Literary Fantasies as Prior Art, Eclipsing True Invention

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Abstract

Current rules allow the U.S. patent office to deny a patent to an inventor because an earlier article, work of fiction, or TV show generally forecasts the possibility of the invention. The patent office has imposed a presumption that such "prior art" which might anticipate future invention is enabling: that it discloses enough concrete detail to enable someone with the requisite skill to make the invention. The reality is that much non-patent prior art is speculative and fanciful; that the author had no practical idea how to implement his ideas. In theory, an inventor applying for a patent can offer evidence to rebut the presumption, but in practice, the office gives short shrift to such rebuttal evidence, using a variety of doctrines that allow the efficacy of the prior art to be assessed, not at the time of its writing, but after a patent for a later invention is applied for. Traditional requirements that the prior art specify each and every element of the new invention in order to be anticipatory have been relaxed. More robust scrutiny of whether prior art enables subsequent concrete innovation and thus blocks patents for inventions in the field is desirable, and it can occur only by eliminating the presumption.

This is especially appropriate as the rise of generative AI enlarges the quantity of material that may qualify as prior art, some of which is manufactured by AI instead of human inventors.

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I. INTRODUCTION

Some years ago, an accused infringer challenged the validity of an e-commerce patent based on a law review article this author wrote in the early days of the Internet. The author, though an engineer and an expert on how the Internet and Internet resources work, had no concrete means in mind to implement his idea at the time he wrote the article. Nevertheless, the parties seeking to invalidate the patent argued that the author's article was prior art¹ and that it anticipated the patent.²

This situation is not unusual. Suppose someone publishes what purports to be a recipe. The recipe includes an accurate listing of ingredients but provides no information on proportions or cooking times and temperatures. Does this antici-

¹ The law review article was offered as prior art. Section 0 explains what prior art is.

²Section 0 explains anticipation.

pate a subsequent invention that has not only the ingredients but also proportions, cooking times, and temperatures merely because it recites all of the ingredients of the invention? In *Procter & Gamble Co. v. Nabisco Brands, Inc.*,³ the district court held a patent claim invalid as anticipated by a recipe in a cookbook. Much argument involved whether the reference taught the details of how ingredients should be combined and how they could be layered to produce a laminated structure. Persuasive evidence of enablement came from testimony by the accused infringers that its employees had successfully used the cookbook to produce cookies within the scope of the challenged claim of the patent.⁴

Should Apple be denied a patent on the Apple Watch⁵ because the Dick Tracey comic strip anticipated Apple's invention with its portrayal of a wristwatch radio in 1946?⁶ This is not as farfetched as it might seem. Reportedly the Dutch patent office denied a patent on a method for salvaging sunken sea vessels based on a Donald Duck exploit with his uncle's sunken yacht. And a patent on a waterbed was denied in the United States based on a science fiction novel.⁷

Telepathy—human to human communication by the exchange of brain waves without any kind of electrical intermediation was a popular capability in the science fiction of the 1940s and 1950s.⁸ It still appears occasionally in fiction.⁹ Quite recently, Elon Musk and Neuralink have demonstrated a device, which, when implanted in a human brain, permits the recipient to control a robot (a computer mouse in the demonstration) merely by thinking about it.¹⁰ Do the stories about telepathy anticipate the Neuralink invention?

Should Arthur C. Clarke's 1945 article on communications satellites¹¹ anticipate patents on Elon Musk's Starlink satellites?¹²

These fictional works forestall patents only if they are *enabling*. To be entitled to a patent, one must invent something, as opposed to describing something that already exists and is in the public domain. If someone else wrote a playbook that described the invention before the purported inventor and applicant for a patent submits his application, no patent is available. At least, no patent is available if

⁸ *Telepathy*, THE ENCYCLOPEDIA OF SCIENCE FICTION (Feb. 2, 2021), https://sf-encyclopedia.com/entry/telepathy (reporting on popularity of telepathy in science fiction of the 1950s).

⁹ See Jane Killick, Mind Secrets: A Science Fiction Telepathy Thriller (Perceivers Book 1) (2016).

¹² See STARLINK, https://www.starlink.com/technology (last accessed May 3, 2024).

³711 F. Supp. 759 (D. Del. 1989).

⁴711 F. Supp. at 772–773.

⁵ In reality, the Apple Watch is not the subject of any single patent, but of hundreds, maybe thousands of patents on its components. *See* Janet Freilich, *Patents' New Salience*, 109 VA. L. REV. 595, 597 (2023) (noting that a smartphone is covered by thousands of patents). But to frame the question posed in the text, assume the Apple Watch is covered by a single patent—or that Apple seeks a single patent to cover it.

⁶ See Erin Blakemore, *How Dick Tracy Invented the Smartwatch*, SMITHSONIAN MAG. (Mar. 9, 2015), https://www. smithsonianmag.com/smart-news/how-dick-tracy-invented-smartwatch-180954506/ (referring to 1946 as year in which Dick Tracy's two-way wrist radio was introduced)

⁷ Daniel H. Brean, *Keeping Time Machines and Teleporters in the Public Domain as Prior Art*, 7 U. PITT. J. T. L. & POL at *3–*4 (2007) (summarizing two unsuccessful efforts to obtain patents).

¹⁰ Neuralink's first human patient able to control mouse through thinking, Musk says, REUTERS, (Feb. 20, 2024), https:// www.reuters.com/business/healthcare-pharmaceuticals/neuralinks-first-human-patient-able-control-mousethrough-thinking-musk-says-2024-02-20/; Rolfe Winker, Elon Musk's Neuralink Shows First Patient Using Its Brain Implant: Man paralyzed in diving accident moves computer cursor with his thoughts, THE WALL STREET JOURNAL (Mar. 20, 2024), https://www.wsj.com/tech/neuralink-shows-first-patient-using-its-brain-implant-device-67a8b03a; See NEURALINK, https://neuralink.com/ (last accessed May 3, 2024).

^{11Arthur} C. Clarke, *Extra-Terrestrial Relays: Can Rocket Stations Give World-wide Radio Coverage?*, WIRELESS WORLD 305, 305 (Oct. 1945), http://clarkeinstitute.org/wp-content/uploads/2010/04/ClarkeWirelessWorldArticle.pdf.

the playbook was sufficiently robust to instruct someone on how to run a winning play—to create the purported invention. The term of art for such robustness is *enablement*.

But the Patent Office and the United States Court of Appeals have virtually extinguished the possibility for exploring enablement in any depth by establishing a presumption that prior art enables,¹³ by allowing hindsight to imply inherency in prior art and by treating prophetic examples in prior-art references as seriously as working examples.

The Supreme Court's decision in *Amgen*, *Inc. v. Sanofi*¹⁴ earlier this year invites consideration of whether the Office should take prior-art enablement more seriously. *Amgen* did not change the standards for enablement in the patent-validity context, and it does not, by implication, change the standards for assessing whether prior art is enabling. *Amgen* does, however, reinforce the need for a rigorous assessment of enablement.

On its face, the presumption of prior-art enablement may appear logical. But the Patent Office and PTAB have applied it mindlessly and in a manner inconsistent with its terms and its rationale.

Making prior-art enablement challenges infeasible with respect to non—patent prior art unnecessarily restricts the universe of inventions that can be patented and subverts achievement of the policies justifying patent law. A strengthened enablement requirement for prior art references is the best assurance that imagination running wild will not undermine the availability of patents for genuine invention.

The USPTO should revise MPEP § 2121 to make the presumption applicable only to patent prior art, and it should require examiners to articulate a prima facie case of enablement for other types of references. If it does not do that, the United States Court of Appeals should grant review, and overturn rejections based on anticipation by non-patent prior art that has been presumed to be enabling.

This article explains why insisting on enablement by non-patent prior art is essential in discovering the boundary between what should be patentable and what should remain in the public domain. Part II, following this introduction, reviews the basic legal requirements for obtaining a patent, and Part III considers section 112's requirements for a description showing possession and enabling the making of an invention. It then explains why that enablement concept is applied to prior art as a precondition for its anticipation of a patent. Part IV introduces USPTO's presumption of prior-art enablement, explains why the presumption more than obvious scope because of the prevalence of prophetic examples in prior-art, has concludes with a review of evidence offered to establish enablement or to rebut a presumption of enablement.

Part V describes the Supreme Court's decision in *Amgen*, and explains why it should reawaken interest in how assessment of enablement of prior-art works.

Part VI applies the law developed in preceding parts of the article to each of the hypotheticals presented earlier in this introduction.

¹³ USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 2121 (9th ed., rev. July 2022) [hereinafter MPEP]. The MPEP is published by the United States Patent and Trademark Office ("USPTO") as guidance for its patent examiners. It is available at https://www.uspto.gov/web/offices/pac/mpep/index.html.

^{14 598} U.S. 594 (2023).

Part VI reviews the arguments in favor of keeping the presumption and those in favor of getting rid of it, concluding that it should be eliminated.

Part VII is the conclusion.

II. PATENT PREREQUISITES

Patents are available only for inventions that involve patentable subject matter, defined by section 101 of the patent statute, that are novel, under section 102, that are not obvious, under section 103, and that are accompanied by disclosures that adequately define the invention and allow anyone to make it, the subject of section 112.¹⁵

A. Patents and Copyrights Clause

Section 8 of Article 1 of the United States Constitution empowers the United States Congress: "To 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 "¹⁶ The very first Congress enacted a law allowing inventors to get patents: temporary, legally enforceable, monopolies over their inventions.¹⁷ After various adjustments in the institutional apparatus for granting patents in the first half of the nineteenth century,¹⁸ patent law settled on a process in which inventors wishing to obtain patents on their inventions apply to a federal agency, the United States Patent and Trademark Office ("USPTO").¹⁹ There, feder-

^{is} Under the Patent Act of 1790, an inventor could petition a panel consisting of the Secretary of State, the Secretary of War, and the Attorney General for a patent, which would be granted if the three officers "shall deem the invention or discovery sufficiently useful and important." Patent Act of 1790, § 1. The Patent Act of Feb. 21, 1793, Ch. 11, 1 Stat. 318-323 (repealed 1836), shifted responsibility to the Secretary of State alone, subject to certification by the Attorney General that the invention satisfied the requirement that the applicant has "invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application." Id. § 1. That statute is generally regarded as having eliminated any government scrutiny of applications; it was a mere registration scheme. See Herbert J. Hovenkamp, The Emergence of Classical American Patent Law, 58 ARIZ. L. REV. 263, 268 (2016). Patent Act of July 4, 1836, Ch. 357, 5 Stat. 117 (repealed 1870) established an examination system under a Commissioner of Patents within the Department of State and required applicants to submit written descriptions and models. Id. §§ 6, 7. The Patent Act of July 8, 1870, Ch. 230, 16 Stat. 198-217, highlighted technical details for patent applications, administrative appeals of rejections, and judicial consideration of infringement claims, and provided for the filing of caveats, the ancestor of the modern provisional application. Id. § 40. In 1849, the Patent Office was transferred from the Department of State to the Department of the Interior, and in 1925 from Interior to the Department of Commerce. The Patent Act of July 19, 1952, Pub. L. 593, 66 Stat. 792 established a board of appeals comprising the examiners in chief, the commission, and the assistant commissioner and rationalized examination practice and criteria, including the addition of a new section 103 to replace the amorphous "invention" requirement of the common law. KENNETH W. DOBYNS, THE PATENT OFFICE PONY: A HISTORY OF THE ÉARLY PATENT OFFICE (1997) (detailing the evolution of patent law, with particular attention to institutional arrangements).

19 35 U.S.C. §§ 1-2.

¹⁵ Sections 101, 102, and 103 are considered in this Part I. Section 112 is considered in Part III.

¹⁶ U.S. Const. art. 1, § 8.

¹⁷ "That if any person or persons shall devise, make, construct, use, employ, or vend within these United States, any art, manufacture, engine, machine or device, or any invention or improvement upon, or in any art, manufacture, engine, machine or device, the sole and exclusive right of which shall be so as aforesaid granted by patent . . . without the consent of the patentee or patentees, . . . every person so offending, shall forfeit and pay to the said patentee . . . damages as shall be assessed by a jury, and moreover shall forfeit to the person aggrieved, the thing or things so devised, made, constructed, used, employed or vended." Patent Act of Apr. 10, 1790, ch. 7, § 4, 1 Stat. 109–112 (repealed 1793) [hereinafter Patent Act of 1790]. Compare with the present-day statute: "[W]hoever 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 therefor, infringes the patent." 35 U.S.C. § 271(a).

al employees known as *patent examiners*²⁰ scrutinize the application to determine whether it meets the requirements of the patent statute, in particular eligible subject matter, novelty, non-obviousness, and a clear and enabling description of the invention.

