Introduction to Intellectual Property: A U.S. Perspective

Amanda Murphy, Michael Stramiello, Stacy Lewis, and Tom Irving

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, D.C. 20001-4413

Correspondence: amanda.murphy@finnegan.com

This review introduces patents and trade secrets, the two mechanisms that U.S. law provides inventors to protect their inventions. These mechanisms are mutually exclusive: One demands disclosure and the other calls for concealment. Many biotechnology innovators opt for patents, which grant legal, time-limited monopolies to eligible inventions. To obtain a patent in the United States, an invention must be useful to the public and made or altered by the hand of man. It must then clear the hurdles of novelty and nonobviousness. If an invention can do that, obtaining a patent becomes a matter of form: Who qualifies as an inventor? Does the application demonstrate possession, stake a clear claim to the protection sought, and enable “ordinary” colleagues to replicate it? Has the inventor purposely withheld anything? This review addresses each of these hurdles as they apply to biotech inventions.

The United States recognizes four categories of intellectual property: copyrights, trademarks, trade secrets, and patents. Copyrights protect writings, illustrations, and other works of authorship. Trademarks protect words, symbols, designs, sounds, fragrances, and colors that designate the origin of a product. This article focuses on patents and trade secrets, the mechanisms by which inventors can protect their inventions.

A trade secret is something that confers a business advantage, is not generally known, and must be maintained as a secret in order to be protected. A patent is a legal monopoly that is granted in exchange for disclosure of how to make and use an invention. Because trade secret protection requires secrecy and patent protection requires disclosure, the two are generally considered to provide mutually exclusive op-

tions for protecting an invention. Ordinarily, an inventor must choose to seek either patent protection for an invention or trade secret protection.¹

In the sections that follow, the authors provide a general overview of these two mechanisms for protecting inventions in the United States. Other articles in this collection contain more detailed discussions of both topics.

¹It remains possible, however, that a trade secret could evolve from an earlier-patented invention, as patent owners have no obligation to disclose later innovations related to patented subject matter. In this regard, patent owners should note that obvious improvements of an earlier patented invention are not eligible for further patent protection beyond the duration of the originally patented subject matter. Thus, trade secret protection may be the only option for such inventions.

Editors: Salim Mamajiwala and Rochelle Seide

Additional Perspectives on Intellectual Property in Molecular Medicine available at www.perspectivesinmedicine.org

Copyright © 2015 Cold Spring Harbor Laboratory Press; all rights reserved; doi: 10.1101/cshperspect.a020776

Cite this article as *Cold Spring Harb Perspect Med* 2015;5:a020776

A. Murphy et al.

TRADE SECRET LAW

What Is a Trade Secret?

In its simplest form, a trade secret is information. The information may relate to anything from a method of manufacturing a product to a recipe for its formulation. The Uniform Trade Secrets Act (UTSA) defines “trade secret” as:

information, including a formula, pattern, compilation, program, device, method, technique, or process that:

- i. derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
- ii. is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.²

The Restatement of the Law of Unfair Competition defines a trade secret as:

any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.³

Thus, for information to qualify as a trade secret, it must remain generally unknown by the public; confer an economic benefit on its owner; and be the subject of reasonable efforts to maintain its secrecy. Trade secret protection generally does not apply to matters of public knowledge or general knowledge in an industry.⁴

Protecting Trade Secrets

Trade secrets are protected by state laws. Most states have enacted some variation of the UTSA, which provides rules for deciding disputes that arise when someone improperly acquires trade secret information.

The owner of a trade secret (often called the “originator”) has the rights to possess the idea and its physical embodiments, to limit its disclosure to others, and to contract for the terms of its use by others (*Larisey v. U.S.* (949 F.2d 1137, 1141) (Fed. Cir. 1991)). An originator may enforce these rights through several legal theories, including trade secret misappropriation, breach of contract, breach of trust or confidence, and quasi-contract.

To recover for trade secret misappropriation, the plaintiff must identify the specific subject matter alleged to be a trade secret. The Restatement (First) of Torts provides several factors that a court may consider in determining whether a trade secret, in fact, exists:

1. the extent to which those outside the originator’s business know the information;
2. the extent to which those involved in the originator’s business know the information;
3. the measures the originator has taken to keep the information secret;
4. the value of the information to both the originator and to his competitors;
5. the amount of effort or money the originator has spent in developing the information;
6. the ease or difficulty with which others could properly acquire or duplicate the information.

In addition, courts may also consider the nature of the alleged misconduct and the public interest in permitting access to the trade secret.

If a trade secret does exist, the plaintiff must then establish ownership of the trade secret. He typically does this by showing sufficient evidence that he developed the trade secret.

After establishing ownership, the plaintiff must then prove that the defendant obtained the trade secret through improper means. Both the UTSA and the Restatement impose liability for acquiring a trade secret through improper means. The defendant, however, may defend against an allegation of trade secret misappropriation by establishing that he properly ob-

²UTSA §1(4) (1985).

³Restatement (Third) of the Law of Unfair Competition, §39.

⁴Restatement (First) of Torts §757, comment (b) (1939).

tained the trade secret through either independent development or by working backward from a publicly available product (a process called “reverse engineering”) (*Aerospace America, Inc. v. Abatement Technologies, Inc.* (738 F. Supp. 1061, 1072) (E.D. Mich. 1990)). This is because public information provided without restriction may be copied at will.

