matter responsibility of this court."
Whether a party waived its right to dispute the sufficiency of the evidence supporting the jury's antitrust verdict. *Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1365 n.7 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006).	No: "Because we decide antitrust issues that do not implicate patent law, including market definition, under the law of the regional circuits, . . . we similarly apply [regional circuit] law to determine whether or not [the party] has preserved its right to appeal."
Whether an injunction against copending patent litigation in another district court is immediately appealable. *Lab. Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1330 (Fed. Cir. 2004).	Yes: "Because of the importance of national uniformity in patent cases, we hold that injunctions arbitrating between copending patent declaratory judgment and infringement cases in different district courts are reviewed under the law of the Federal Circuit."

Prior to September 16, 2011, the well-pleaded complaint rule introduced an additional wrinkle to the choice-of-law analysis. Where the district court's original jurisdiction did not stem from § 1338 because, for example, the plaintiff did not assert a patent claim, the Federal Circuit had no appellate jurisdiction and the district court was instead bound by its regional circuit law. This situation could arise where the patent case stemmed from the defendant's counterclaim to a nonpatent cause of ac-

tion. *See, e.g.*, *Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002). The AIA closed this gap in the Federal Circuit's jurisdiction by amending § 1295 so as to provide the Federal Circuit with exclusive jurisdiction over all patent appeals, including those cases where the patent-related cause of action exists only as a counterclaim. AIA § 19. This statutory amendment, which overrules the holding in *Holmes Group*, applies to actions filed on or after September 16, 2011.

14.6.1.3 Interlocutory Appeals

The Federal Circuit has appellate jurisdiction over any interlocutory appeal from a case based on the district court's original jurisdiction over patent cases. § 1292(c)(1). As with other federal courts of appeals, the Federal Circuit has discretion to decline an interlocutory appeal. *See, e.g.*, *In re Convertible Rowing Exerciser Patent Litig.*, 903 F.2d 822 (Fed. Cir. 1990).

District courts most frequently encounter the question of interlocutory appealability with respect to claim construction issues. However, the Federal Circuit almost always refuses to entertain interlocutory appeals on claim construction orders. *See Nystrom v. TREX Co., Inc.*, 339 F.3d 1347, 1351 (Fed. Cir. 2003) ("Such appeals are rarely granted."). Nevertheless, the Federal Circuit may grant an appeal on a claim construction order if it already has jurisdiction over a prior claim construction order, for example, if a preliminary injunction is already on appeal. *See, e.g.*, *Regents of the Univ. of Cal. v. Dako N. Am., Inc.*, 477 F.3d 1335 (Fed. Cir. 2007).

14.6.2 Parallel Litigation Forums

Some patent cases spawn parallel litigation, presenting a host of issues regarding stays and coordination of discovery that was dealt with in prior chapters. A district court should be aware of the potential for parallel litigation and where it might be filed.

14.6.2.1 International Trade Commission

Under 19 U.S.C. § 1337, the U.S. International Trade Commission (ITC) has jurisdiction to bar importation of articles that infringe a valid and enforceable U.S. patent (as well as other federal intellectual property rights). *See generally* Peter S. Menell, et al., Section 337 Patent Investigation Management Guide (Lexis 2012). The ITC has become increasingly popular over the past decade due to its speed and expertise in patent litigation. The typical ITC proceeding is completed in under eighteen months. Although the ITC may not award damages, it can issue exclusion orders preventing the importation of infringing goods into the United States.

ITC cases are heard by an administrative law judge (ALJ), who conducts an evidentiary hearing that resembles a bench trial. The ALJ's determinations are reviewed by the ITC's six-member commission, whose decisions are subject to review by the President. If the President fails to disapprove the ITC's determination within sixty days, it becomes final, and the losing party may file an appeal to the Federal Circuit.

Because ITC proceedings are governed by the Administrative Procedure Act, the Federal Circuit reviews the ITC's factual findings for substantial evidence and its legal conclusions de novo. 5 U.S.C. § 706(2)(A), (E). ITC decisions are not binding on district courts, and have no *res judicata* or collateral estoppel effect. *See Tex. Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996). Patent actions may proceed simultaneously in district court and in the ITC, especially if the patentee seeks both damages (only available in the district court) and an exclusion order (only available from the ITC). Under 28 U.S.C. § 1659(a), parties to a civil action that are also respondents in a parallel proceeding before the ITC can move for a stay of the district court proceedings as a matter of right. *See* § 2.2.6.2.1.