Under the 2012 America Invents Act,²¹ the critical date for determining priority is the date on which an inventor files an application for a patent,²² not, as under the previous law, when he conceived of the invention, assuming he sought to reduce it to practice with reasonable diligence thereafter.²³

B. Eligible Subject Matter

The Patent Act begins by describing eligible subject matter:

"§101. Inventions patentable

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."²⁴

Patents are available for: processes, machines, articles of manufacture, and new compositions of matter. Even inventions falling into one of these four categories may not be eligible for patent protection if they involve algorithms, laws of nature, or natural phenomena,²⁵ unless the invention adds something significant beyond what is found in nature.²⁶

Inventions claiming the impossible are outside the scope of eligible subject matter under section 101.²⁷

C. Novelty

Patents are available only for something new, not already found in the public domain.

²⁰ 35 U.S.C. § 3(b)(4) (referring to examiners).

²¹Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011), amending various provisions of title 35, United States Code. *See* 35 U.S.C. § 102(b)(2) (giving priority to inventor who files first).

^{22 35} U.S.C. § 102(b).

 $^{^{23}}$ "A person shall be entitled to a patent unless, ... another inventor ... establishes, to the extent ... that before such person's invention thereof the invention was made by such other inventor" 35 U.S.C. § 102(g) (2000) [popularly known as "pre-AIA 102"].

^{24 35} U.S.C. § 101.

²⁵ Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 70 (2012) ("The Court has long held that this provision [§ 101] contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable.").

²⁶ Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 221 (2014) ("At *Mayo* step two, we must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application. A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'") (some internal quotations omitted).

²⁷ MPEP 2107.01(II) (citing examples of incredible utility, outside the scope of section 101).

§102. Conditions for patentability; novelty

(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.

Language with meaning similar to that of section 102 has been in the law since the first Patent Act of 1790.28

Whether an invention is novel depends on what is already known. The types of information that may disqualify an invention for patenting under section 102 are known as *prior art.*²⁹ The language in section 102 most significant for this article is "described in a printed publication."³⁰

Section 102 has been interpreted to disqualify invention—to anticipate it—only when a single prior art reference contains all of the elements in the invention. Anticipation requires that "each and every limitation of the relevant claim [be] disclosed in a single prior art reference."³¹ When that occurs, the prior art reference is said to anticipate the invention and therefore to disqualify it under section 102. Under the language of section 102, novelty is negated if "[t]he claimed invention . .. was described in a printed publication."³² Merely describing an *idea* that leads to the claimed invention is not enough. The invention itself must be described, and the use of the singular article "a" — "a printed publication"—suggests that the invention must be described in a single publication. The text supports the generally accepted notion that anticipation (a negation of novelty) requires that every element of the invention be disclosed in a single prior art reference.

Collateral references can be used in section 102 rejections to show enablement by the primary reference, to interpret terms in the primary reference, and to show that a characteristic not disclosed in the primary reference is inherent.³³ Additional references may show enablement by showing what was known before the anticipating invention.³⁴ Inherency supplies elements not explicitly present in the primary reference, available along with the explicit elements to anticipate a later invention. It can be shown by proof of what persons holding ordinary skill in the art ("PHOSITAs") knew at the time of the anticipating invention and would have found it unnecessary to disclose explicitly.³⁵

The American Intellectual Property Law Association has drafted jury instructions for patent cases. Among them are instructions on anticipation:

An invention must be new to be entitled to patent protection under the U.S. patent laws. If a device or process has been previously invented and disclosed to

²⁸ Amgen Inc. v. Sanofi, 598 U.S. 594, 604–605 (2023) (quoting Patent Act of 1790) ("invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used") (emphasis added).

²⁹ The scope of the prior-art block depends on the meaning of *described*, in section 102 and *obvious*, in section 103. ³⁰ 35 U.S.C. § 102. Subsections (a) and (b) use the word "describe" in connection non-patent publications, but

subsection (d) uses the word to cover patent publications, as well. MPEP 2126.02 makes it clear that patent prior art includes the specification as well as the claims of a patent, suggesting that it does not matter which subsection of 102 is involved. The Patent Office interprets disclosure in this broad sense. MPEP § 2152.04.

³¹ Timothy R. Holbrook, Patent Anticipation and Obviousness as Possession, 65 EMORY L. J. 987, 1007 (2016). 32 35 U.S.C. § 102(a).

³³ MPEP 2131.01 (discussing multiple reference 102 rejections).

³⁴ MPEP 2131.01(I).

³⁵ MPEP 2131.01(III).

the public, then it is not new, and therefore the claimed invention is "anticipated" by the prior invention. To prove anticipation, [the Defendant] must prove that it is highly probable that the claimed invention is not new.

. . . .

To anticipate a claim, each element in the claim must be present in a single item of prior art and arranged or combined in the same way as recited in the claim. You may not combine two or more items of prior art to find anticipation. In determining whether every one of the elements of the claimed invention is found in the prior [[publication] [patent] [etc.]], you should consider what a person of ordinary skill in the art would have understood from his or her review of the particular [[publication] [patent] [etc.]].³⁶

In *Schering Corp. v. Geneva Pharmaceuticals*, the Federal Circuit held that inherency may work to anticipate entire inventions, as well as single limitations within an invention.³⁷ It also held that inherency need not be recognized at the time the anticipatory reference was disclosed; inherency can be understood later.³⁸ Such a broad understanding of inherent anticipation closes in on obviousness doctrine, because it allows evidence of post-reference technology developments.³⁹

The AIPLA instruction on inherency tracks Schering.⁴⁰

Dan L. Burk and Mark A. Lemley⁴¹ argue that confusion about inherency is unnecessary. They urge a simple test: "If the public already benefits from the invention, even if they don't know why, the invention is inherent in the prior art. If the public doesn't benefit from the invention, there is no inherency."⁴²

To qualify as prior art, a reference must antedate the date on which the inventor applies for a patent. Section 102(a) says, "before the effective filing date of the claimed invention."

D. Non-Obviousness

Even if the novelty requirement of section 102 is satisfied, an invention nevertheless may not be qualified for a patent if it is "obvious," in light of the prior art.⁴³

§103. Conditions for patentability; non-obvious subject matter A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in sec-

³⁸ Id. at 1379–1380.

43 35 U.S.C. § 103.

³⁶ 2018 AIPLA Model Patent Jury Instructions, AIPLA, at 24, https://www.aipla.org/docs/default-source/default-document-library/2018-07-23-clean---aipla-model-patent-jury-instructions.pdf.

^{37 339} F.3d 1373, 1380 (Fed. Cir. 2003).

³⁹ See Holbrook, supra note 32, at 1024–1025 (explaining why Schering may be wrong, but also explaining why is consistent with interpreting enablement as evolving over time).

⁴⁰ 2018 AIPLA Model Patent Jury Instructions, *supra* note 37, at 25.

⁴¹Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM & MARY L. REV. 371, 372 (2005) (discussing how inherency is at issue in anticipation, the on-sale bar, priority disputes, double-patenting, and enablement).

⁴² Id. at 374. See also Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUSTON L. REV. 1101, 1108–1110 2008) (arguing for inevitability of result test for inherent anticipation, merging it with enablement requirement).

tion 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.⁴⁴

The section 103 obviousness requirements was added by the 1952 Patent Act,⁴⁵ to replace the common-law "invention" standard.⁴⁶ In *Graham v. John Deere Co.,*⁴⁷ the Supreme Court held that section 103 is meant to codify the standard of inventiveness articulated by *Hotchkiss v. Greenwood.*⁴⁸ Interpreting *John Deere*, USPTO crystallized a "teaching-suggestion or motivation" ("TSM") test for obviousness. Obviousness depends on (1) all of the elements of a patent claim being found in a plurality of prior-art references, and (2) some teaching, suggestion, or motivation in the literature to combine them to come up with the new invention.

In *KSR International Co. v. Telefax Inc.*,⁴⁹ the Supreme Court reversed the Federal Circuit for taking a "rigid approach"⁵⁰ to TSR and articulated a more flexible, multi-factor test for obviousness under section 103.⁵¹

In Virtek Vision International ULC v. Assembly Guidance Systems, Inc., dba Aligned Vision, the Federal Circuit reiterated the essentiality of a motivation to combine as a precondition for an obviousness finding. It reversed PTAB's IPR obviousness decision, finding that the Board was not warranted in finding motivation to combine elements from two difference references.⁵² The mere fact that alternatives exist does not, without more, provide a motivation to combine.⁵³ "KSR," it said, "did not do away with the requirement that there must exist a motivation to combine various prior art references in order for a skilled artisan to make the claimed invention."⁵⁴

"There was no evidence that there are a finite number of identified, predictable solutions. There is no evidence of a design need or market pressure. In short, this case involves nothing other than an assertion that because two coordinate systems were disclosed in a prior art reference and were therefore "known," that satisfies the motivation to combine analysis. That is an error as a matter of law. It does not suffice to simply be known. A reason for combining must exist."⁵⁵

55 Id. at *8.

⁴⁴35 U.S.C. § 103. The phrase, "person having ordinary skill in the art" frequently is expressed by the acronym: PHOSITA.

⁴⁵ Pub. L. 593, 66 Stat. 792 (July 19, 1952), revising and recodifying title 35, United States Code.

⁴⁶ Giles S. Rich, *Why and How Section 103 Came to Be*, 14 FED. CIR. B. J. 181 (2004–2005) (recounting history and purpose to replace ambiguous "invention" standard). The invention requirement originated in Hotchkiss v. Greenwood, 52 U.S. 248 (1850), in which the Supreme Court required that an invention, to quality for a patent must be the work of an "inventor," not merely that of a "skillful mechanic." 52 U.S. at 267 (affirming judgment invalidating a patent).

^{47 383} U.S. 1 (1966).

⁴⁸ 52 U.S. 248 (1851). 383 U.S. at 13–19 (rejecting argument that section 103 was meant to lower the barrier imposed by "inventiveness").

^{49 550} U.S. 398 (2007).

⁵⁰ 550 U.S. at 415. The Federal Circuit's test for obviousness had depended on finding "teaching, suggestion, or motivation (TSM)" that encouraged combining prior art references." 550 U.S. at 407 (characterizing Federal Circuit's test). It rejected obviousness based on a simple "obvious to try." 550 U.S. at 414.

⁵¹ 550 U.S. at 419–422.

⁵² Nos. 2022-1998, 2024 WL 1292734 at *5 (Fed. Cir. Mar. 27, 2024).

⁵³ Id. at *6.

⁵⁴ Id. at *7.

The Virtek court may have overreached in its effort to get away from KSR. While rejecting the Federal Circuit's rigid application of a TSR test, the KSR Court acknowledged that, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."56 So it left room for requiring motivation, although it is not clear it left room for it to be the sine qua non of obviousness.

The Patent Office offers examiners detailed guidance on how to apply KSR to obviousness evaluation.⁵⁷ All the KSR factors have at their core the question whether a PHOSITA would have a reasonable expectation of success in trying what appears in the new invention.

TSR, and the more flexible KSR analysis, focus on identifying patent elements in prior art references and assessing the probability of success of a PHOSITA who attempts to combine them. So-called "secondary considerations" also matter. Even when PHOSITAs would be motivated to try the elements of the invention, the inventor may be able to avoid a finding of obviousness by showing secondary considerations. In Yita LLC v. MacNeil IP LLC,58 PTAB found that secondary considerations were compelling and indicated non-obviousness of a patent subject to IPR, notwithstanding evidence that a PHOSITA would have been motivated to combine elements from prior art references.⁵⁹ The court of appeals reversed. It recalled the universe of secondary considerations from John Deere: "whether the claimed invention has been commercially successful, whether it solved a long-felt but unsolved need in the art, and whether the relevant industry praised it." It held that the evidence failed to tie the evidence of commercial success closely enough to the unique features of the patent.⁶⁰

In Graham v. John Deere Co.,⁶¹ the Supreme Court, while not finding strong enough evidence of secondary considerations to overcome obviousness in the cases before it, nevertheless acknowledge the legitimate role of secondary considerations. "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy."62 It cited to Judge Learned Hand's opinion in *Reiner v. I. Leon Co.*,⁶³ explaining how secondary considerations are probative:

There are indeed some sign posts [for determining inventiveness]: e.g., how long did the need exist; how many tried to find the way; how long did the surrounding and accessory arts disclose the means; how immediately was the invention recognized as an answer by those who used the new variant? In the case at bar the answers to these questions all favor the

⁵⁶ KSR Intern. Co. v. Telefax Inc., 550 U.S. 398, 418 (2007).