After establishing that the defendant improperly obtained the trade secret, the originator must prove that the defendant actually used or disclosed the information without authorization. Mere possession of a trade secret, without more, will not support a claim for trade secret misappropriation (*Gibson-Homans Co. v. Wall-Tite Inc.* (26 U.S.P.Q.2d 1867) (C.D. Cal. 1992)).

But “slavish copying” is not required to establish trade secret misappropriation (*Richardson v. Suzuki Motor Co.* (868 F.2d 1226, 1244) (Fed. Cir. 1989)). A defendant who uses another’s trade secret is liable even if he modifies or improves upon the trade secret, as long as the substance of the defendant’s use is derived from the originator’s secret (*Forest Laboratories, Inc. v. Pillsbury Company* (452 F.2d. 621, 625) (7th Cir. 1971)).

If a court ultimately finds trade secret misappropriation, UTSA §§ 2–4 provide remedies for the plaintiff. These include injunctions, monetary damages (including the plaintiff’s actual loss and the defendant’s unjust enrichment due to the misappropriation), and attorney’s fees.

Trade Secrets versus Patents

There are several reasons why an inventor might choose to protect an invention as a trade secret rather than seek patent protection. Of course, if an invention is not patentable (e.g., because it is not subject-matter eligible or because it is not novel and nonobvious over the prior art), trade secret protection may be the only option. But even if an invention is patentable, an inventor may choose to maintain it as a trade secret for other reasons. For instance, if an invention will have a long shelf life, the unlimited duration of trade secret protection provides a clear advantage

over the finite duration of patent protection (discussed below). Alternatively, for inventions that may soon become obsolete, trade secret protection provides a promising alternative to the lengthy process of patenting. And businesses seeking to protect inventions that are difficult to reverse engineer, such as complex manufacturing methods or formulations (e.g., Coca Cola®), might prefer trade secret protection to the limited duration of a patent monopoly.

Ultimately, however, the decision of whether to seek patent protection or to maintain an invention as a trade secret must be made on a case-by-case basis after examining the specific facts of each case. The role of trade secrets in protecting biotech innovations is discussed in greater detail in other articles of this publication.

PATENT LAW

What Is a Patent?

A patent is a grant, from the U.S. federal government, of a limited monopoly. Of note, a patent does not give its owner the right to *practice* an invention—but it does confer the right to exclude others from making, using, or selling the claimed invention in the United States and to exclude others from importing the invention into the United States.⁵

The patent owner’s right to exclude runs for the life of the patent, which is fixed by statute to be, in most cases, 20 years from its earliest relevant filing date. This monopoly, limited in terms of geography and time, is justified by the benefit to society of having inventors share their ideas as soon as possible. But because issued patents are not self-enforcing, a patent owner must bring a legal action against an infringer to secure the benefits of his granted patent.

To obtain a U.S. patent, an inventor must file, with the U.S. Patent and Trademark Office (USPTO), a patent application that contains one or more “claims.” In much the same way that a fence defines the boundaries of a person’s real property, a claim defines the boundaries of an inventor’s intellectual property. And as with

⁵35 U.S.C. §271(a).

A. Murphy et al.

real property, patents may be bought, sold, shared, or rented (“licensed”).

The USPTO recognizes two types of patent applications: provisional and nonprovisional. The USPTO is tasked with examining non-provisional applications to determine whether the inventors are entitled to the full scope of protection requested in the claims. Provisional applications are not examined by the USPTO and serve only to secure an effective filing date for an invention that will ultimately be claimed in a nonprovisional patent application. Thus, generally speaking, a provisional application marks the point after which any disclosures of the invention will not prevent patentability.⁶

Sources of Patent Law

The U.S. Constitution establishes that patents are governed by federal law:

The Congress shall have the power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]⁷

Acting under its Constitutional authority, Congress has promulgated the patent laws, which are codified in Title 35 of the United States Code (35 U.S.C. §101 et seq.). These laws govern, among other things, the requirements for patentability, the examination of patent applications, the issuance of patents, and the enforcement of patents against infringement.⁸ Congress also created the USPTO as an administrative agency under the executive branch. Congress authorized the USPTO to promulgate

rules implementing the patent laws. Those rules are contained in Title 37 of the Code of Federal Regulations (37 C.F.R. §1.1 et seq.). The USPTO also publishes a *Manual of Patent Examining Procedures* (MPEP) providing instructions for USPTO personnel regarding the examination of patent applications. Finally, Congress created a single appellate court, the United States Court of Appeals for the Federal Circuit, to hear appeals in most patent-related cases.

With one exception, the U.S. federal courts have exclusive jurisdiction over causes of action arising under the patent laws. There are 94 federal district courts, which are the courts of first instance for patent infringement litigation. The one exception is the United States International Trade Commission (USITC), which is an executive branch agency that hears cases in the first instance to stop importation of infringing goods. Under the U.S. common law system, the judicial branch (i.e., the federal courts) has developed a body of case law interpreting the patent laws. Figure 1 presents a graphical depiction of the U.S. federal court system and the interplay of the USITC and USPTO.