14.6.2.2 Patent Office Reexamination or Review

As discussed previously (*see* §§ 14.2.5.5–7) litigants can request that the USPTO reexamine or review the validity of issued patents. High-stakes patent litigation often leads to requests for reexamination or review to invalidate a patent or alter its scope. To avoid duplicative proceedings, district courts may decide to stay the litigation pending reexamination or review. *See* § 2.2.6.4.1.

14.6.2.3 Other District Courts and MDL Proceedings

Patent litigation can lead to the proverbial "race to the courthouse," especially where declaratory judgment jurisdiction is available. In other instances, a defendant may choose to file a countersuit for infringement of its own patents in a different jurisdiction. Lastly, the Judicial Panel on Multidistrict Litigation occasionally consolidates patent cases nationwide before a single judge for pretrial proceedings. *See* § 2.2.6.3; U.S. Judicial Panel on Multidistrict Litigation, Pending MDLs, http://www.jpml.uscourts.gov/pending-mdls-0.

14.6.2.4 Foreign Courts

Complex patent litigation may be occurring simultaneously overseas because each nation operates its own patent system. While many nations have harmonized their patent laws to a significant extent, it is an abuse of discretion for a district judge to take jurisdiction over infringement claims based on other nation's patents. *See Voda v. Cordis Corp.*, 476 F.3d 887 (Fed. Cir. 2007). Indeed, the Federal Circuit's holding that the U.S. district courts cannot consolidate patent-infringement claims from multiple countries ensures that parallel litigation will occur over particularly valuable inventions. In such cases, district courts should be sensitive to the potential for strategic effects that certain types of motions (for example, regarding depositions or privileged documents) can create.

Appendix A
Patent Glossary

Note: Many of these definitions are derived from the USPTO glossary, available at http://www.uspto.gov/main/glossary/index.html.

abandonment: A patent application becomes abandoned for failure to file a complete and proper reply within the time period provided under 37 C.F.R. § 1.134 and § 1.136 unless an office action indicates otherwise. Abandonment may be either of the invention or of an application. An abandoned application, in accordance with 37 C.F.R. §§ 1.135 and 1.138, is one which is removed from the Patent Office docket of pending applications. *See* § 14.3.4.1.6.

abstract of the disclosure: A concise statement of the technical disclosure, including that which is new in the art to which the invention pertains.

agent (practitioner, representative): One who is not an attorney but is authorized to act for or in place of the applicant(s) before the USPTO, that is, an individual who is registered to practice before the USPTO.

all-limitation rule (all-elements rule): A doctrine requiring that an allegedly infringing device contain every element of a claim to establish infringement, either literally or under the doctrine of equivalents. *See* § 14.4.1.4.2.1.1.

analogous art (pertinent art, relevant art): In a nonobviousness analysis, art that a person having ordinary skill in the art would have consulted in attempting to solve the problem addressed by the innovation. Analogous art must be either within the same field of endeavor as the invention, or from a different field but reasonably pertinent to the same problem. *See* § 14.3.5.3.2.

antedate (swearing behind a reference): A procedure whereby a patent applicant can establish an invention date earlier than the effective date of prior art that has been cited against his claims in a rejection for non-obviousness (§ 103) or lack of novelty (§§ 102(a) or (e)).

anticipation: A single prior art reference anticipates a claim when it contains all the elements of the claim. The claim is rejected for lack of novelty under § 102.

assignment: A transfer of ownership of a patent application or patent from one entity to another. Record all assignments with the USPTO Assignment Services Division to maintain clear title to pending patent applications and patents.

benefit claim: The claiming by an applicant in a nonprovisional application of a benefit of an invention disclosed in a prior-filed, co-pending (under examination at

the same time), provisional, or nonprovisional application, or international application designating the United States for the purposes of securing an earlier effective filing date for the nonprovisional application.

best mode: The specification must set forth the best mode, or preferred embodiment, contemplated by the inventor at the time of filing, of making and using his or her invention (§ 112), or the patent may be declared invalid. *See* § 14.3.3.3. The AIA eliminated failure to set forth best mode as a basis for patent invalidity.

blocking patent: Two or more patented inventions block each other when one cannot be practiced without infringing the other, and vice versa. Blocking patents often arise when an improvement on an invention is patented: the improvement cannot be practiced without infringing the original patent, and the original inventor cannot practice the improvement without infringing the improvement patent. The parties commonly agree to a cross-license to resolve the issue.

central claiming: A claiming regime in which a claim recites the preferred embodiment of the invention but is deemed to cover a range of equivalents to that preferred embodiment.