⁵⁷ MPEP 2141-2151.

^{58 69} F.4th 1356 (Fed. Cir. 2023).

^{59 69} F.4th at 1358 (characterizing PTAB decision).

^{60 69} F.4th at 1365.

^{61 383} U.S. 1 (1966). 62 383 U.S. at 17-18.

^{63 285} F.3d 501 (2d Cir. 1960).

conclusion that it demanded more intuition than was possessed by the 'ordinary' workers in the field. The needs were known, but the purpose to fulfil them with that minimum of material and labor disclosed in the patent had not appeared; and economy of production is as valid a basis for invention as foresight in the disclosure of new means. In the case at bar the saving of material as compared to anything that had preceded, was very great indeed; the existing devices at once yielded to Reiner's disclosure; his was an answer to the 'long-felt want.'⁶⁴

The *John Deere* Court also cited a law review article by Richard L. Robbins.⁶⁵ The Robbins article points out the problems associated with limited judicial knowledge of modern technology and the partisanship of expert witnesses and aims at offering a factual test more within the ken of judges and jurors. Long felt demand is relevant, because "the defect would not persist were the solution "obvious."⁶⁶ If a product achieves a high degree of market success that achievement is probative of the face that innovators attempted a solution but failed.⁶⁷ The more widespread the commercial acquiescence in the form of licensing of the patent indicates patent validity.⁶⁸ Simultaneous solution, on the other hand, indicates obviousness.⁶⁹ Professional approval also matters. "If trade publications all hail a product as a boon to consumers and deserving of a patent, a court could properly use such facts in support of validity."⁷⁰

The word experiment or experimentation does not appear in the text of the *KSR* opinion, but *KSR* does not mandate a finding of obviousness when the degree of experimentation involved would be akin to "merely throwing metaphorical darts at a board' in hopes of arriving at a successful result."⁷¹

Patent examiners reject applications as obvious when they find one or more prior art references that, when combined, motivate a person skilled in the art to attempt the elements of the invention and have reasonable expectations of success in the attempt.⁷² "Obviousness requires a reasonable expectation of success."⁷³ The reasonable expectation of success arising from an expectation of only routine experimentation⁷⁴ means that undue experimentation undermines a reasonable expectation of success.

Anticipation and obviousness are distinct, through related. Anticipation says, "Someone else already invented it." Obviousness says, "No one invented it be-

⁷³ MPEP 2143.02(I) (section heading).

⁷⁴ See Purdue Pharma L.P. v. Accord Healthcare Inc., 669 F. Supp.3d 286, 303 (D. Del. 2023) (finding obviousness because of reasonable expectation of success with only routine experimentation).

^{64 285} F.2d at 504.

⁶⁵ Richard L. Robbins, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. PA. L. REV. 1169 (1964).

⁶⁶ 112 U. PA. L. REV. at 1172.

⁶⁷ 112 U. PA. L. REV. at 1175–1176.

 ⁶⁸ 112 U. Pa. L. Rev. at 1178.
 ⁶⁹ 112 U. Pa. L. Rev. at 1180.

⁷⁰ 112 U. PA. L. REV. at 1180.

⁷¹ Leo Pharmaceutical Products, Ltd. v. Rea, 726 F.3d 1346, 1357 (Fed. Cir. 2013) (noting that each of many possible formulations would take one to three months to try).

⁷² *In re* Gorris, 847 Fed. Appx. 889, 892 (Fed. Cir. 2021) (explaining why evidence showed that PHOSITA would have had reasonable expectation of success, making invention obvious; expectation of no more than routine experimentation can give rise to motivation to try).

fore, but your innovation is only a trivial contribution to the state of the art--" it involves "matters of design well within the expected skill of the art and devoid of invention."⁷⁵

In *Cohesive Techs., Inc. v. Waters Corp.,*⁷⁶ the Federal Circuit reversed the district court's refusal to send the question of anticipation to a jury in an infringement case. The district court reasoned that the evidence of obviousness and anticipation overlapped and that "It did not understand . . . why a defendant would want a charge on anticipation when they get one on obviousness."⁷⁷

Despite the oft repeated statement that "anticipation is the epitome of obviousness," the two are distinct concepts, the Federal Circuit said.⁷⁸ Most significantly, "Obviousness can be proven by combining existing prior art references, while anticipation requires all elements of a claim to be disclosed within a single reference."⁷⁹ Secondary considerations are relevant to obviousness, but not to anticipation.⁸⁰

It rejected the idea that anticipation by inherency is equivalent to obviousness.⁸¹

Laura G. Pedraza-Fariña & Ryan Whalen argue that the caselaw, reaching back to *Hotchkiss*, embraces, and often conflates, two philosophical justifications for the non-obviousness requirement: one economic, the other cognitive. The economic justification denies patents to inventions that would have occurred anyways, induced by market forces. The cognitive justification denies patents to mere mechanics, with only humdrum skill in extending what is already know, while granting them to more exalted inventors who have a flash of genius.⁸²

"How we conceptualize [non-obviousness] has clear implications for how we measure it: Should [non-obviousness] rely on ascertaining how creative a particular invention is? Or should it instead focus on mapping the strength of market forces to determine whether it would have been achieved regardless of patent incentives?"⁸³

They use network techniques to probe how innovators search and build on existing knowledge to generate new ideas.⁸⁴ In these network models, lack of network connections ("network holes") and network distance indicates likely market failure in providing inducements for innovation.⁸⁵ It is boundary-crossing thinking and behavior that is most innovative.⁸⁶ They build a network based on USPTO

⁷⁵ Graham v. John Deere Co., 383 U.S. 1, 22-23 (1966) (quoting patent examiner making obviousness rejection).

^{76 543} F.3d 1351 (Fed. Cir. 2008).

 $^{^{77}}$ 543 F.3d at 1363 (quoting district court) (internal quotation marks omitted).

^{78 543} F.3d at 1363–1364.

⁷⁹ 543 F.3d at 1364.

⁸⁰ 543 F.3d at 1364; MPEP 2131.04 (explaining secondary considerations irrelevant to anticipation).

⁸¹543 F.3d at 1364. *See also* KoveIO, Inc. v. Amazon Web Services, Inc., Case No. 18 C 8175, 2024 WL 450028 at *23–*24 (N.D. Ill. Feb. 6, 2024) (citing and rejecting anticipation defense in infringement suit; multiple references cannot be combined to show section 102 anticipation); Sonos, Inc. v. Google LLC, No. C 20-06754 WHA, 2023 WL 2962400 at *5 N.D. Cal. Apr. 13, 2023) (citing *Cohesive Techs.* for proposition that anticipation must be shown by single reference, while obviousness allows several references).

⁸² Laura G. Pedraza-Fariña & Ryan Whalen, A Network Theory of Patentability, 87 U. Chi. L. Rev. 63, 68–69 (2020) (explaining economic and cognitive theories) [hereinafter Network Theory].

⁸³ Network Theory at 68.

⁸⁴ Network Theory, 87 U. CHI. L. REV. at 98.

⁸⁵ Network Theory, 87 U. CHI. L. REV. at 98–100.

⁸⁶ Network Theory, 87 U. CHI. L. REV. at 104.

classification categories⁸⁷ which expose distances between conceptual areas. These distances can be combined and quantified to develop an obviousness score.⁸⁸

Application of theoretical work like this would produce a more stable and predictable law of patent eligibility under section 103, instead of what Judge Learned Hand called, the "fugitive, impalpable, wayward, and vague a phantom as exits in the whole paraphernalia of legal concepts. It involves, or it should involve, as complete a reconstruction of the art that preceded it as is possible. The test of invention is the originality of the discovery, and discovery depends upon the mental act of conceiving the new combination, for substantially every invention is only a combination. Nothing is more illusory, as nothing is more common, than to assume that this can be measured objectively by the magnitude of the physical readjustments required."⁸⁹

Too much flexibility in establishing obviousness swallows up anticipation and its requirements for enablement. Even if a challenger cannot find a single reference that anticipates, she can find a plurality of them that make a new invention obvious.

III. PATENT LAW'S ENABLEMENT REQUIREMENT

A. Section 112's Two Requirements

This article is about enablement of prior-art; not enablement in new patent applications. Nevertheless, understanding enablement in the prior-context depends on understanding the basic concept and why it is required of patents.

To be entitled to a patent, an applicant also must describe his invention, even if novel and non-obvious, so as to *enable* one skilled in the art to practice it.⁹⁰

§112. Specification

In General.-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 or joint inventor of carrying out the invention.⁹¹

"[T]he threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility the written description requirement of § 112 requires disclosing more than a mere "wish" or "plan")."⁹²

⁸⁷ Network Theory, 87 U. CHI. L. REV. at 112.

⁸⁸ Network Theory, 87 U. CHI. L. REV. at 114-120.

[»] Harries v Air King Products Co, 183 F.2d 158, 162 (2d Cir. 1950).

^{∞35} U.S.C. § 112.

⁹¹35 U.S.C. § 112(a) (emphasis added).

⁹² In re Starrett, 2022-2209, 2023 WL 3881360 at *4 (Fed. Cir. June 8, 2023) (affirming PTAB rejecting of claims for organization of telepathic data).

Section 112 is interpreted to impose two requirements material to this article: adequate description and enablement.⁹³ Section 112(a)'s written-description requirement is distinct from its enablement requirement.⁹⁴ One can fully describe an invention without enabling it by explaining how to make it. Conversely, one can enable without fully describing.⁹⁵

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.,*⁹⁶ the United States Court of Appeals for the Federal Circuit quoted *Gill v. Wells*⁹⁷ for the three "great ends" of the language that became section 112:

(1) That the government may know what they have granted and what will become public property when the term of the monopoly expires; (2) that licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention; (3) that other inventors may know what part of the field of invention is unoccupied.98

1. Possession

The first and third "ends" or section 112 requires a description, separate from the claims and enablement:

In Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.,⁹⁹ the Federal Circuit was presented with two competing interpretations of 112. Ariad argued that the 1936 statute assigned the definition-of-the-invention requirement to the claims, leaving only enablement as the purpose of the remainder of the specification.¹⁰⁰ Ariad argued that the purpose of the two requirements diverged after enactment of the 1836 Patent Act, which required explicit claims, separate from the written description for the first time.¹⁰¹

The court rejected this argument:

[W]e see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the written description of the invention must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase 'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . .to make and use the same' modifies only the written description . . .of the manner and process of making and using [the invention], as Lilly argues, without violating the rules of grammar. That the adequacy of the description of the manner and process of *making* and *using* the invention is judged by whether that description enables

⁹³ The best-mode requirement is not material.

⁹⁴MPEP 2161 (II) (written-description, enablement, and best-mode are separate and distinct from each other). ⁹⁵MPEP § 2161 (II).

^{96\ 598} F.3d 1336 (Fed. Cir. 2010).

^{97 89} U.S. (22 Wall.) 1 (1874).

^{98 89} U.S. at 25-26.

^{99 598} F.3d 1336 (Fed. Cir 2010).

^{100 598} F.3d at 1343.

¹⁰¹ Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1367, 1369 (Fed. Cir 2010) (Linn, J., dissenting in part) (interpreting Act of Feb. 27, 1793, 1 Stat. 318, 321–22, ch. 11, § 3).

one skilled in the art to *make* and *use* the same follows from the parallelism of the language.¹⁰²

The court explained why the requirement for a description is separate from the requirement for enablement:

[A] separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the laws other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (*i.e.*, enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office ("PTO") to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.¹⁰³

[W]hile it is true that original claims are part of the original specification, *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973), that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims. Ariad believes so, arguing that original claims identify whatever they state, *e.g.*, a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention. We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the applicant has invented species sufficient to support a claim to a genus.¹⁰⁴

The quoted passage is talking about the requirement that the specification demonstrate *possession*, although it does not use that word. An inventor must not only conceive of an invention; he must also reduce it to practice. When he does so actually and physically, he can prove possession according to its common meaning.¹⁰⁵ When he does so constructively, it is the written description that shows possession.¹⁰⁶

^{102 598} F.3d at 1344 (internal citations to record omitted).