Requirements for Obtaining a Patent

The USPTO grants three general types of patents:

1. utility patents, relating to a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”;⁹
2. plant patents, relating to “any distinct and new variety of plant”;¹⁰
3. design patents, relating to “any new, original and ornamental design for an article of manufacture.”¹¹

This section focuses on the requirements for obtaining utility patents, which are the most common category of patents in the field of molecular medicine.

⁶The authors encourage all inventors, and especially those in disciplines that encourage public presentation and written publication of new innovations, to file provisional applications before publicly disclosing their inventions.

⁷U.S. Constitution, Article I, Section 8, Clause 8.

⁸With the signing of the America Invents Act (AIA) on September 16, 2011, the U.S. patent law underwent a major overhaul. Some of the changes applied immediately, on September 16, 2011; others 1 year later, on September 16, 2012; and still more 18 months later, on March 16, 2013. The AIA was not retroactive, however, so the old law (pre-AIA) will be in effect and coexist with the new law (AIA) until approximately 2034.

⁹35 U.S.C. §101.

¹⁰35 U.S.C. §161; a plant can also be the subject of a utility patent if it satisfies the standard requirements.

¹¹35 U.S.C. §171.

Figure 1. Graphical representation of the U.S. federal court system and its interplay with the USITC and USPTO.

What Can Be Patented?

Not all scientific research—regardless of how innovative it may be—will result in a patentable invention. An invention must be directed to patent-eligible subject matter and must also have utility. These requirements are set forth in 35 U.S.C. §101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

An invention is “useful” under §101 if it is capable of providing some identifiable benefit to the public (*Juicy Whip, Inc. v. Orange Bang, Inc.* (185 F.3d 1364, 1366) (Fed. Cir. 1999)). Section 101 has been interpreted to exclude inventions deemed to be immoral (*Tol-o-matic, Inc. v. Proma Produkt-und Marketing Gesellschaft* (945 F.2d 1546, 1522–1553) (Fed. Cir. 1991)). In addition, if an invention is scientifically impossible, it lacks utility (*EMI Group North America, Inc. v. Cypress Semiconductor Corp.* (268 F.3d 1342, 1349) (Fed. Cir. 2001)). Generally speaking, the threshold for satisfying the utility requirement is not difficult to demonstrate for most biological inventions. Nevertheless, a mere “unsupported hypothesis” generally will not satisfy the utility requirement (*In re ’318 Patent Infringement Litigation* (583 F.3d 1317, 1327) (Fed. Cir. 2009)). In addition, any asserted utility should be commensurate with the scope of the claims.¹²

¹²*Id.*

Besides having utility, the invention must also be of a nature that is appropriate for patent coverage. Section 101 authorizes patents only for machines, compositions of matter, articles of manufacture, and processes. Subject matter must fall within one of these four categories to be eligible for patent protection.

Generally speaking, “anything under the sun that is made by the hand of man” should be patent-eligible (*Diamond v. Chakrabarty* (447 U.S. 303, 309) (1980)). For example, in the *Chakrabarty* case, the U.S. Supreme Court held that a living, genetically engineered bacterium was patent-eligible as an article of manufacture because it did not exist in nature.

Still, there exist exceptions to “anything under the sun.” Long-standing case law bars patenting of certain innovations directed to “laws of nature, physical phenomena, and abstract ideas” (*Diamond v. Chakrabarty*). Two recent examples impact biotech innovators. First, the U.S. Supreme Court decided that naturally occurring gene sequences are not patent-eligible because they exist in nature.¹³ Second, the Supreme Court decided that claims instructing practitioners to gather data and then draw certain inferences in light of newly discovered therapeutic correlations are not patent-eligible, because they merely recite a law of nature and ineligible mental steps (*Prometheus Labs., Inc. v. Mayo Collaborative Services* (132 S. Ct. 1289, 1297) (2012)). A more detailed discussion of patent eligibility with respect to biotech inventions is provided in other articles of this publication.

Who Can Obtain a Patent?

Section 101 authorizes patents only for those who “invent” or “discover.” Therefore, in the United States, an inventor can obtain a patent. And for patent applications filed after September 15, 2012, an assignee of an inventor can also obtain a patent.¹⁴ In either case, the patent application must identify the true and original

¹³*Association for Molecular Pathology v. Myriad Genetics, Inc.* (133 S. Ct. 2107) (2013) (holding that synthetically produced gene sequences are patent-eligible).

¹⁴35 U.S.C. §118.

A. Murphy et al.

inventor(s), and those inventors must submit an oath declaring their true inventorship.¹⁵

Determining inventorship is a key step in preparing and prosecuting patent applications, as well as when enforcing issued patents. The case law concerning inventorship disputes provides some guidance for identifying inventors. Completing an invention requires three steps: (1) conception, (2) activities leading toward a reduction to practice, and (3) reduction to practice. Reduction to practice may be “actual,” by making the invention and demonstrating that it works for its intended purpose, or “constructive,” by filing a patent application that complies with the applicable disclosure requirements.

To be an inventor, one must have made or contributed to the conception of the invention (*Burroughs Wellcome Co. v. Barr Laboratories, Inc.* (40 F.3d 1223, 1227–1228) (Fed. Cir. 1994)). Although the inventor, or someone acting under the inventor’s direction, can accomplish the second and third steps to complete an invention,¹⁶ only the inventor can complete the step of conception. Unless a person participates in the conception of the invention, he or she does not qualify as an inventor (*In re Hardee* (223 U.S.P.Q. 1122, 1123) (Comm’r Pat. 1984)).