Certificate of Correction: Minor errors in an issued patent can be corrected with a Certificate of Correction. *See* § 254 (correction of USPTO mistake); § 255 (correction of applicant mistake).

claim restriction: A discretely claimed component of a patent claim. *See also element*.

claim vitiation: An accused device cannot be infringing if it would effectively vitiate (or eliminate) any claim limitation. This doctrine is a corollary of the all-elements rule. *See* § 14.4.1.4.2.1.1.1.

claims: Claims delineate the patented invention. The patent specification must conclude with a claim or claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his or her invention or discovery.

classification: Patents are classified by a system using a three-digit class and a three-digit subclass to describe every similar grouping of patent art. Multiple classification codes may describe a single invention.

combination patent: A patent granted for an invention that unites existing components in a novel way.

composed of (used when defining the scope of a claim): A transitional phrase that is interpreted in the same manner as either *consisting of* or *consisting essentially of*, depending on the facts of the particular case.

comprising (used when defining the scope of a claim): A transitional phrase that is synonymous with *including*, *containing* or *characterized by*; is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Comprising* is a term of art used in claim language that means that the named elements are essential in describing the invention.

conception: The formation in the mind of the inventor of the definite and permanent idea of the complete invention that is thereafter reduced to practice. *See* § 14.3.4.1.2.1.

consisting essentially of (used when defining the scope of a claim): A transitional phrase that limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. For the purposes of searching for and applying prior art under §§ 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, *consisting essentially of* will be construed as equivalent to *comprising*.

consisting of (used when defining the scope of a claim): A transitional phrase that is closed and excludes any element, step, or ingredient not specified in the claim.

continuation: A second application for the same invention claimed in a prior nonprovisional application and filed before the first application becomes abandoned or patented.

continuation-in-part (CIP): An application filed during the lifetime of an earlier nonprovisional application that repeats some substantial portion or all of the earlier nonprovisional application and adds matter not disclosed in the earlier nonprovisional application. *See* § 14.2.3.4.

contributory infringement: Section 271(c) imposes liability when a party "offers to sell or sell 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." *See* § 14.4.1.3.2.

counterpart: An application filed in a foreign patent office that is substantially similar to the patent application filed with the USPTO and is based on some or all of the same invention. The two applications would generally have the same applicant.

covered business method review (CBMR): The America Invents Act instituted a variant of the postgrant review process for business method patents of all filing dates. Patent validity can be challenged on any ground, and covered business method review is broader than inter partes review. *See* § 14.2.5.8.1.

critical date: The date one year prior to the date a patent application is filed. The patent will be invalid for lack of novelty if the invention was in public use in the United States, or patented or described anywhere in the world, prior to the critical date. *See* § 102(b); § 14.3.4.1.5.

declaration (of inventor): A document in which an applicant for patent declares that he or she (1) made or authorized the application, (2) believes that he or she is the original inventor or an original joint inventor of a claimed invention in the application; and (3) acknowledges that any willful false statement made in the declaration is punishable under 18 U.S.C. § 1001 by fine or imprisonment of not more than five (5) years, or both. These requirements apply to applications filed after September 15, 2012. *See* M.P.E.P § 602.01(a)–(b). For applications filed prior to that date, the declaration also required the inventor's country of citizenship. An oath or declaration must be filed in each nonprovisional patent application.

definiteness: Shorthand for the requirement, under § 112(b), that the claims particularly point out and distinctly claim the subject matter that the applicant regards as his or her invention. *See* § 14.3.3.4.

dependent claim: A claim that refers back to and further limits a preceding dependent or independent claim. A dependent claim includes by reference every limitation of the claim from which it depends.