^{103&}lt;sup>=</sup> 598 F.3d at 1345.

^{104 598} F.3d at 1349 (internal citations to record omitted).

¹⁰⁵Holbrook, 65 Emory L. J. at 1010 (real world acts such as use and sale show possession inherently).

¹⁰⁶ See Vas-Cath Inc. v. Mahurkar, 935 F.3d 1555, 1563–1564 (Fed. Cir. 1991) (holding that purpose of written description requirement is to show possession); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 969 (Fed. Cir. 2002) (explaining how written description and possession requirements overlap but also are distinct). "The patent document, therefore, provides the evidence of possession. . . . The patent system channels the delineation of the "thing" into the patent document." Timothy R. Holbrook, Patent Anticipation and Obviousness as Possession, 65 Emory L. J. 987, 990 (2016).

2. Enablement

Section 112 also requires enablement: the second "end" of section 112 enumerated by the *Ariad Pharmaceuticals* court.¹⁰⁷

The Patent Office says that the test for enablement articulated by the Supreme Court in *Minerals Separation Ltd. v. Hyde*,¹⁰⁸ is still the test: "Is the experimentation needed to practice the invention undue or unreasonable?"¹⁰⁹ "Any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein."¹¹⁰

Noting that enablement is a question of law for the court, the AIPLA model instructions offer the following for cases in which factual disputes underlie an enablement controversy:

"A patent must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention, as of the effective filing date of the claimed invention, to make and use the full scope of the claimed invention without undue experimentation. This requirement is known as the enablement requirement. If a patent claim is not enabled, it is invalid.

In considering whether a patent complies with the enablement requirement, you must keep in mind that patents are written for persons of ordinary skill in the field of the invention. Thus, a patent need not expressly state information that persons of ordinary skill would be likely to know or could obtain.

The fact that some experimentation may be required for a person of ordinary skill to practice the claimed invention does not mean that a patent does not meet the enablement requirement. Factors that you may consider in determining whether persons of ordinary skill in the field of the invention would require undue experimentation to make and use the full scope of the claimed invention include:

- the quantity of experimentation necessary and whether that experimentation involves only known or commonly used techniques. The question of undue experimentation is a matter of degree. Even extensive experimentation does not necessarily make the experiments unduly extensive where the experiments are routine, such as repetition of known or commonly used techniques. But permissible experimentation is not without bounds.
- 2. the amount of direction or guidance disclosed in the patent;
- 3. the presence or absence of working examples in the patent;
- 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 of the art; and
- 8. the breadth of the claims.¹¹¹

^{107 598} F.3d at 1346.

¹⁰⁸ 242 U.S. 261, 270–271 (1916) (holding that variations in treatment of different kinds of ores under the patent were not unreasonable given variation in ores themselves).

¹⁰⁹ MPEP 2164.0.

¹¹⁰ MPEP 2164.01.

¹¹¹ 2018 AIPLA Model Patent Jury Instructions 40–41.

Unreasonable experimentation, the predominant test for enablement, links inextricably to expectation of success, the core concept in obviousness evaluation. The phrase, "unreasonable experimentation" or "undue experimentation" is not prominent in most analyses of obviousness, but "reasonable expectation of success," is pervasive in discussions of obviousness. A reasonable expectation of success is missing when a PHOSITA expects to have to engage in undue experimentation. It is, thus, hard to disentangle enablement from obviousness, and yet section 103 and section 112 represent distinct requirements and are supposed to be applied independently.

The Federal Circuit considered the relationship between enablement and obviousness in *Raytheon Technologies Corp. v. General Electric Co.*¹¹² It reiterated two opposing principles: first, if the overall evidence is enabling, it does not matter whether any particular reference is;¹¹³ and, second, "if an obviousness case is based on a non-self-enabled reference, and no other prior art reference or evidence would have enabled a skilled artisan to make the claimed invention, then the invention cannot be said to have been obvious."¹¹⁴

PTAB had invalidated a Raytheon patent for a geared gas turbine engine as obvious, based on an earlier NASA technical memorandum, envisioning "superior performance characteristics for an imagined "advanced [turbofan] engine" "incorporating all composite materials."¹¹⁵ The Board determined that the reference was enabling because it "because it provided enough information to allow a skilled artisan to "determine a power density as defined in claim 1, and within the range proscribed in claim 1...."¹¹⁶

The court reversed. The challenger, GE, relied entirely on the NASA paper to show obviousness, and Raytheon presented expert testimony proving that the advanced composite materials at the heart of the NASA design were not available at the time. The only reference, therefore, was not enabling, and therefore the obviousness finding could not stand.¹¹⁷

One might paraphrase the holding of Raytheon to say that collective enablement is possible, but that an obviousness rejection still must be premised on prior art that collectively is enabling.

B. History of Section 112

The possession and enablement requirements long predate the current version of section 112. The statute has maintained virtually the same language requiring enablement since the Patent Act of 1790.¹¹⁸ Two distinct requirements are clear. In

^{112 993} F.3d 1374 (Fed. Cir. 2021).

¹¹³ "For example, a reference that does not provide an enabling disclosure for a particular claim limitation may nonetheless furnish the motivation to combine, and be combined with, another reference in which that limitation is enabled. Alternatively, such a reference may be used to supply claim elements enabled by other prior art or evidence of record. " 993 F.3d at 1380 (internal citations omitted).

^{114 993} F.3d at 1377.

^{115 993} F.3d at 1378.

^{116 993} F.3d at 1379 (quoting PTAB).

^{117 993} F.3d at 1382.

¹¹⁸ Amgen, 598 U.S. at 595. The 1790 act required the recipient of a patent to deliver to the Secretary of State a specification, "which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct,

*"Evans v. Eaton,*¹¹⁹ the Supreme Court recognized just two requirements under § 3 of the 1793 Act, the requirements "to enable" the invention and "to distinguish" it from all things previously known.¹²⁰

The specification, then, has two objects; one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim any thing that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.¹²¹

The Patent Act of 1836,¹²² which established the Patent Office in the Department of State, created the office of Commissioner of Patents, and set up an examination system for patent applications reimposed the enablement requirement¹²³ and also required applicants to "furnish a model of his invention, in all cases which admit of a representation by model, of a convenient size to exhibit advantageously its several parts."¹²⁴ A model constituted an actual reduction to practice and was proof of both possession and enablement.

The Patent Act of 1870,¹²⁵ eliminated a statutory model requirement, still authorizing the Commissioner of Patents to require one.¹²⁶ The Commissioner stopped requiring models in most cases after 1880¹²⁷ because many of the existing models had been destroyed in a Patent Office fire in 1877¹²⁸ and because the Office was running out of room to store all the models.

The model requirement has been replaced by a requirement for constructive reduction to practice: a written description sufficiently detailed that "one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention."¹²⁹

126 § 29, Ch. 230, 16 Stat. 198–217 (July 8, 1870).

¹²⁷ See Kenneth W. Dobyns, The Patent Office Pony: A History of the Early Patent Office, 258 (2016) (describing 1880 regulation dropping general requirement for models).

¹²⁸ See id. at 243–252 (recounting "The Second Patent Office Fire").

or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term . . . " § 2, Patent Act of 1790, Ch. 7, 1 Stat. 109–112 (April 10, 1790).

¹¹⁹20 U.S. 356, 433–34 (1822).

^{120 598} F.3d at 1345.

¹²¹20 U.S. at 433-434.

¹²²Ch. 357, 5 Stat. 117 (July 4, 1836).

 $^{^{123}}$ Section 6 required "a written description of his invention . . . in such full, clear, and exact terms . . . as to enable any person skilled in the art . . . to make, construct, compound, and use the same " Id. § 6.

¹²⁴§ 6, Ch. 357, 5 Stat. 117 (July 4, 1836).

¹²⁵Ch. 230, 16 Stat. 198–217 (July 8, 1870).

¹²⁹ MPEP 2163(I); Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 675–676 (2019) (explaining how writtendescription and drawing requirements replaced models as ways of showing reduction to practice). Of course, actual reduction to practice also may be shown.

In *Wood v Underhill*,¹³⁰ the plaintiff in an infringement case defended against an argument that his "his description of the relative proportions of coal-dust and clay [for manufacturing bricks and tiles], as given in his specification, is upon the face of it too vague and uncertain to support a patent."¹³¹ The Court stated the requirement: "The specification must be in such full, clear, and exact terms as to enable any one skilled in the art to which it appertains to compound and use the invention; that is to say, to compound and use it without making any experiments of his own."¹³² It gave an example of what would not be enabling:

But when the specification of a new composition of matter gives only the names of the substances which are to be mixed together, without stating any relative proportion, undoubtedly it would be the duty of the court to declare the patent to be void. And the same rule would prevail where it was apparent that the proportions were stated ambiguously and vague-ly.¹³³

It held that such a degree of vagueness and uncertainty did not exist in the challenged patent, which proffered the general rule that three-fourths of a bushel of coal dust to one-thousand bricks as the proportion, to be varied somewhat depending on the nature of the clay. Whether the enablement requirement was met was a jury question, and the Court reversed the circuit court for instructing the jury "that the specification was too vague and uncertain to support the patent."¹³⁴

C. Rationales

Multiple rationales exist for these requirements. The compromise codified in patent law says that an inventor should be eligible for a temporary monopoly on his novel contributions to knowledge, but that he should not be able to withdraw existing knowledge from the public domain and claim a monopoly on it. Diminishing the public domain and replacing it with monopolies was precisely the evil from Stuart England that Thomas Jefferson and the other framers of the U.S. Constitution meant to avoid.¹³⁵ To achieve that balance, an applicant for a patent must

He went on to explain the "difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." *Id.* Jefferson, as Secretary of State, served as a member of the cabinet board responsible for granting patents under the first U.S. patent statute.

But see Adam Mossoff, Who Cares What Thomas Jefferson Thought about Patents — Reevaluating the Patent Privilege in Historical Context, 92 CORNELL L. REV. 953, 955 (2007) (purporting to rebut the "myth" of Jefferson's hegemony over the history of American patent law; advancing alternative under Locke's labor view of property). Id. at 967 (explaining how English Crown granted manufacturing monopolies to promote economic development).

^{130 46} U.S. 1 (1847).

¹³¹46 U.S. at 5 (framing the question before the court).

^{132 46} U.S. at *4.

^{133 46} U.S. at *5.

^{134 46} U.S. at *5-*6.

¹³⁵In an 1813 letter to Isaac McPherson, he said:

[&]quot;England was, until we copied her, the only country on earth which ever by a general law, gave a legal right to the exclusive use of an idea. in some other countries, it is sometimes done, in a great case, and by a special & personal act. but generally speaking, other nations have thought that these monopolies produce more embarrassment than advantage to society. and it may be observed that the nations which refuse monopolies of invention, are as fruitful as England in new and useful devices." Thomas Jefferson to Isaac McPherson, 13 August 1813, https://founders.archives.gov/documents/Jefferson/03-06-02-0322#Jlaut75180918130813U813_4-ptr.

describe his invention clearly enough that the patent office, in evaluating eligibility for a patent, can understand the boundaries between the monopoly and what remains in the public domain. Likewise, after a patent is granted, anyone should be able to determine what is within the inventor's monopoly and what someone else may use freely from the public domain. That is the justification for the clear description or possession requirement in section 112.

The other part of the bargain is that an inventor obtains a temporary monopoly in exchange for giving up his trade secret protection after the monopoly expires. After the patent is terminated, the invention goes into the public domain. But, it does not really go into the public domain unless information in the patent is sufficient to enable other people to practice the invention. That is the justification for the enablement requirement of section 112.

These rationales for the enablement requirement in an application do not apply to non-patent prior art. Some prior art references involve persons who already have obtained patents. A patent examiner has already determined that enablement exists in those patents. The authors of non-patent references are not seeking patents. But prior art nevertheless must be enabling, as explained in section III.D.

D. Enablement of Prior Art

The concept of enablement plays two different roles in patent prosecution.¹³⁶ The first role assesses the sufficiency of the application. If it does not provide sufficient detail and concreteness to enable another to make the invention, it must be denied because the inventor has not fulfilled his half of the bargain enshrined in the Patent and Copyright Clause. The second role is to assess whether a new invention is novel. In this role the question of enablement is applied, not to the new application, but to prior art.