Conception is the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice” (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.* (802 F.2d 1367, 1376) (Fed. Cir. 1986)). “[T]he test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention. . . . An idea is definite and permanent when the inventor has a specific, settled idea, a

particular solution to the problem at hand, not just a general goal or research plan that he hopes to pursue” (*Burroughs Wellcome v. Barr*). Thus, vague notions of a goal to be achieved, or general suggestions of an approach to a problem, do not rise to the level of conception.

Joint inventorship is also allowed in the United States. This is particularly useful for biotech inventions, which often result from collaborative efforts among multiple inventors. Section 116(a) of the patent statute, as recently amended by §20 of the America Invents Act (AIA), states that inventors may jointly apply for a patent even if they did not physically work together, did not make the same type or amount of contribution, or did not contribute to every claim in the patent. A party claiming joint inventorship must “prove his contribution to the conception of the claims by clear and convincing evidence” (*Symantec Corp. v. Computer Associates Int’l, Inc.* (522 F.3d 1279, 1295) (Fed. Cir. 2008)). For joint inventorship, each “joint inventor must contribute in some significant manner to the conception of the invention” (*Gemstar-TV Guide Int’l, Inc. v. ITC* (383 F.3d 1352 at 1381) (Fed. Cir. 2004), quoting *Fina Oil and Chemical Co. v. Ewen* (123 F.3d 1466, 1473) (Fed. Cir. 1997); see also *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.* (670 F.3d 1171) (Fed. Cir. 2012)).

Improper inventorship may invalidate a patent. It may also serve as grounds for a finding of unenforceability if the applicant had deceptive intent when listing improper inventors (see, e.g., *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.* (228 F.3d 1338) (Fed. Cir. 2000) and *Frank’s Casing Crew & Rental Tools v. PMR Technologies* (292 F.3d 1363) (Fed. Cir. 2002)). If a litigant alleges invalidity based on improper inventorship, the patent owner may have the opportunity to correct inventorship before a court declares the patent invalid (*Checkpoint Systems, Inc. v. All-Tag Security S.A.* (412 F.3d 1331, 1340) (Fed. Cir. 2005), quoting *Pannu v. Iolab Corp.* (155 F.3d 1344) (Fed. Cir. 1998)).

Inventorship also has ownership implications because in the United States, the inventor is the first owner of a patent. This is important because co-owners of a U.S. patent may make,

¹⁵35 U.S.C. §115 requires that a patent applicant “shall make oath that he believes himself to be the original and first inventor. . . .” See also 77 Fed. Reg. 48776 (Aug. 14, 2012) for the USPTO’s rules relating to the AIA changes in the inventor’s oath provisions that went into effect for applications filed after September 15, 2012.

¹⁶“An inventor may solicit the assistance of others when perfecting the invention without ‘losing’ any patent rights.” *Trovan, Ltd. v. Sokymat SA* (299 F.3d 1292, 1302) (Fed. Cir. 2002).

use, offer to sell, and sell the patented invention without regard to the wishes of any other co-owner.¹⁷ Finally, proof of inventorship may have implications for derivation proceedings and eligibility for prior art exceptions under new AIA provisions.¹⁸ Thus, care should be taken to maintain a proper chain of title in all assignments. Inventorship and ownership considerations are discussed in greater detail in other articles of this publication.

Novelty

An invention must be new to qualify for patent protection. This “novelty” requirement stems from §§ 101 and 102 of the patent statute: §101 authorizes patents only for “new” inventions, while §102 “covers in detail the conditions relating to novelty” (*Diamond v. Diehr* (450 U.S. 175, 189) (1981)).

An invention’s novelty is necessarily measured against the background of what has come before. This background information is called “prior art.” Section 102 of the patent statute defines the items of prior art against which an invention’s novelty will be assessed, and includes prior patents and patent applications, printed publications, prior knowledge and use, and prior sales.

Two policies underlie the novelty requirement for patentable inventions: “firstness” and “promptness.” The firstness requirement generally guarantees that only the first inventor is eligible to receive a patent, although situations can exist in which the second party to file receives the patent (see, e.g., *Chen v. Bouchard* (347 F.3d 1299) (Fed. Cir. 2003) (interference proceeding granting priority to second filer)). The promptness requirement generally ensures that inventors file their patent applications at an early date.

The AIA brought major changes to U.S. patent law. Some of the most significant changes

involved the novelty provisions of §102. The AIA’s changes to §102 are discussed in the next article of this publication. Here we discuss pre-AIA §102,¹⁹ which will coexist with the new law until at least approximately 2034.

Pre-AIA (and AIA) §102 defines circumstances under which an inventor is not entitled to a patent. Pre-AIA §102(a), (e), (f), and (g) address the firstness requirement of novelty and proscribe an inventor from receiving a patent for an invention if the invention was:

¹⁹Pre-AIA §102: A person shall be entitled to a patent unless:

- (a) 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 invention thereof by the applicant for a patent, or
- (b) 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 application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in—(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) (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.

¹⁷35 U.S.C. §262. See also *Falana v. Kent State University* (669 F.3d 1349) (Fed. Cir. 2012) and *Ethicon, Inc. v. United States Surgical Corp.* (135 F.3d 1456, 1461) (Fed. Cir. 1998).