derivation proceeding: The AIA established this new proceeding to allow an inventor to challenge an earlier-filed third-party application or patent claiming subject matter that was derived from the inventor's own work. This proceeding partially substitutes for interference proceedings. *See* § 14.3.4.2.5.

design patent: A patent for a new, original, and ornamental design for an article of manufacture.

designation: A selection made by the applicant, in the Request for an International Application filed under the Patent Cooperation Treaty (PCT), as to the countries in which protection for an invention is desired.

diligence: To establish a conception date as the date of invention, the inventor must have worked diligently following conception to reduce the invention to practice. In the course of an interference, a party can establish its conception date as the date of invention by showing reasonable diligence from before the other's conception until their own reduction to practice date. *See* § 102(g); § 14.3.4.1.2.3.

direct infringement: A person is liable for direct infringement if he or she "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore." § 271(a). An accused infringer's intent is immaterial, as patent infringement is a strict liability offense. *See* § 14.4.1.1.

disclaimer: There are two types of disclaimers under § 253: statutory disclaimers and terminal disclaimers. A patentee may make a statutory disclaimer of any complete claim, stating therein the extent of his or her interest in such patent. A patentee may make a terminal disclaimer to disclaim or dedicate to the public the remaining time of the term of the patent granted. A terminal disclaimer may be filed for the purpose of overcoming a judicially created double-patenting rejection. Disclaimers are required to be in writing and recorded in the USPTO, and are considered part of the original patent to the extent of the interest actually possessed by the disclaimant and by those claiming under him or her.

disclosure: In return for a patent, the inventor gives as consideration a complete disclosure of the invention for which protection is sought. *See* § 14.3.3.

divisional application: A later application for an independent or distinct invention disclosing and claiming only a portion of the subject matter disclosed in the earlier or parent application.

doctrine of equivalents: A judicially developed principle for finding patent infringement when the accused process or product falls outside the literal scope of the patent claims. The essential objective inquiry is: "Does the accused product or process contain elements equivalent to each claimed element of the patented invention?" *See* § 14.4.1.4.2.

double patenting: An inventor may not obtain claims in more than one patent directed either to the same invention or an obvious variation of the same invention. A rejection by the USPTO based on obviousness can be overcome by filing a terminal disclaimer stating that the additional patents will expire on the same date as the first patent. A terminal disclaimer, therefore, eliminates any improper extension of the initial patent term. *See* § 14.4.2.4.1.

effective filing date: The filing date of an earlier-filed application accorded under §§ 119/365(a)/365(b) (foreign filing or domestic provisional application), 120/365(c) (earlier U.S. filing date), or 121 (divisional applications), or if none of these sections is satisfied, the actual filing date of the patent.

electronic file wrapper: A system that provides a way to access electronic copies of the correspondence, documents, and other pertinent records used in considering a particular patent application.

element: A discretely claimed component of a patent claim. *See also claim restriction*.

embodiment: A manner in which an invention can be made, used, practiced, or expressed. *See best mode.*

enablement: The specification must describe in "full, clear, concise, and exact terms" how to make and use the invention such that any person skilled in the art can do so without undue experimentation. *See* § 14.3.3.2.

ex parte reexamination: A procedure whereby patentees and third parties can seek reexamination of issued patents. *See* § 14.2.5.5.2.

experimental use: Experimental use has two distinct meanings within patent law. First, experimental use is an exception to the public-use statutory bar under § 102(b). So long as the public use was to test or experiment with the invention, it is not counted in computing the one-year statutory bar. Second, experimental use is a defense to infringement and requires that the construction and use of the patented invention be for scientific purposes only. *See* § 14.3.4.1.5.1.

express abandonment: *See abandonment*.

file wrapper: The folder into which papers for a particular application are collected and maintained. It contains a complete record of proceedings in the USPTO from the filing of the initial patent application to the issued patent. The file wrapper of a patent application that is maintained by the USPTO is the official record.

file wrapper estoppel: *See prosecution history estoppel.*

filing date: The date of receipt in the USPTO of an application which includes (1) a specification containing a description and, if the application is a nonprovisional application, at least one claim, and (2) any required drawings.

final office action: A USPTO action on the second or any subsequent examination or consideration by an examiner that is intended to close the prosecution of a nonprovisional patent application.