If the prior-art reference does not enable what it discloses, it is not really inventive in character, and leaves the work of invention to someone else—the new inventor and applicant. Conversely, if the prior-art reference fully enables what it discloses, then the invention claimed by the new applicant had already been made and the new applicant's work was anticipated.

Section 112 imposes an enablement requirement only on new patent applications. But, enablement is demanded of prior art as well to show that it really anticipates an invention rather than merely expressing a hope that someone, someday might translate an idea into practice.

The proper test of a publication as a § 102(b) bar is whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought. In particular, one must be able to make the claimed invention without undue experimentation.¹³⁷

¹³⁶The two roles also are distinct when accused infringers challenge patent validity.

¹³⁷ In re Elsner, 381 F.3d 1125, 1128 (Fed. Cir. 2004) (internal quotation and citation omitted). The reference to 102(b) is to the pre-AIA statute. Now, the reference would be to section 102(a).

Whether a prior art reference is enabling presents a question of law based upon underlying factual findings. This court reviews the ultimate question of enablement without deference while reviewing the underlying factual inquiries for clear error. Under the clear error standard, the district court's findings will not be overturned in the absence of a definite and firm conviction that a mistake has been made.¹³⁸

Pictures and drawings may be sufficiently enabling to anticipate.¹³⁹ "[T]he picture must show all the claimed structural features and how they are put together," however.¹⁴⁰ Not all non-patent references enable, however, any more than patent references.141

Entitlement to a patent depends on the applicant's having invented something new and operative. A claimed invention is not new if it is not novel or if it is obvious, or both, and its is not novel if someone else already invented it. But, it has not already been invented unless someone else reduced the invention to practice, actually or constructively,¹⁴² or unless previous discoveries or general knowledge in an industry made it obvious for a person skilled in the art to create the same invention.

Prior reduction to practice has not occurred unless the earlier inventor described his invention in sufficient detail to enable someone to make it. Obviousness cannot exist unless the prior inventors or commentators have given a person skilled in the art enough information to allow him to make the invention with a reasonable expectation of success.

If the prior-art reference does not enable, but the new application does, then the applicant has invented something new and satisfies the novelty requirement for a patent.

Although the two tests under section 112-possession and enablement--are distinct in the examination process, they may be difficult to separate cleanly in assessing prior art. The question with respect to prior art is whether someone else, before the new inventor, has possessed the invention, whether she has reduced it to practice—or, whether she has provided instructions sufficient to allow a stranger to reduce it to practice, in either event putting it in the public domain or creating a preemptive invention.

Scrutiny of enablement of prior art non-patent prior art benefits from considering indicia of possession indicated by the reference as well as the robustness of the instruction to another provided by the reference.

When prior art is used in obviousness rejection, not all of the prior art must be enabling. One reference that is enabling, but not anticipatory, might be combined

¹³⁸ Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., 545 F.3d 1312,1315 (Fed. Cir. 2008) (internal citations omitted).

¹³⁹ MPEP 2121.04, citing In re Bager, 47 F.2d 951, 953, 8 USPQ 484, 486 (CCPA 1931).

 $^{^{140}}Id.$

¹⁴¹ See Preemption Devices, Inc. v. Minnesota Min. & Mfg. Co., 559 F. Supp. 1250, 1259 (E.D. Pa. 1983) ("While the brochures contained the idea behind the patent, they did not include the mechanical information that would allow an expert in the area to create the same or a similar device;" rejecting invalidity claim; making no reference to presumption of enablement).

¹⁴² MPEP 2138.05 (stating that reduction to practice may be actual or constructive; if constructive; constructive reduction to practice requires compliance with section 112).

with another non-enabling reference that provides the motivation to extend the first reference and predicts success if it is.

The question whether a reference is enabling is interesting in the section 102 context; not the section 103 context.

If the prior art reference has fully enabled its invention, there is nothing more for the new "inventor" to do – nothing for him to invent. If, on the other hand, the prior art reference has merely sketched an idea that requires substantial further development and experimentation before it becomes real, one who achieves that development after conducting that experimentation has done something justifying the incentive represented by the temporary patent monopoly. So, enablement in a prior art reference is an important—indeed, essential—inquiry in deciding whether a gap exists between the prior art and the new invention: whether the applicant for a patent can establish novelty.

Obviousness is not irrelevant to whether that gap is real. If it is obvious to one skilled in the art how to close the gap, then the new "inventor" has done no more than is obvious and flunks section 103. But, whether the obviousness inquiry should be conducted as a part of the 102 anticipation assessment or separately as a part of 103 is a legitimate question. Long practice in separating the 102 and 103 inquiries suggests that obviousness should not be a way of satisfying the requirement to find anticipation by a single reference.

IV. PRESUMPTIONS AND PROPHESIES

A. USPTO and the Federal Circuit Take Enablement Out of Contention in Prior Art

The Patent Office presumes that prior art, even non-patent prior art, is enabling. MPEP 2121 says that

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. In other words, once anticipation is found under section 102, enablement presumptively follows. Conversely, if an applicant can show that a reference does not anticipate, he has rebutted the presumption. Once such a reference is found, the burden is on applicant to rebut the presumption of operability.¹⁴³

*In Amgen Inc. v. Hoechst Marion Roussel, Inc.,*¹⁴⁴ the court suggested, without deciding, that the presumption be applied to non-patent publications as well as to patents.¹⁴⁵ Quite recently, in *Ex parte Thomas Edward Shafovaloff,*¹⁴⁶ the Board held that presumption of enablement extends with the same force to non-patent publications as to patents.¹⁴⁷

¹⁴³ MPEP 2121.

^{144 314} F.3d 1313 (Fed. Cir. 2003).

^{145 314} F.3d at n.22.

¹⁴⁶ Appeal 2022-004103, Application 15/173,604, 2023 WL 2329637 (PTAB Feb. 28, 2023).

¹⁴⁷ Federal Circuit has established a legal presumption that both issued patents and non-patent printed publications

The presumption has been operative and applied to non-patent references for more than thirty years. In *Procter & Gamble Co. v. Nabisco Brands, Inc.*,¹⁴⁸ the district court considered and rejected an enabling argument against a reference in a cookbook that anticipated a type of cookie patented by Proctor and Gamble. Much argument involved whether the reference taught the details of how ingredients should be combined and how they could be layered to produce a laminated structure. Persuasive evidence of enablement came from testimony by the accused infringers that its employees had successfully used the cookbook to produce cookies within the scope of the challenged claim of the patent.¹⁴⁹ "[P]rior art references are presumed to be enabling," the court said, without any discussion of the basis for the presumption.¹⁵⁰

PTAB admits that non-patent publications lack the examiner scrutiny that underpins the presumption of enablement for patent prior art, but it nevertheless affords them the same presumption.¹⁵¹

In its brief before the Federal Circuit in *Finjan*,¹⁵² the Patent Office said, "examiners have long presumed that any reference that contains every limitation claimed in a patent is enabling. And since 1995, the Manual of Patent Examining Procedure ("MPEP") has explicitly stated that examiners may apply a rebuttable presumption of enablement."¹⁵³

In *In re Antor Media Corp.*,¹⁵⁴ the court of appeals held that "during patent prosecution, an examiner is entitled to reject claims as anticipated by a prior art publication or patent without conducting an inquiry into whether that prior art reference is enabling. As long as an examiner makes a proper prima facie case of anticipation by giving adequate notice under § 132, the burden shifts to the applicant to submit rebuttal evidence of [non-enablement]."¹⁵⁵ MPEP 2121 cites *Antor*.

The language of MPEP 2121 may seem to constrain the operation of presumed enablement narrowly. But it does not do so for two reasons. First, the office has applied inherency in prior art to supply missing elements or, indeed, all of the elements of a prior art reference even when they are not present explicitly.¹⁵⁶ Second, application of the presumption in obviousness as well as anticipation contexts is inconsistent with how prior art references are used under 103. It is not necessary that every reference be enabling by itself; what matters is whether all of the references are enabling, collectively.¹⁵⁷

But the main shortcoming of the presumption is that it applies to non-patent references as well as to patents. Patents have been subject to examination, during

are enabled." Id. at *7 citing Antor.

¹⁴⁸711 F. Supp. 759 (D. Del. 1989).

¹⁴⁹711 F. Supp. At 772–773.

¹⁵⁰711 F. Supp. at 772 (citing *In Re Sasse*, 629 F.2d 675, 681 (C.C.P.A.1980) (citing *In Re Jacobs*, 318 F.2d 743, 745–46 (C.C.P.A.1963)); and *In Re LeGrice*, 301 F.2d 929, 933 (C.C.P.A.1962)).

¹⁵¹ Ex parte Thomas Edward Shafovaloff, Appeal 2022-004103, 2023 WL 5321165 at *4–*5 (PTAB Aug. 16, 2023) (presumption of enablement extends with the same force to non-patent publications as to patents).

¹⁵² Brief for Appellee Director of the United States Patent and Trademark Office, In re Finjan, Inc., No. 2011-1542, 2012 WL 831197 (Fed. Cir. Filed Feb. 13, 2012).

¹⁵³*Id.* at *16.

¹⁵⁴689 F.3d 1282 (Fed. Cir. 2012).

¹⁵⁵689 F.3d at 1289.

¹⁵⁶ See § 0, supra, discussing inherency.

¹⁵⁷ See § III.A.2, supra, discussing Raytheon.

which the question of enablement was before the examiner. Non-patent publications have not been subject to such scrutiny.

Cases questioning the presumption or refusing to apply are sparse. In *Takeda Pharmaceutical Co., Ltd v. Handa Pharmaceuticals*,¹⁵⁸ the district court reviewed the rational for *Antor Media* and declined to apply the presumption of enablement to an action for infringement brought in district court.¹⁵⁹

In *Morsa*,¹⁶⁰ the prior art was a press release. The examiner determined that the press release anticipated certain claims and made others obvious. Morsa argued that the press release was not enabling. "In particular, he identifies specific defects in the PMA's disclosure, including a lack of operational structures and features of HelpWorks, Web Edition, the way those features and structures interact together, and the specific steps that HelpWorks, Web Edition uses to match users to benefits. Morsa also contends that a press release containing only 117 words of disclosure may be considered non-enabling on its face."¹⁶¹

In Morsa I,¹⁶² the court of appeals, finding that the level of detail in the application far exceeded the level of detail in the press release, vacated the PTAB's finding that the prior art was sufficiently enabling to anticipate the claims. It found that the Board performed an incorrect enablement analysis. The Board held that the applicant failed to rebut the presumption of enablement because it submitted no affidavits or other factual evidence. The court started with the presumption of enablement from *Antor*, not questioning whether it should be applied to non-patent publications.

The presumption in *Antor* is a procedural one—designed to put the burden on the applicant in the first instance to challenge cited prior art; the PTO need not come forward with evidence of enablement before it may rely upon a prior art reference as grounds for a rejection.¹⁶³ Once an applicant makes a non-frivolous argument that cited prior art is not enabling, however, the examiner must address that challenge. While an applicant must generally do more than state an unsupported belief that a reference is not enabling, and may proffer affidavits or declarations in support of his position, we see no reason to require such submissions in all cases. When a reference appears to not be enabling on its face, a challenge may be lodged without resort to expert assistance. Here, Morsa identified specific, concrete reasons why he believed the short press release at issue was not enabling, and the Board and the examiner failed to address these arguments.¹⁶⁴

The court held that such submissions are not necessary; a non-frivolous legal or factual argument is enough to rebut the presumption and to obligate the examiner to establish enablement.¹⁶⁵ It affirmed the obviousness rejections, however.

¹⁵⁸LLC, Case No. C-11-00840 JCS, 2013 WL 9853725 (N.D. Cal. 2013).

¹⁵⁹ Id. at *64-*65.

^{160 803} F.3d 1374, 1377 (Fed. Cir. 2015).

¹⁶¹713 F.3d at 109 (describing argument).

¹⁶² In re Morsa, 713 F.3d 104 (Fed.Cir.2013) (Morsa I).

¹⁶³ *Id.* at 1288.

^{164 713} F.3d at 110.

^{165 713} F.3d at 110.