¹⁸AIA 35 U.S.C. §102(b).

A. Murphy et al.

- “known or used by others in this country” before the inventor’s date of invention (pre-AIA §102(a));
- “patented or described in a printed publication in this or a foreign country” before the inventor’s date of invention (pre-AIA §102(a));
- described in a published patent application that was filed in the United States before the inventor’s date of invention (pre-AIA §102(e));
- described in a patent that was “granted on an application for patent by another filed in the United States” before the inventor’s date of invention (pre-AIA §102(e));
- invented by someone else (pre-AIA §102(f)); or
- “made in this country by another inventor who had not abandoned, suppressed or concealed it” before the inventor’s date of invention (pre-AIA §102(g)).

Unless it can be shown that the inventor’s date of invention was earlier than any of these events, the inventor will not be granted a patent for his invention. To satisfy the firstness provisions of pre-AIA §102(a), (e), (f), and (g), the date of invention needs to be earlier than the effective date of the prior art event in question.

Pre-AIA §102(b), (c), and (d) address the “promptness” requirement of novelty and proscribe an inventor from receiving a patent for an invention if he waited too long before filing a patent application. For example, §102(b) states that an inventor is not entitled to a patent if, more than 1 year before the priority date of the inventor’s U.S. patent application, the invention was “patented or described in a printed publication in this or a foreign country”²⁰ or “in

public use or on sale in this country.” Similarly, §102(c) prevents an inventor from obtaining a patent for an invention he has abandoned. Finally, §102(d) bars an inventor from receiving a patent if the inventor has already received a patent for his invention in a foreign country based on an application filed more than 1 year prior to the filing date of his U.S. application. Thus, §102(d) provides an incentive for inventors who have filed a patent application in a foreign country to file a corresponding U.S. application within 12 months.

The promptness sections of pre-AIA §102(b), (c), and (d) are referred to as “statutory bars” to patentability. This is because, unlike the firstness provisions of pre-AIA §102(a), (e), (f), and (g), an inventor cannot overcome the promptness prior art events by showing an earlier date of invention.

Another important difference between the firstness provisions of pre-AIA §102(a), (e), and (g) and the promptness provisions of pre-AIA §102(b) and (d) is that an inventor’s own work may preclude patentability for lack of promptness, but is not considered prior art in determining firstness. Thus, if an inventor publishes a scientific article disclosing his invention more than 1 year before filing a patent application, that publication will prevent the inventor from obtaining a patent under pre-AIA §102(b) because he did not promptly file his application. On the other hand, if the inventor filed his patent application within a year of the publication, the firstness provisions will not necessarily negate patentability.

In the jargon of patent law, an invention lacks novelty if it is “anticipated” by the prior art. Anticipation requires a two-step analysis: First, the claim must be construed to determine what the inventor has invented, and second, the prior art must be compared to that invention.

²⁰Inventors should take care when sharing their findings. Although a presentation including a transient display of slides will not necessarily count as a “printed publication,” continuously displaying slides on poster boards for two and a half days at a conference has barred at least one inventor from patenting. See *In re Klopfenstein* (380 F.3d 1345) (Fed. Cir. 2004). Likewise, giving a paper to the head of a conference, then orally presenting it at that conference, and then distributing copies “on request, without any restrictions, to as many as six persons” has barred another inventor from

patenting. See *Massachusetts Institute of Technology v. A.B. Fortia* (774 F.2d 1104, 1108–1109) (Fed. Cir. 1985). On the other hand, sending six copies of an article to a “friend” may not serve as a bar to patenting. See *Preemption Devices, Inc. v. Minnesota Mining & Manufacturing Co.* (732 F.2d 903, 906) (Fed. Cir. 1984). Of course, the best advice is to file a provisional application before making any public disclosures of an invention.

In general, an invention is anticipated if all of its elements are contained, either expressly or inherently, in a single item of prior art. If one must “reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention,” the invention is not anticipated.²¹ In addition, the reference must teach those skilled in the art “to make or carry out what it discloses in relation to the claimed invention” (*In re Antor Media Corp.* (689 F.3d 1282, 1290) (Fed. Cir. 2012)). Thus, the prior art reference must generally provide an enabling disclosure in order to anticipate a claimed invention.²²

The purpose of the novelty requirement is to ensure that patents will not issue if an invention is already in the public’s possession. An applicant will not be permitted to remove technology from the public domain. Thus, §102 of the patent statute serves a gatekeeping function by guaranteeing that only truly innovative technologies are granted as U.S. patents.

Nonobviousness

Under pre-AIA (and AIA) U.S. patent law, an invention is not patentable if it would have been obvious to someone of ordinary skill in the art at the time of the invention. Even when an invention is novel over the prior art, if the inventor has merely made an obvious modification to the existing body of knowledge, he will not be awarded a patent. The requirement that an invention be nonobvious over the prior art is set forth in §103(a) of the pre-AIA patent statute and was largely unchanged in the AIA.²³

²¹*Scripps Clinic & Research Foundation v. Genentech, Inc.* (927 F.2d 1565, 1577) (Fed. Cir. 1991).

²²The one exception to this enablement requirement is prior public use. See pre-AIA §102(b).