First Sale Doctrine/Exhaustion Principle: The first unrestricted sale of a patented product exhausts the patentee's control over that product, and it can be resold and repaired without implicating the patent owner's rights. This is a form of implied license. *See* § 14.4.2.2.1.1.

grace period: The one-year period between the critical date and the filing date, during which the invention may be offered for sale or used publicly in the United States,

or described in a printed publication or patented anywhere in the world without invalidating the patent under § 102(b).

***Handgards* claim**: An antitrust counterclaim to a patent infringement suit, alleging that the patentee either knew the patent was invalid or was not being infringed. *See Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979).

having (used when defining the scope of a claim): A transitional phrase that is synonymous with *including*, *containing*, or *characterized by*; is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

improvement patent: A patent based on an improvement to a preexisting invention.

indefiniteness: *See definiteness*.

independent claim: A claim that does not refer back to or depend on another claim.

indirect infringement: Indirect infringement covers conduct by a person who assists or supports another's direct infringement of a patented invention. Direct infringement must be established as a predicate for each act of indirect infringement. *See* § 14.4.1.3.

inducement: Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." A finding of inducement requires that a patent owner establish evidence of culpable conduct directed toward encouraging another's infringement. *See* § 14.4.1.3.1.

inequitable conduct: Where a patent applicant breaches the duty to prosecute a patent application in good faith and candor. *See* 37 C.F.R. § 1.56; *see also* § 14.4.2.3.1.

information disclosure statement (IDS): A list of patents, publications, U.S. applications, or other information submitted for consideration by the USPTO in a nonprovisional patent application filed under § 111(a) to comply with applicant's duty to submit information that is material to the patentability of the claimed invention. *See* § 14.2.2.1.

inter partes reexamination: A procedure allowing third parties to seek invalidation by the USPTO of patents granted on applications filed on or after November 29, 1999. It was phased out beginning on September 16, 2011, and replaced by the AIA's inter partes review procedure. *See* § 14.2.5.5.3.

inter partes review (IPR): A procedure established by the AIA for third parties to seek invalidation of patents. *See* § 14.2.5.6.

interference: A proceeding, typically conducted before the Board of Patent Appeals and Interferences or in certain circumstances before a district court, to determine priority of invention between a pending application and/or one or more unexpired patents.

intervening rights: Claims that were modified at reissue, for any reason, are subject to a reliance-type interest (intervening rights). Third parties may rely on the claims of an issued patent. *See* § 14.2.5.4.2.2.

invention: Any art or process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.

invention date: The date either on which an invention is reduced to practice or conceived, so long as the inventor can show reasonable diligence from conception until reduction to practice.

issue date: The date that a patent application becomes a U.S. patent. The issue date is the date that patent rights can be exercised.

***Jepson* claim format**: A claim containing a preamble explaining the current state of the art, followed by a description of the claimed patentable improvement.

joint infringement: Liability for joint infringement can be found only where one party controlled or directed each step in the process. *See* § 14.4.1.3.3.

joint inventor: An inventor who is named with at least one other inventor in a patent application, wherein each inventor contributes to the conception of the invention set forth in at least one claim in a patent application.

laches: An equitable defense that the plaintiff unreasonably delayed in asserting an infringement claim. If a patentee files suit more than six years after he or she became (or reasonably should have become) aware of the alleged infringement, a presumption of laches arises, and the patentee must establish legitimate reasons for the delay. This defense does not bar the plaintiff's action entirely, but prevents the recovery of any damages accrued prior to the filing of the action. *See* § 14.4.2.3.4.

license: An agreement between a patent owner and a licensee that the patent owner will not sue the licensee for acts that would otherwise constitute infringement.

limitation: A component of an invention described in a patent claim. *See element*.

literal infringement: Literal infringement requires an accused device to satisfy every element of the asserted patent claim precisely. *See* § 14.4.1.4.1.