On remand, the board found the press release to be enabling. It used Morsa's specification to determine what a person of ordinary skill in the art would know. Only ordinary computer programming skills were needed to make and use Morsa's invention. It then found that the disclosure in the press release, combined with that level of skill made the reference enabling and therefore anticipatory of Morsa's claims 271 and 272.¹⁶⁶

*Morsa II*¹⁶⁷ affirmed the Board's finding of enablement. It used the applicant's specification against it, finding that the specification showed that one with only ordinary programming skills was the relevant PHOSITA,¹⁶⁸ and that such level of skill made the press release enabling. Each limitation in the reference mapped onto the limitations in the application, and that "that the application's specification indicates that a person of ordinary skill in the art is capable of programming the invention."¹⁶⁹

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,¹⁷⁰ the court of appeals, reversing the district court in material part, held that

"[i]n patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue.¹⁷¹

It cited *In re Sasse*,¹⁷² for the proposition that, when the PTO cites a disclosure which expressly anticipates the present invention, and the applicant raises a question whether one skilled in the art would be able to make the invention based on what was explicitly disclosed, the burden shifts back to the Patent Office to establish enablement.¹⁷³

The presumption of enablement in MPEP 2121 exists in tension with other statements about enablement in prior art. Section 2121.01 of the Manual of Patent Examining Procedure ("MPEP")¹⁷⁴ makes it clear that prior art does not render an invention not novel under section 102 unless it contains an enabling disclosure.¹⁷⁵ "Mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation."¹⁷⁶ A prior-art disclosure may become enabling when it is combined with other prior art.¹⁷⁷

Section 2131.02 of the MPEP makes it clear that prior art disclosure of a genus does not anticipate claims to species within the genus unless the prior art "clearly names the species"¹⁷⁸ or unless they can be "at once envisioned" from the disclosure.¹⁷⁹

175 MPEP § 2121.01.

¹⁶⁶803 F.3d at 1376 (describing procedural history).

^{167 803} F.3d 1374, 1377 (Fed. Cir. 2015).

¹⁶⁸ 803 F.3d at 1377. ¹⁶⁹ 803 F.3d at 1377.

¹⁷⁰ 314 F.3d 1313 (Fed. Cit. 2003).

¹⁷¹ 314 F.3d at 1355.

^{172 629} F.3d 675 (Ct. Cus. & Pat. App. 1980).

^{173 314} F.3d at 681.

¹⁷⁴ United States Patent and Trademark Office, Manual of Patent Examining Procedure (2022 ed.).

¹⁷⁶MPEP § 2121.01 (citing Elan Pharm., Inc., v. Mayo Found. For Medi. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003)).

¹⁷⁷ Id.

¹⁷⁸ MPEP § 2131.02(II).

¹⁷⁹ MPEP § 2131.02(III).

Section 2144.08 of the MPEP considers genus/species situations in the context of obviousness. It says, "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness."¹⁸⁰ Section 2164.03 of the MPEP says that the enablement requirement becomes more stringent the greater the unpredictability of the art. Thus, generic disclosures in prior art should be viewed more skeptically when they cover new and rapidly evolving technologies such as AI.

The test for enablement of a stand-alone section 103 reference is the same as for a section 102 anticipatory reference.¹⁸¹

Section 2164.03 of the MPEP says that the enablement requirement becomes more stringent the greater the unpredictability of the art. Thus, generic disclosures in prior art should be viewed more skeptically when they cover new and rapidly evolving technologies such as AI.

The MPEP virtually negates challenges to embodiment as a basis for disqualifying prior art. While a patent applicant can seek to rebut the presumption of enablement, such efforts rarely succeed.

"Whether a prior art reference is enabling presents a question of law based upon underlying factual findings." Resolution of that legal question is reviewable on appeal without deference while the factual findings are reviewed for clear error. "Under the clear error standard, the district court's findings will not be overturned in the absence of a definite and firm conviction that a mistake has been made."¹⁸² Under *Chevron*,¹⁸³ reviewing courts defer to Patent Office interpretation of ambiguous statutory provisions, when it appears that the Congress meant for the agency to apply its policy and technical expertise to the interpretation.¹⁸⁴ The Supreme Court overruled Chevron earlier this year, in Loper Bright Enterprises v. Raimondo,¹⁸⁵ The impact of Loper Bright on judicial review of patent office decisions is yet to be seen,¹⁸⁶ but it opens the door to greater scrutiny of the entablement presumption for prior art.

The standard for prior art enablement – without undue experimentation by one skilled in the art – is indistinguishable from the standard for obviousness. Application of this standard to determine anticipation conflates section 102 and section 103 scrutiny.

Whether the presumption in the MPEP resolves the question depends on whether scenarios exist in which the description of a new invention is enabling but a recitation of all of its elements is not. Suppose prior art discloses all of the

¹⁸⁰ MPEP § 2144.08(II), citing In re Baird, 16 F.3d 380, 382 (Fed. Cir. 1994).

¹⁸¹ Raytheon Technologies Corp. v. General Electric Co., 993 F.3d 1374, 1381 (Fed. Cir. 2021) (reversing PTAB and holding that prior-art reference was not enabling). *See also* Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc, 545 F.3d 1312, (Fed. Cir. 2008) (affirming judgment for patent holder; prior art did not anticipate invention because it was not enabling; guidelines in reference were general and offered no working examples); In Morsa, 803 F.3d 1374, 1377 (Fed. Cir. 2015) (affirming board; prior art in the form of a press release identified every limitation in patent claim for Internet-based social-benefits eligibility and was enabling).

¹⁸²Impax Laboratories v. Aventis Pharmaceuticals, Inc., 548 F.3d 1312, 1315 (Fed. Cir. 2008).

¹⁸³Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

¹⁸⁴ Facebook, Inc. v. Windy City Innovations, LLC, 973 F.3d 1321, 1338 (Fed. Cir. 2020) (refusing Chevron deference to PTO's interpretation of IRP joinder rules; statute was not ambiguous).

¹⁸⁵ ____ U.S. ____, 144 S.Ct. 2244, 2273 (2024).

¹⁸⁶ See SoftView LLC v. Apple, 108 F.4th 1366, 1372 n.2 (Fed. Cir. 2024) (noting that consideration of impact of Loper Bright and its impact on patent office statutory interpretation lies in the future).

elements of a kit for, say, a cloth top for a Jeep Wrangler automobile. A subsequent invention claims the same elements but explains how they can be assembled to put the top together, to install it on a Jeep, and to raise and lower it. In fact, the assembly of a cloth top for a Jeep is quite complicated. Installing it and raising and lowering it is non-trivial.

One evaluation of this hypothetical says that the prior art for a kit does not disclose all of the elements of the invention because it omits the structure that connects the elements.¹⁸⁷

[Unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.¹⁸⁸

A competing evaluation, however, would say that enablement is in the instructions for assembly, installation, and use and need not be in the claims. So, each element of the prior art can correspond to each element of the invention, while the description in the prior art is insufficient to be enabling.

Despite the difficulty, some patent holders are able to show that prior-art patents are not enabling.¹⁸⁹

B. Prophesies

An inventor, the author of a technical article, or a storyteller need not offer working examples for every claim; prophetic examples suffice. Prophetic examples permit prior inventors and other authors of prior art to enable by hypothesizing—using their imaginations rather than their hands and physical tools. Prophetic examples abound in non-patent prior art. A prophetic example in a patent specification describes an embodiment based on predicted results, as opposed to being based on work actually performed.¹⁹⁰ The Patent Office expressly allows prophetic examples in patent specifications, as opposed to working examples.¹⁹¹

Prophetic examples are necessary because "[a]n applicant need not have actually reduced the invention to practice prior to filing."¹⁹² But prophetic examples should be presented in a manner, e.g., using the present or future tense, that allows them to be distinguished from working examples, which are presented in the past tense.¹⁹³

¹⁹²MPEP 2164.02 (citing Gould v. Quigg, 822 F.3d 1074, 1078 (Fed. Cir. 1987)).
 ¹⁹³MPEP 2164.02.

¹⁸⁷ Holbrook, 65 Emory L. J. at 1013–1019 (marshaling authority for proposition that anticipation requires not only same elements but also same relationship among them and questioning doctrine).

¹⁸⁸ Net MoneyIN, Inc. v. Verisign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008), Incept LLC v. Palette Life Sciences, Inc., 77 F.4th 1366, 1371 (Fed. Cir. 2023) (applying *Net MoneyIN* same-arrangement requirement and finding anticipation); quoted approvingly in Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. CIVIL NO. 1:22-CV-61 (KLEEH), 2024 WL 382495 at *41 (N.D. W.Va. Jan 21, 2024).

¹⁸⁹ See § IV.D, supra.

¹⁹⁰ MPEP § 2164.02.

¹⁹¹ The USPTO first officially sanctioned prophetic examples in the 1981 edition of the MPEP. Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 678 (2019).

Law review scholarship¹⁹⁴ and recent PTAB cases say that the presumption of enablement can be based on prophetic examples.¹⁹⁵

In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,¹⁹⁶ the court of appeals agreed with the district court that patents were invalid for lack of enablement. It noted that the examples relied on by the patent owner were "paper examples" rather than "working examples," but this made little difference in its analysis which found the examples "insufficient to enable the breadth of the claims here, especially in light of the unpredictability in the art."¹⁹⁷

Janet Freilich¹⁹⁸ conducted empirical research into more than two million patents and published patent applications from the biological and chemical industries and found prophetic examples in seventeen percent of them.¹⁹⁹

If the prior art reference contained no working examples, but only prophetic ones, it is less likely to be enabling.

C. Timing of Enablement

The appropriate model of a PHOSITA depends quite a lot on *when* ordinary skill in the art is assessed.²⁰⁰ When prior art is being evaluated, should skill be assessed only as of the time that the reference was published? Or should it be assessed at the time of the new application for a patent? If the reference was published in 2010 and an application for a new patent is filed by someone else in 2024, is the relevant year for fixing PHOSITA knowledge 2010, or is it 2024?

Either point is plausible. What the reference actually enabled depends on what was known at the time it was written—2010. But what the new inventor has invented, different from what is known, depends on what is known as the time of the invention–or the time of the application under the AIA—2024.²⁰¹

If enablement is at the time the prior art is published, a PHOSITA will know less than if it is tested at the time a later inventor applies for a patent, when a PHOSITA will know more, because of advances in technology. "In other words, we expect the PHOSITA to get smarter over time."²⁰²

Sections 102 and 103 point in two different directions. Section 102 suggests evaluating whether the prior art enables the invention at the time the prior art

¹⁹⁴ Richard D. Kelly, *Prophetic "Examples" Past, Present and Future* OBLON (July 14, 2021), https://www.oblon.com/ prophetic-examples-past-present-and-future#:~:text=3d%201282%20(Fed.,enablement%20shifting%20to%20the%20 patentee.

¹⁹⁵ See Ex Parte Larry Green and Hiroaki Shizuya, Appeal 2022-003986, Application 15/095,889, 2024 WL 863949 at *10 (PTAB Feb. 27, 2024) (allowing presumptive enablement of prior art based on prophetic example; affirming claim rejection); Replimune Limited v. Amgen Inc., IPR2023-00106, Patent 10,034,938 B2, 2023 WL 5166725 at *13 (PTAB May 18, 2023) (granting institution of IPR based on presumed enablement based on prophetic example).

^{196 928} F.3d 1340 (Fed. Cir. 2019).

^{197 928} F.3d at 1348.

¹⁹⁸ Janet Freilich, Prophetic Patents, 53 U.C. DAVIS L. REV. 663 (2019).

¹⁹⁹53 U.C. DAVIS L. REV. at 692–697.

²⁰⁰ See Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1460 (2016) ("Patents reflect various snap shots in time that reflect the state of the art at a particular moment. Patent law must constantly wrestle with time).

²⁰¹ See Rebecca S. Eisenberg, Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA, 19 BERKELEY TECH. L. J. 885, 887 (2004) (explaining timing controversies despite apparent clarity of the phrase "at the time the invention is made" in section 103).

²⁰² Holbrook at 1470.

became public. Section 103 evaluates whether the prior art references, collectively, enable the PHOSITA to make the invention at the time an application is filed for the new invention. Section 103 says, "before the effective filing date of the claimed invention."²⁰³

Using 2024 knowledge to evaluate events in 2010 is known as *hindsight bias*. The hindsight-bias risk is greatest when patent validity is challenged in infringement litigation, because the litigants and decisionmaker must put themselves back in time to the point of invention, the date of application, or the date the prior art was published, almost certainly years before the lawsuit comes to trial. The challenge and risk are more modest when enablement is assessed in patent prosecution.