²³Pre-AIA §103(a): “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 negated by the manner in which the invention was made.”

AIA §103: “A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not

As the statutory language makes clear, non-obviousness does not require a “flash of genius.” Still, “the results of ordinary innovation are not the subject of exclusive rights under the patent laws” (*KSR International Co. v. Teleflex, Inc.* (550 U.S. 398, 427) (2007)). To be patentable, an invention must be “more than the predictable use of prior art elements according to their established functions.”²⁴

The Supreme Court has identified four factors that must be considered when determining whether a prior art reference, or combination of references, renders a claim obvious (*Graham v. John Deere Co.* (383 U.S. 1) (1966)):

- the scope and content of the prior art;
- the differences between the prior art and the claimed invention;
- the level of skill in the art;
- any objective indicia of nonobviousness.

The provisions of §102 define what is prior art for purposes of an obviousness determination. However, the prior art must be analogous to the claimed invention; art that is “too remote” should not negate patentability. Prior art is analogous to a claimed invention if it is within the field of the invention or in a field that is reasonably pertinent to the problem the inventor tried to solve, such that a person skilled in the art would look to the reference to solve that problem.

The proper inquiry under §103 is whether the invention, as a whole, would have been obvious to someone of ordinary skill in the art at the time of invention. However, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”²⁵ This is so because inventions in most, if not all, instances build on work that was known

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.”

²⁴*Id.* at 417.

²⁵*KSR*, at 418.

A. Murphy et al.

in the prior art.²⁶ A key question is whether the claimed invention would have been predictable in view of the teachings of the prior art. Put differently, an invention is obvious if those skilled in the art would have had a reasonable expectation of success in arriving at the invention based on the teachings of the prior art. In this regard, it is important to note that “[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton.”²⁷ Thus, the nonobviousness requirement extends beyond what is expressly taught in the prior art.

In addition to comparing the claimed invention to the prior art, an obviousness determination should also evaluate objective indicia of nonobviousness. Such considerations include:

- long-felt but unresolved need;
- commercial success;
- unexpected results;
- copying by others;
- praise for the invention;
- disbelief or skepticism of those skilled in the art;
- evidence that others tried and failed;
- licenses.

Factors such as these can be used to demonstrate the nonobviousness of a claimed invention. However, any such evidence should generally be commensurate in scope with the claims if it is to weigh against a finding of obviousness for the claimed invention.

Disclosure and Claiming

A U.S. patent application must contain a specification, including at least one claim. Section 112 of the pre-AIA and AIA patent statutes governs those requirements:

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.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.²⁸

The first paragraph of §112 deals solely with the written disclosure of the invention, and the second paragraph deals exclusively with the claims.

§112, First Paragraph—Requirements for the Specification

The first paragraph of §112 recites three independent and distinct requirements for the specification:

1. To describe the manner and process of making and using the claimed invention in such full, clear, concise, and exact terms as to enable one skilled in the art to make and use the invention. This is referred to as the “enablement requirement” and is itself made up of two separate elements: “how-to-make” and “how-to-use.”
2. To describe the subject matter defined in the claims. This is referred to as the “written description requirement.”
3. To set forth the best mode contemplated by the inventor of carrying out the invention at the time of filing. This is referred to as the “best mode requirement.”

These requirements ensure that the public will receive something in exchange for the period of exclusivity granted to the inventor. A full and complete disclosure of the invention, including the manner of making and using it, confers two benefits to the public. First, it increases the body of public knowledge available for further research and innovation. Second, it

²⁶*Id.*

²⁷KSR, at 421.

²⁸35 U.S.C. §112. (The AIA did not change the substance of the pre-AIA §112 requirements of a patent application; it simply redesignated the paragraphs of §112 with letters.)

ensures that the invention will be freely available to the public once the patent term has expired.

To satisfy the enablement requirement, one skilled in the art, upon reading the disclosure, must be able to practice the claimed invention. Generally speaking, the patent disclosure should satisfy both the “how-to-make” and “how-to-use” prongs mentioned above for the full scope of the claims in order to be enabling. Still, the enablement requirement generally does not require a patent disclosure to enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment of the invention (*CFMT, Inc. v. Yieldup Int’l Corp.* (349 F.3d 1333, 1338) (Fed. Cir. 2003)).

A patent application may be enabling even if those skilled in the art would have to conduct some amount of routine experimentation to practice the claimed invention. But if it would require undue experimentation to practice the invention in view of the disclosure, the application likely will not satisfy the enablement requirement (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.* (802 F.2d 1367) (Fed. Cir. 1986)).

A determination of whether undue experimentation is needed to practice an invention is a fact-intensive inquiry and typically involves analysis of one or more of the following factors:

- the nature of the invention;
- the breadth of the claims;
- the state of the prior art;
- the predictability or unpredictability of the art;
- the level of skill in the art;
- the quantity of experimentation needed;
- the amount of direction or guidance provided by the application;
- the presence or absence of working examples in the application.

These are often called the “Wands factors,” after the Federal Circuit decision that provided the factors as useful guidance for determining enablement (*In re Wands* (858 F.2d 731, 737) (Fed. Cir. 1988)). If a patent application provides sufficient guidance, in view of these factors, such that one skilled in the art can practice the claimed invention without undue experi-

mentation, the disclosure should satisfy the enablement requirement.