***Markush* claim format**: A *Markush* claim claims a genus of inventions in a single claim where the family of inventions all share a common trait, for example, "a chemical compound of the formula COOH–CH2-R, where R is selected from the group consisting of _____." *Markush* claims normally do not occur outside of the field of chemistry.

means-plus-function claim format: A means-plus-function claim defines one or more elements of the claim as a "means for [performing a function]." This special type of limitation is interpreted to cover the structure(s) described in the specification for performing the claimed function as well as equivalents of that/those structure(s) as of the time of filing. *See* § 112(f); § 14.4.1.4.1.1.

method claim: A claim covering a way of doing something, typically conveyed as a series of steps.

multiple dependent claim: A dependent claim that further limits and refers back in the alternative to more than one preceding independent or dependent claim. Acceptable multiple dependent claims shall refer to preceding claims using the terms *or*, *any one of*, *one of*, *any of*, *either*. A multiple dependent claim may not depend on another multiple dependent claim, either directly or indirectly.

national stage application: An application that has entered the national phase of the Patent Cooperation Treaty by the fulfillment of certain requirements in a national patent office. Such an application is filed under § 371 in the United States and is referred to as a "371 application."

new matter: Information in an amendment to a pending patent that departs from the original disclosure. Under § 132, amendments cannot introduce new matter into the disclosure of the invention.

nonfinal office action: An office action made by the examiner where the applicant is entitled to reply and request reconsideration or further examination, with or without making an amendment.

nonobviousness: The requirement that to be patentable, an invention be sufficiently different from the prior art that, at the time it was made, it would not have been obvious to a person having ordinary skill in the art. *See* § 14.3.5.

nonpatent literature: Documents and publications that are not patents or published patent applications but are cited as references for being relevant in a patent prosecution. For example, a magazine article or doctoral thesis relevant to a claimed invention might be cited as nonpatent literature. Typically, references cited in an application are grouped into domestic patents and patent application publications, foreign patents, and nonpatent literature.

nonprovisional application: The "regular" type of patent applications, as distinct from provisional applications filed under § 111(b), often referred to simply as "applications." *See* § 14.2.2.2.1.

nonresponsive amendment: An amendment filed by the applicant that does not fully respond to the examiner's office action in accordance with 37 C.F.R. § 1.111.

normal publication: Regular 18-month publication or redacted publication of a nonprovisional application.

notice: The practice of marking a patented article with the word *patent* followed by the patent number. Without notice, the patentee may recover only for damages that occurred after the infringer received a charge of patent infringement.

notice of abandonment: A written notification from the USPTO that an application has been declared abandoned or, in other words, is no longer pending. If the application was abandoned unintentionally or due to USPTO error, the applicant has a deadline of two months from the issue date of the notice of abandonment to file either (1) a petition to revive the application or (2) a request to reinstate the application.

notice of allowance: A notification to the applicant that he or she is entitled to a patent under the law and requesting payment of a specified issue fee (and possibly a publication fee as well) within three months (non-extendable) from the mailing date of the notice of allowance.

notice of references cited (also known as a PTO-892 form): A list of relevant references cited by a patent examiner in an office action. The following are some examples of such references: domestic patents, domestic patent application publications, foreign patents or patent publications, publications, electronic documents, and affidavits.

novelty: The requirement under § 102 that an invention be sufficiently new relative to the prior art. *See* § 14.3.4.

oath: *See declaration (of inventor)*.

obviousness: *See nonobviousness*.

office action: The patent examiner's responses to the patent application and subsequent amendments.

on-sale bar: Section 102(b) specifies an on-sale bar, such that if an invention has been on sale for over one year, it is no longer patentable. *See* § 14.3.4.1.5.2.

opposition: A procedure allowing a third party to request a patent application's refusal or an issued patent's annulment.

original application: *Original* is used in the patent statute and rules to refer to an application that is not a reissue application. An original application may be a first filing or a continuing application.

parent application: The term *parent* is applied to an earlier application of the inventor disclosing a given invention.

patent: A quasi-property right granted by the government of the United States to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention.

Patent Cooperation Treaty (PCT): A mechanism by which an applicant can file a single application that, when certain requirements have been fulfilled, is equivalent to a regular national filing in each designated country. There are currently over 130 PCT contracting states.

patent pending: A phrase that often appears on manufactured items. It means that someone has applied for a patent on an invention that is contained in the manufactured item. It serves as a warning that a patent may issue that would cover the item and that copiers should be careful because they might infringe if the patent issues. Once the patent issues, the patent owner will stop using the phrase "patent pending" and start using a phrase such as "covered by U.S. Patent Number XXXXXXX."

patent term: The period of time during which a patent is enforceable. For patent applications filed after June 8, 1995, the expiration date is twenty years from the earliest effective filing date, subject to various extensions for delays occurring during prosecution and regulatory approval for drug-related patents. *See* § 14.2.4.