Hindsight bias often arises in the context of non-obviousness:²⁰⁴

[A]scertaining [non-obviousness] requires fact finders to travel back in time to the moment of invention and, from this temporal vantage point, determine whether the invention would have been obvious . . . to a person having ordinary skill in the art. This exercise—the reconstruction of the incentives and hurdles facing the inventor, and the mapping of the relevant universe of knowledge available to the inventor—entails a high risk of hindsight bias on the part of the fact finder, who has prior knowledge of the completed invention and the steps taken to create it. In short, most inventions will appear obvious in hindsight.²⁰⁵

But hindsight bias also confronts evaluations of enablement of prior art, because the gap between the time when the prior art was published and the time when the application for a patent the prior art is said to anticipate is likely to be significant.²⁰⁶

Someone reading a patent a few years after it issues may be able to glean far more from the disclosure than someone could back at the time of the original disclosure. It is conceivable, therefore, that a disclosure that was not enabled at its effective prior art date could actually become enabled later in time because the PHOSITA's knowledge has expanded to fill any such gap in knowledge.²⁰⁷

Timing also is important for evaluating inherency,²⁰⁸ which further relaxes the single-reference rule for anticipation.

^{203 35} U.S.C. § 103.

²⁰⁴ See Holbrook at 1460.

²⁰⁵ Laura G. Pedraza-Fariña & Ryan Whalen, A Network Theory of Patentability, 87 U. Chi. L. Rev. 63, 68–69 (2020) (internal quotations omitted).

²⁰⁶ Holbrook, 69 VAND. L. REV. 1459 at 1461 (noting importance of considering hindsight bias in the anticipation context); 1475 (hindsight bias is a problems in the anticipation inquiry).

²⁰⁷ Holbrook, 69 VAND. L. REV. 1459 at 1474–1475.

²⁰⁸ Holbrook, 69 VAND. L. REV. 1459 at 1473–1474 (timing of PHOSITA is important in anticipation context: to evaluate inherency and to evaluate enablement). Inherency is discussed in § II.C.

D. Proving Enablement and Disproving Presumption of Enablement

To establish enablement, or to rebut a presumption of enablement, a party may rely on good argument and factual assertions,²⁰⁹ but in most cases, expert testimony is necessary. Who has the burden of production and persuasion depends on the operative presumption.

Evidentiary contests over enablement arise in two different contexts, and in two different ways, in each context. Enablement may be questioned in patent prosecution, either because the examiner claims that the disclosure in an application is not enabling or because prior art is asserted to be enabling and, therefore, anticipatory. Enablement also arises in infringement litigation when patent validity is challenged. In such litigation the challenged patent's enablement may be questioned, or an accused infringer may claim that the patent is invalid because it is anticipated by an enabling reference.

Enablement is presumed in any prior art reference containing all the elements of a claim.²¹⁰ A patent applicant or patent holder can negate the presumption only by showing that not all the elements are present in the reference or by proving lack of enablement.

Regardless of the context and the presumptions, the types of proof likely to be persuasive on the question of enablement are the same. So, cases from one context are useful in others.

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,²¹¹ the Federal Circuit affirmed the district court's finding that the patentee had rebutted the presumption of enablement because it showed a failure to describe adequately how to derive the starting materials and a failure to deposit the cells comprising the starting point for a cell line used to produce a claimed pharmaceutical agent: erythropoietin ("EPO"). The patent holder presented three expert witnesses who testified that they attempted to duplicate the disclosure in the patent application, that "they searched for a long time and in many different ways to find a suitable cell line, and finally settled on a liver tumor cell line—not a kidney tumor cell line like the patent application. Furthermore, the prior-art patent did not deposit EPO-producing kidney tumor cells."²¹²

In *Alza Corp. v. Mylan Laboratories, Inc.*,²¹³ the district court found that the patent holder failed to rebut the presumption of enablement in a prior-art patent. Alza asserted that Mylan "made at least 29 formulations of the Morella dosage form" before producing a dosage form that fell within the claims of its patent. But, the court said:

Alza offers no corroborating evidence indicating that the Morella formulations constituted undue experimentation. To the contrary, both Dr. Peppas and Dr. Amidon agreed that the Morella formulations were within the

²⁰⁹ In re Morsa, 713 F.3d 104, 110 (Fed.Cir.2013) (Morsa I).

²¹⁰ See § IV.A discussing MPEP 2121(I).

²¹¹457 F.3d 1293 (Fed. Cir. 2006).

^{212 457} F.3d. at 1307.

²¹³388 F. Supp.2d 717 (N.D. W.Va. 2005).

bounds of routine experimentation for one skilled in the art. Therefore, the Court finds that Alza fails to present persuasive evidence of [non-en-ablement].²¹⁴

In *Impax Laboratories v. Aventis Pharmaceuticals, Inc.*,²¹⁵ the court of appeals found the prior-art patent not to be enabling;

Weighing the *Wands* factors, the trial courts findings properly support its conclusion that an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention. As shown by the trial court, the '940 patent's dosage guidelines are broad and general without sufficient direction or guidance to prescribe a treatment regimen. The alleged prior art also contains no working examples. Finally, nothing in the '940 patent would have led one of skill in the art to identify riluzole as a treatment for ALS. In sum, each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the ' 940 patent. Because the '940 patent does not enable a person of ordinary skill in the art to treat ALS with riluzole, it does not anticipate claims 1–5 of the '814 patent.²¹⁶

The plaintiff appellant had argued:²¹⁷ (1) that the district court had improperly failed to presume enablement of a prior art reference (a patent)²¹⁸; (2) that the district court erred in finding overwhelming evidence of non-enablement sufficient to rebut the presumption,²¹⁹; and (3) that the district court erroneously applied a heightened standard of "possession" appropriate for claim-supporting disclosures to the claim-anticipating context.²²⁰

The court, distinguishing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,²²¹ found that the district court properly placed the burden of disproving enablement on the patent holder, and held that a district court need not explicitly mention the presumption.²²²

In infringement litigation, patent validity is presumed. In *Ormco Corp. v. Align Technology, Inc.*,²²³ the Federal Circuit held that a "party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention. "²²⁴

²¹⁸ Id. at II.

224 498 F.3d at 1318.

^{214 388} F. Supp.2d at 734.

^{215 548} F.3d 1312, 1315 (Fed. Cir. 2008).

^{216 545} F.3d at 1315-1316.

²¹⁷ Impact Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., No. 07-15-13 2007 WL 461 8644 (Fed.Cir. reply brief of plaintiff-appellant Impax, filed Dec. 10, 2007).

²¹⁹ Id at. II.

²²⁰*Id.* at III(A).

²²¹ 314 F.3d 1313, 1355–56 (Fed.Cir.2003) (holding that district court inappropriately placed burden of showing enablement on accused infringer).

^{222 545} F.3d at 1316.

^{223 498} F.3d 1307 (Fed. Cir. 2007).

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,²²⁵ the patent holder successfully established enablement for its own patent by presenting expert testimony that "one of ordinary skill in the art, me, my students, would have understood this not to be limited to the specific types of cells that were used in this example, that other vertebrate cells, mammalian cells, could have been used."²²⁶

In *Immunex Corp. v. Sandoz Inc.*,²²⁷ the patent holder deflected a validity challenge in an infringement action by proving enablement through expert testimony. The testimony showed that the necessary proteins and DNA sequences were known before the initial application, that a PHOSITA could have produced a necessary fusion protein by "ordinary and routine methods. Testimony and text also showed that the patents at issue provided sufficient guidance on how to make the compound, offering a recipe in the specification.²²⁸

In *Rothschild v. Cree, Inc.*,²²⁹ a challenge to patent validity in an infringement suit failed. The challenger claimed lack of enablement, but pointed only to the language of the patent specification in teaching away from MOCVD. "his procedure is extremely expensive and has not produced suitable results reliably."²³⁰ The challenger failed to present evidence presumably in the form of expert testimony, that the teaching away would have necessitated undue experimentation to practice the patent using MOCVD a method for producing semiconductors with desirable properties.²³¹

*Ormco Corp. v. Align Technology, Inc.,*²³² involved patents for computer-aided design and manufacture of custom orthodontic appliances. The principal controversy was whether the patented invention was capable of determining initial tooth positions without human intervention. The challenger to patent validity argued that "an inventor's inability to actually practice his invention is proof of lack of enablement, that mere uncorroborated inventor testimony on enablement is insufficient to create triable issues of fact."²³³

But during his May 12, 2004, deposition, Dr. Andreiko, one of the inventors of the Ormco patents, testified that Ormco had never attempted to create a computerized system that automatically determined tooth positions without human decision making. He also testified that the manual override had been used on all of the approximately forty cases treated using the Insignia product and that, while it was a goal to have the software generate final tooth positions that would not require use of the override, variations in human anatomy had prevented the attainment of that goal. Dr. Andreiko was also unsure if the problems due to variations in human anatomy could be overcome. No convincing countering evidence was produced by Ormco.²³⁴

^{225 314} F.3d 1313 (Fed. Cir. 2003).

²²⁶ 314 F.3d at 1336.

²²⁷ 395 F. Supp.3d 366 (D. N.J. 2019).

²²⁸ 395 F. Supp.3d at 390.

²²⁹711 F. Supp.2d 173 (D. Mass. 2010).

²³⁰711 F. Supp.2d at 197 (quoting specification).

²³¹711 F. Supp. 198–199.

²³² 498 F.3d 1307 (Fed. Cir. 2007).
²³³ 498 F.3d at 1318.

²³⁴498 F.3d at 1319.

The court of appeals said:

If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement. Substantial doubt concerning the enablement of the invention was cast by the inventors in this case.²³⁵

It affirmed summary judgment for the accused infringer based on lack of enablement.

In *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.,*²³⁶ expert testimony that determining how to practice the patent at issue in an infringement case "would be very difficult" and "complicated" and "would require I think the partnering with a clinician to talk about the timing effects and volume effects and how this would actually be translated to a patient actually doing this. I don't know" was not enough to overcome the presumption of validity, which extended to enablement. "Dr. Mumper's *ipse dixit* statements that co-administration would be 'difficult' and 'complicated,' however, cannot be enough to constitute clear and convincing evidence."²³⁷

*Hitkansut LLC v. United States*²³⁸ was a claim against the United States for using patented methods and apparatus for stress relief during research at Oak Ridge National Laboratories. The Government claimed the patents were invalid for lack of enablement, pointing to significant errors in the calculations supporting the claims. It also pointed to "incorrect and an inconsistent use of units for time and temperature, and the improper use of a natural logarithm rather than a base–10 logarithm."²³⁹ The patent holder offered declarations by the inventor and another person, both of whom it qualified at experts and as persons of ordinary skill in the art.

The court rejected these arguments finding that persons having ordinary skill in the art ("PHOSITA") would recognize the errors and easily correct them.²⁴⁰ One of the experts testified:

[b]ased on the extent of the disclosure in the specification, not only is no undue experimentation required to practice the process set forth in the '722 patent, but no experimentation at all is required to practice it All that is required is simple calculations and basic analysis, no experimentation. These circumstances are readily distinguishable from those encountered in decisions finding lack of enablement because of a need for extensive experimentation.²⁴¹

^{235 498} F.3d at 1318-1319.

^{236 707} F.3d 1330 (Fed. Cir. 2013).

^{237 707} F.3d at 1338.

^{238 119} Fed. Cl. 258 (2014).

²³⁹113 Fed. Cl. at 264 (summarizing arguments).

²⁴⁰ 119 Fed. Cl. at 265.

^{241 119} Fed. Cl. at 267 (internal citations omitted).

In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,²⁴² the court of appeals agreed with the district court that patents were invalid for lack of enablement. One of the inventors and a CEO of the patent owner "admitted at the time, it was thought aggressive chemical modification of nucleic acid would lead to destruction of his [sic] content."²⁴³ Another expert testified similarly. Yet another testified in deposition:

Q: . . . But if they had been motivated to make this probe, non-Ward labeled probe, your view is that they would have to make it and test it in order to predict whether it would actually hybridize as of June 1982, right?

A: Well, they would have to make it and assure against the prevailing wisdom that it could work.²⁴⁴

The court found lack of enablement because of the need for undue experimentation.²⁴⁵

But enablement of prior art is still presumed, as well. The patent defender must rebut the presumption. If the alleged infringer claims that the patent is invalid because of anticipation, the presumption of enablement by the prior art reference continues to operate against the patent.