In March 2010, the Federal Circuit reiterated, en banc, that the enablement requirement is separate from the written description requirement (*Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* (598 F.3d 1336, 1341) (Fed. Cir. 2010) (en banc)). Specifically, a patent specification must teach one of ordinary skill in the art how to make and use the invention and, separately, must describe the invention sufficiently so that one of ordinary skill in the art would understand that the inventor possessed the subject matter claimed.

To satisfy the written description requirement, the specification should demonstrate that the inventor had possession of the claimed subject matter as of the filing date of the application. It generally will not be sufficient that the disclosure renders the claims obvious (*Lockwood v. American Airlines, Inc.* (107 F.3d 1565) (Fed. Cir. 1997)). The written description requirement is satisfied if one skilled in the art, reading the original disclosure, is able to discern the claimed invention from the words, structures, figures, diagrams, and/or formulas set forth in the patent application (*Purdue Pharma L.P. v. Faulding, Inc.* (230 F.3d 1320, 1323) (Fed. Cir. 2000)).

Whether a claim is supported for purposes of the written description requirement depends on a variety of factors, including (see *Ariad* at 1351; see also *Capon v. Eshhar* (418 F.3d 1349, 1359) (Fed. Cir. 2005) and *In re Smythe* (480 F.2d 1376, 1382–1383) (C.C.P.A. 1973)):

- the nature of the claim;
- the scope of the claims;
- the level of detail provided;
- the extent and content of the prior art;
- the complexity and predictability of the prior art;
- the existing knowledge in the field;
- the maturity of the technology.

If the art is predictable, a very brief disclosure may be sufficient to satisfy the written description requirement. But when the art is unpredictable, a more extensive disclosure may be

A. Murphy et al.

required. That being said, the written description generally need not include information that is well-known to those skilled in the art at the time the application is filed (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.* (802 F.2d 1367, 1384) (Fed. Cir. 1986)). And the written description generally need not describe the invention in exactly the same words that are used in the claims (*Martin v. Johnson* (454 F.2d 746, 751) (C.C.P.A. 1972)).²⁹ As long as the disclosure reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the application's filing date, the disclosure should satisfy the written description requirement.

Finally, the first paragraph of §112 also requires that the specification set forth the best mode contemplated by the inventor for carrying out his invention. Although the best mode is still a required part of the specification under the AIA, as of September 16, 2011, failure to disclose the best mode for practicing the invention cannot be the grounds for finding a patent invalid or unenforceable.³⁰

The best mode requirement can be considered as requiring disclosure of information that might otherwise be considered a trade secret. However, this does not necessarily mean that the inventor must disclose the optimum mode for practicing the invention—the patent law allows patent applications to be filed when the invention has never been reduced to practice in any form, much less commercial form. Moreover, there is no requirement that the best mode be identified as such in the application. And when the inventor does not know of a best mode, there is no duty to find one. When a best mode is known, however, the inventor should disclose it in the specification so that

the public receives what it bargained for in conferring a patent by allowing competitors to compete fairly with the patentee following expiration of the patent.

§112, Second Paragraph—Requirements for the Claims

Certain conventions must be applied when drafting claims for U.S. patent applications. Each claim is a fragment of a single sentence that begins with the phrase “I claim” or “We claim” or “What is claimed is” and ends with a period. Claims can start with a preamble phrase announcing the general subject matter of the claim, for example, a product, a process of making, a process of using, or a method. The preamble is followed by a transition phrase (usually “comprising,” “consisting essentially of,” or “consisting of”), which is then followed by a statement of the invention.

The second paragraph of §112 contains two requirements for the claims of a patent application. The first requirement calls for precision and definiteness. In other words, one skilled in the art must be able to tell with a reasonable degree of certainty whether his or her conduct is within or outside the scope of the claim. Simply stated, the claims should not be “vague or indefinite” and should clearly set out the boundaries of the subject matter for which the patent grants protection.

The second requirement is that the claims must be directed to the subject matter that the applicant regards as his or her invention. The claims should distinguish the invention from what came before in the art and circumscribe what is foreclosed from future enterprise during the limited period of exclusivity associated with the patent (*United Carbon Co. v. Binney & Smith Co.* (317 U.S. 228, 236) (1942)). This means not only that an applicant may claim whatever he regards as his invention, but also that an applicant may not claim subject matter that he does not regard as his invention.

Consequently, a claim that is understandable to one skilled in the art, and that defines subject matter that the applicant regards as the invention, should meet the requirements of the second paragraph of §112. In other words, if

²⁹Stating “the description need not be in *ipsis verbis* (i.e., ‘in the same words’) to be sufficient.”

³⁰AIA Sec. 15(c), 125 Stat. 328. Under the AIA's amendments, 35 U.S.C. §282 now reads:

- (3) Invalidity of the patent or any claim in suit for failure to comply with—
 - (a) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or
 - (b) any requirement of section 251.

the claims set out and circumscribe, with a reasonable degree of precision, a particular area that the applicant regards as the invention, the claims should satisfy the statutory requirements of §112, second paragraph.³¹ This calls for specificity that allows one of ordinary skill in the art to determine the boundaries of the claim (*Haliburton Energy Services, Inc. v. M-I LLC* (514 F.3d 1244, 1249–1250) (Fed. Cir. 2008)).