Patent Trial and Appeal Board (PTAB): The AIA created this administrative body to replace the Board of Patent Appeals and Interferences (BPAI). It hears appeals by a patent applicant from a USPTO patent examiner's final refusal to allow a patent application or adverse decision in an ex parte patent reexamination proceeding, inter partes and postgrant review proceedings filed by a party challenging the validity of an issued patent, derivation proceedings filed by a subsequent patent applicant claiming that an earlier patent applicant for the same invention derived the invention from the subsequent patent applicant, and interference proceedings to determine the first inventor of an invention commenced before September 16, 2012. PTAB decisions concerning inter partes and postgrant reviews and ex parte reexamination proceedings may be appealed only to the U.S. Court of Appeals for the Federal Circuit. In several circumstances, a civil action against the USPTO in the U.S. District Court for the Eastern District of Virginia may be instituted after a final

PTAB decision: (1) where a patent applicant is dissatisfied with a PTAB decision concerning the final rejection of the patent application unless the applicant has appealed to the Federal Circuit (*see* § 145); (2) in a derivation proceeding where the losing party initially filed a notice of appeal from the PTAB decision to the Federal Circuit, the adverse party may request that further proceedings instead be conducted in the Eastern District of Virginia (*see* AIA § 7); and (3) where a party is dissatisfied with the decision in an interference proceeding over which the PTAB has jurisdiction, unless that party has appealed to the Federal Circuit (*see* § 146).

peripheral claiming: A regime in which an applicant delineates the precise boundaries of the claimed area of exclusivity, in contrast to central claiming in which the applicant defines the claim directly.

person: For purposes of small entity determination, a person is defined as any inventor or other individual (e.g., an individual to whom an inventor has transferred some rights in the invention) who has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license any rights in the invention.

person having ordinary skill in the art (PHOSITA): A hypothetical person with knowledge of all analogous art from whose perspective nonobviousness, written description, and enablement are analyzed. *See* §§ 103, 112; *see also* §§ 14.3.3, 14.3.5.3.1.

petition to make special (PTMS): An applicant may petition the USPTO to examine his or her application ahead of other pending applications. A petition to make special may be granted on the basis of an inventor's age or poor health, that the patent will enable manufacture of the invention, is presently being infringed, relates to certain fields including superconductivity, HIV/AIDS, and counter-terrorism, or several other reasons.

post-grant review (PGR): Under this new procedure added by the AIA, third parties may file a petition seeking to cancel one or more patent claims within nine months of a patent's issue or reissue date. *See* § 14.2.5.8.

preferred embodiment: How the inventor sets forth the best mode for carrying out the claimed invention in the application.

printed publication: A reference that is sufficiently accessible to the public interested in the invention. *See* § 14.3.4.1.1.2.

prior art: The general category of technologies and events against which novelty and nonobviousness are evaluated. What qualifies as prior art is specified in §§ 102 and 103.

priority claim: Claims under §§ 119(a)–(e) and 120 for the benefit of the filing date of earlier filed applications.

priority date: The first filing of a patent application anywhere in the world describing an enabled invention usually establishes the priority date for that invention. *See* § 14.2.2.2.3.

pro se: Used to designate an independent inventor who has elected to file an application by himself or herself without the services of a licensed representative.

prosecution: The process for applying for and obtaining a patent from the USPTO.

prosecution history estoppel: A doctrine that prevents a patentee from obtaining coverage through the doctrine of equivalents over subject matter that was surrendered during prosecution. *See* § 14.4.1.4.2.1.2.

provisional application: A provisional application for patent is a U.S. national application for patent filed in the USPTO under § 111(b), which allows filing without a formal patent claim, oath or declaration, or any information disclosure (prior art) statement. A provisional application can establish an early effective filing date in a nonprovisional patent application filed under § 111(a) and automatically becomes abandoned after one year. It also allows the term *patent pending* to be applied. *See* § 14.2.2.2.4.