Claims satisfy the definiteness requirement if they provide both a clear definition of the invention (to facilitate determinations of patentability) and a clear warning to others (to place potential infringers on reasonable notice of what they can and cannot do).³² These aspects of the definiteness requirement ensure that the walls an inventor has erected to define his patent claims are made of something other than quicksand.³³ The claims of a patent should be designed to provide adequate notice to other parties regarding the metes and bounds of the patented invention.

Duty of Disclosure

In the United States, everyone involved in obtaining a patent owes the USPTO a duty of candor and good faith.³⁴ This duty, which is grounded in a long history of judicial decisions, seeks to prevent patent applicants from deliberately deceiving the USPTO to procure

a patent. Failure to comply with the duty may render a patent unenforceable if an accused infringer raises a defense of inequitable conduct and a court determines that the duty of good faith and candor was breached in obtaining the patent.

The duty of good faith and candor extends to inventors, agents, attorneys, and every other person who is substantively involved in preparing, prosecuting, or assigning an application. One way to comply with the duty is to disclose to the USPTO, in writing, all information known to be material to patentability.

According to USPTO Rule 1.56, information is material if it refutes or is inconsistent with a position the applicant takes during prosecution. In other words, the USPTO considers information to be material if it establishes, either alone or in combination with other information, a prima facie case of unpatentability of a claim. A prima facie case of unpatentability is established when information compels, by a preponderance of the evidence, the conclusion that a claim is unpatentable, giving each claim term its broadest reasonable interpretation in light of the written description and before considering any rebuttal evidence.³⁵

As mentioned in footnote 34, however, the USPTO has suspended 37 C.F.R. §1.56 in response to a recent decision by the Federal Circuit that raised the standard for materiality (*Therasense Inc. v. Becton, Dickinson and Co.* (649 F.3d 1276) (Fed. Cir. 2011) (en banc)). Specifically, the Federal Circuit held that to prove inequitable conduct, a defendant must establish “but-for” materiality. In other words, if the USPTO would not have allowed the claim had it been aware of the undisclosed information, then the information is material. Because such determinations are often difficult to make absent guidance from the USPTO or a court, the USPTO recommends erring on the side of disclosure when the materiality of information seems unclear.³⁶

³¹See *Nautilus, Inc. v. Biosig Instruments, Inc.* (134 S. Ct. 2120) (2014), holding that a patent is invalid for indefiniteness if its claims, read in light of the patent’s specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

³²Chisum DS. 2014. *Chisum on patents*. Matthew Bender, New York.

³³*Enzo Biochem, Inc. v. Applera Corp.* (605 F.3d 1347, 1349) (Fed. Cir. 2010) (Plager, J., dissenting from denial of rehearing en banc).

³⁴37 C.F.R. §1.56: “Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability[.]”

Author commentary: As of the writing of this article, the USPTO has suspended Rule 1.56. Nevertheless, many practitioners still continue to follow the rule, and courts continue to hold patents unenforceable for inequitable conduct if the USPTO was deliberately deceived into issuing the patent.

³⁵MPEP §2001.

³⁶*Id.* at §2004.

Cold Spring Harbor Perspectives in Medicine

Introduction to Intellectual Property: A U.S. Perspective

Amanda Murphy, Michael Stramiello, Stacy Lewis and Tom Irving

Cold Spring Harb Perspect Med 2015; doi: 10.1101/cshperspect.a020776 originally published online March 27, 2015

Subject Collection [Intellectual Property in Molecular Medicine](#)

Patentability of Stem Cells in the United States

Sarah E. Fendrick and Donald L. Zuhn, Jr.

Inventorship and Authorship

Antoinette F. Konski and Linda X. Wu

The Patentability of Stem Cells in Australia

Jenny Petering and Prue Cowin

Impact of America Invents Act on Biotech Intellectual Property

Amanda Murphy, Michael Stramiello, Jonathan Stroud, et al.

Introduction to Intellectual Property: A U.S. Perspective

Amanda Murphy, Michael Stramiello, Stacy Lewis, et al.

The Role of Regulatory Agencies and Intellectual Property: Part I

Kevin E. Noonan

Canada's Patented Medicines (Notice of Compliance) Proceedings and Intellectual Property

Henry Bian and Conor McCourt

Patentability of Genes: A European Union Perspective

Paul Cole

The Impact of *Myriad* on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics

Michele Wales and Eddie Cartier

Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?

Prashant Reddy and Malathi Lakshmikumaran

Protecting Trade Secrets in Canada

Noel Courage and Janice Calzavara

Inherent Anticipation in the Pharmaceutical and Biotechnology Industries

Michael Goldman, Georgia Evans and Andrew Zappia

The Role of Regulatory Agencies and Intellectual Property: Part II

Kevin E. Noonan

Baseball Bats and Chocolate Chip Cookies: The Judicial Treatment of DNA in the *Myriad Genetics* Litigation

Ian Binnie and Vanessa Park-Thompson

The Impact of *Myriad* and *Mayo*: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?)

Jennifer Gordon

Trade Secrets in Life Science and Pharmaceutical Companies

Tara Nealey, Ronald M. Daignault and Yu Cai

For additional articles in this collection, see <http://perspectivesinmedicine.cshlp.org/cgi/collection/>