reads on: An accused device, manufacture, composition, or process "reads on" (and hence infringes) a patent claim if it embodies each of the claim limitations. Similarly, a patent claim "reads on" a prior art reference (and hence is invalid) if the prior art reference contains each of the claim limitations.

reasonable diligence: First-to-conceive inventor must have been reasonably diligent in working to reduce the invention to practice between the time "just prior" to the later inventor's date of conception until the first-to-conceive inventor's reduction to practice. Reasonable diligence is only at issue when the inventor was first to conceive but second to reduce to practice. *See* § 14.3.4.1.2.3.

recapture rule: Bars a patentee from seeking reissue claims that regain subject matter that was surrendered to obtain allowance during the original prosecution. *See* § 14.2.5.4.2.1. This rule is similar to prosecution history estoppel. *See* § 14.4.1.4.2.1.2.

record copy: Original copy of an international application filed under the Patent Cooperation Treaty maintained by the International Bureau of the World Intellectual Property Organization.

redacted publication: A patent application publication that omits material that was present in the specification or claims of the nonprovisional patent application filed in the USPTO. *See* 37 C.F.R. § 1.217 and MPEP § 1132.

reduction to practice: Following conception, reduction to practice is the final step in the inventive process. Reduction to practice can be actual (by constructing a physical embodiment of the invention) or constructive (by filing a patent application that satisfies the disclosure requirements of § 112). *See* § 14.3.4.1.2.2.

reexamination proceeding: At any time during the enforceability of a patent, any person may file a request for the USPTO to conduct a second examination of any claim of the patent on the basis of prior art patents or printed publications which that person states to be pertinent and applicable to the patent and believes to have a bearing on the patentability (*see* 37 C.F.R. § 1.501). For the request for reexamination to be granted, a substantial new question of patentability must be present with regard to at least one patent claim. The request must be in writing and must be accompanied by payment of a reexamination request filing fee as set forth in 37 C.F.R. § 1.20(c). *See* § 14.2.5.5.

reference: *See prior art*.

reissue application: An application for a patent to take the place of an unexpired patent that is defective in one or more particulars. Resissues may narrow or broaden the application. *See* § 14.2.5.4.

rejoinder: The returning to active consideration of claims previously withdrawn from consideration to due to a restriction requirement—i.e., a determination by the USPTO that an application contains more than one invention.

request for continued examination (RCE): A request filed in an application in which prosecution is closed (e.g., the application is under final rejection or a notice of allowance) that is filed to reopen prosecution and continue examination of the application.

restriction: If two or more independent and distinct inventions are claimed in a single application, the examiner may require the applicant to elect a single invention to which the claims will be restricted. This requirement is known as a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action (final rejection).

reverse doctrine of equivalents: A doctrine excusing infringement where an accused device literally infringes a patent, but should nonetheless be excused because it substantially differs in operative principle and results. Although it has not been applied in over a century to excuse infringement, it continues to be raised. *See* § 14.4.1.4.3.

specification: A written description of the invention and the manner and process of making and using the same.

statutory disclaimer: *See disclaimer*.

submarine patent: An informal term for a patent that is intentionally delayed in prosecution by the applicant to let an infringing user continue to develop its business, with the intention of claiming later-invented technology once the patent finally "surfaces" from the PTO. As of November 29, 2000, most patent applications must be published within eighteen months of filing, so submarine patents have become less common.

substitute patent application: An application that is, in essence, a duplicate of a prior application by the same applicant abandoned before the filing of the substitute application. A substitute application does not obtain the benefit of the filing date of the prior application.

supplemental Examination: A procedure added by the AIA authorizing a patentee to seek further consideration of additional information relevant to patentability. *See* § 14.2.5.3.

terminal disclaimer: *See disclaimer*.

utility: To be patentable, an invention must have specific, substantial, and credible utility. *See* § 14.3.2.

***Walker Process* claim**: An antitrust counterclaim to a patent infringement suit, alleging that the patent was fraudulently obtained so as to exert monopolistic power and is therefore invalid. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

written description: The portion of a patent specification, as required by § 112(a), describing the background of the invention, a summary of the invention, and a detailed description of the invention. The patentee must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and the written description must enable a person having ordinary skill in the art to practice the invention without undue experimentation. *See* § 14.3.3.1.