In its brief before the Federal Circuit in *Finjan*,²⁴⁶ the Office explained why it found Finjan's rebuttal of the presumption of prior-art enablement insufficient:

Finjan provided no evidence to support its theory that a person of ordinary skill in the art could not make the disclosed programs without undue experimentation. For example, Finjan did not describe who a person of ordinary skill in the art was and why the disclosure would be insufficient for that person to practice the invention, nor did Finjan rely on its expert.²⁴⁷

Likewise in Ex Parte Andrey M. Akhmeteli And Andrey V. Gavrilin:²⁴⁸

Although the Appellants make the conclusory allegation that "Armstrong is a good example of 'blue-sky thinking' in that the pressurized fabric structure it discloses is inherently incapable of achieving buoyancy before collapsing," the Appellants have not provided any persuasive evidence or reasoning that would tend to show that Armstrong is not enabling."²⁴⁹

While one must keep in mind a complex array of presumptions to understand burdens of proof, the types of evidence necessary to show enablement or lack

^{242 928} F.3d 1340 (Fed. Cir. 2019).

^{243 928} F.3d at 1348.

²⁴⁴ 928 F.3d at 1348.

^{245 928} F.3d at 1349.

²⁴⁶ Brief for Appellee Director of the United States Patent and Trademark Office, In re Finjan, Inc., No. 2011-1542, 2012 WL 831197 (Fed. Cir. Filed Feb. 13, 2012).

²⁴⁷ Id. at *19.

²⁴⁸ Appeal 2010-005001, Application 11/517,915, 2013 WL 1331753 (PTAB Mar. 28, 2013).

²⁴⁹ Id. at *4 (upholding examiner's application of presumption of enablement) (internal citations to record omitted).

thereof are the same. *Morsa I*,²⁵⁰ allows an applicant to rebut the presumption of enablement by argument; presentation of factual evidence in the form of witnesses or otherwise is not always necessary.²⁵¹ But as a practical matter, expert witness testimony about enablement gaps is likely to be necessary.

The guidance the MPEP gives examiners on how to evaluate enablement of a new application is helpful in understanding what might support a finding of enablement or non-enablement in the prior art context.

When enablement is at issue in prosecution, the applicant is burdened to establish enablement if the examiner established a prima facie basis for questioning enablement. In prosecution, an examiner "has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention."²⁵² A specification disclosure that teaches the manner and process of making and using a claimed invention must be accepted unless the examiner explains why the truth or accuracy of the disclosure is doubtful and presents evidence or reasoning supporting those doubts.²⁵³ Once the examiner has done that, and thereby established a *prima facie* case of lack of enablement, the burden falls on the applicant "to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide."254 Such evidence may take the form of: a declaration that the claimed invention works; evidence of efficacy presented to other government agencies; or other "argument and / or evidence that the disclosure would have enabled one of ordinary skill in the art to make and use the claimed invention at the time of filing."255

A particularly persuasive way to rebut the presumption of enablement or to contest proof of enablement is to retain an expert who is unfamiliar with the new invention and the patent application on it. The expert should be tasked with taking the prior art reference and, using it, along with his knowledge of the art as of the date of the reference, to try to make it use the invention covered by the prior art. The expert should then be allowed to use his knowledge of the art as of the time of the application for the new patent. Assuming the expert can qualify as an appropriate person skilled in the relevant art, his testimony of failure or undue experimentation should be powerful proof of non-enablement. The two different times for his estimate of the necessary experimentation permit legal argument as to application of hindsight bias.

Another effective approach in the patent-prosecution context is to show the details that enable the patent application under consideration and contrast them with the lack of detail in the prior art reference.

²⁵⁰In re Morsa, 713 F.3d 104 (Fed.Cir.2013) (Morsa I).

²⁵¹ See text accompanying note 164, supra (discussion Morsa I).

²⁵² MPEP 2164.04.

²⁵³ MPEP 2164.04.

²⁵⁴ MPEP 2165.05.

²⁵⁵ MPEP 2164.05.

E. Jury Instruction

The model AIPLA jury instruction for prior art in the form of printed publications addresses enablement:

The disclosure of the claimed invention in the printed publication must be complete enough to enable one of ordinary skill in the art to use the invention without undue experimentation. In determining whether the disclosure is enabling, you should consider what would have been within the knowledge of a person of ordinary skill in the art as of [Cutoff Date], and you may consider evidence that sheds light on the knowledge such a person would have had.²⁵⁶

The more detailed instruction on enablement in general, presented in § III.A.2 is also relevant.

V. Amgen Invites Renewed Attention to Enablement

The Supreme Court's 2023 decision in *Amgen* invites renewed attention to enablement, even though the case did not involve prior-art enablement.

A. Amgen Itself

In *Amgen, Inc. v. Sanofi*,²⁵⁷ the Supreme Court of the United States unanimously affirmed the United States Court of Appeals for the Federal Circuit and held that the burden of the enablement requirement in section 112 varies proportionately with the scope of a patent's claims. "The more one claims, the more one must enable."²⁵⁸ Controversy has erupted in law review articles, ²⁵⁹ blogs, and magazine articles over the impact of *Amgen*'s "full-scope-enablement" requirement.²⁶⁰

It is not immediately apparent why the Supreme Court granted *certiorari* in *Amgen*. Both the district and the appeals courts had decided that the Amgen patent was invalid for lack of enablement, and the Supreme Court unanimously agreed. No one dissented from the Federal Circuit panel decision. The Supreme Court

²⁵⁶ Id. at 31.

²⁵⁷ 598 U.S. 594 (2023).

²⁵⁸598 U.S. at 610.

²⁵⁹ See Jie Yang, Enablement for Genus Claims: A Bifurcated Approach, 23 Chicago-Kent J. I.P. 20 (2023) (evaluating Amgen and proposing that functional claims be limited to structures for enablements actually disclosed); Oskar Livak, Comments on Amgen v. Sanofi, 23 Chicago-Kent J. I.P. 154, 160–161 (2023) applauding Amgen and arguing that enablement cannot extend beyond what applicant actually invented).

²⁶⁰Compare Christopher M. Holman, *Is the Chemical Genus Claim Really 'Dead' at the Federal Circuit?: Part I*, 41 Biotech. L. Rep. 4 (2023) (arguing that *Amgen* does not represent a shift in 112(a) law) and Dominic A. Frisna, *Amgen is Not the End of Chemical Innovation*, (July 17, 2023), https://www.bdblaw.com/amgen-is-not-the-end-of-chemical-innovation/ (arguing that Amgen changes little) with Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 Yale L. J. 994 (2023) (arguing that "full-scope requirement threatens some of the most valuable patents) and Gene Quinn, *SCOTUS Ushers in a New Era of Enablement Law in Amgen Ruling*, IPWatchdog, May 18, 2023 (excoriating Amgen decision).

usually grants *cert*. when a circuit split exists—not possible given the exclusive appellate jurisdiction of the United States Court of Appeals for the Federal Circuit²⁶¹—when the Court of Appeals has reversed a district court opinion, or when a panel of the Court of Appeals is split and a dissenting opinion is persuasive. None of these circumstances existed in *Amgen*. Commentary after the Federal Circuit opinion was sparse. One commentator said, before the Supreme Court granted certiorari, that the Court of Appeals was simply trying to harmonize precedent behind the use of the *Wands* factors²⁶² and to quash speculation that a few Federal Circuit opinions had embraced a more aggressive full-scope enablement requirement—hardly a reason for the Supreme Court to get involved.

Amgen, however, tried to persuade the Supreme Court that the sky was falling. It sought reversal on the grounds that the full-scope enablement test applied by the Federal Circuit has no "foundation in the text of section 112 or this Court's precedent."²⁶³

In its principal brief it argued:

Departing from statutory text, precedent, and history, the decision below announces a different standard-one that fundamentally alters the patent bargain. It is no longer sufficient that the patent enable skilled artisans to make and use the invention. Instead, skilled artisans must be able to *"reach the full scope* of claimed embodiments-*i.e.*, to cumulatively identify and make all, or nearly all, possible variations of the invention-without substantial time and effort. That standard, the panel acknowledged, raises the bar, imposing high hurdles in fulfilling the enablement requirement."

The Patent Act nowhere imposes that standard. There may be myriad variations on James Watt's steam engine or the Wright Brothers' airplane. But the law has never required that, for those inventions to be patentable, skilled artisans must be able to cumulatively identify and make every variation without substantial time and effort. The folly of a make all embodiments requirement has been recognized by learned commentators from the 19th century.²⁶⁴

Scores of amicus briefs were filed. The United States Government filed one urging affirmance.²⁶⁵

Timothy Bonis, in concluding that the impact of the Supreme Court decision would be modest,²⁶⁶ suggested that Amgen has attracted so much attention be-

²⁶¹ 28 U.S.C. §1295(a) (granting exclusive jurisdiction to Untied States Court of Appeals for the Federal Circuit over appeals from U.S. district courts in patent cases).

²⁶² In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (articulating factors for determining whether a disclosure is enabling under 35 U.S.C. § 112).

 ²⁶³ Reply Brief for Petitioners, Amgen, Inc. v. Petitioners, No. 21-757, 2023 WL 2431330 at *2. (U.S. filed Mar. 6, 2023).
 ²⁶⁴ Brief for Petitioners, No. 21-757, 2022 WL 18108787 at *1 (U.S. filed Dec. 27, 2022) (internal quotations omitted, emphasis in the original).

²⁶⁵ Brief for the United States as Amicus Curiae Supporting Respondents, No. 21-757, 2023 WL 2020074 (U.S. filed Feb. 10, 2023).

²⁶⁶ Timothy Bonis, *Don't Be Too Alarmed by the New SCOTUS Antibody Ruling*, Harvard Law Bill of Health, Dec. 8, 2023, https://blog.petrieflom.law.harvard.edu/2023/12/08/dont-be-too-alarmed-by-the-new-scotus-antibody-ruling/ (summarizing opposing arguments about impact of Amgen decision and concluding that impact will be modest).

cause inventors believe that USPTO and the Federal Circuit have made patents too hard to obtain in the biological and chemical field, especially in applications containing genus claims. Patents in these industries, particularly monoclonal antibody patents, are among the most valuable types of intellectual property protection.²⁶⁷ The technology is advancing rapidly, and monoclonal antibodies can be created to bind to almost any type of cells, thus enabling them to treat specific types of cancer, autoimmune diseases and degenerative diseases such as Alzheimer's.²⁶⁸

In *ESCO Group LLC v. Deere & Co.*,²⁶⁹ the district court distinguished *Amgen* and held that a patent for attaching teeth to excavating equipment was sufficiently enabling. Unlike the facts in *Amgen*, the evidence in *ESCO* showed a genus with only a few embodiments.²⁷⁰ In *Baxalta Inc. v. Genentech, Inc.*,²⁷¹ the Federal Circuit held the facts before it to be indistinguishable from *Amgen*. The patent covered missions of species and offered no disclosures such as a quality common to functional embodiments "that would allow a skilled artisan to predict which antibodies will perform the claimed functions."²⁷² Citing *Amgen* and *Bexalta*, the district court in *Teva Pharmaceuticals International GmbH v. Eli Lilly and Co.*,²⁷³ held that "[t] hese facts amount to nothing more than a 'roadmap' for a 'trial and error' process to identify and make antibodies within the scope of the Asserted Claims."²⁷⁴ It approved a jury verdict indicating lack of enablement.²⁷⁵

In *MHL Custom, Inc. v. Waydoo USA, Inc.,*²⁷⁶ the district court applied *Amgen* to approve a jury finding of lack of enablement in a public report on watercraft design.²⁷⁷ The report culminated a Swedish capstone project for engineering students to "create a vehicle which looks like an eFoil."²⁷⁸ The report was offered to invalidate a patent supporting an infringement suit, arguing that it anticipated the invention covered by the patent.

When a patent seeks protection for a genus, coverage of particular species within the genus encounters the metaphor expressed in *Purdue Pharma L.P. v. Faulding Inc.*:²⁷⁹

one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.²⁸⁰

²⁶⁷ Id.

²⁶⁸ Amgen Inc. v. Sanofi, 598 U.S. at 598 (noting that antibody drugs have yielded life-changing therapies for conditions ranging Crohn's Disease, to cancer, to heart attacks, and strokes).
²⁶⁹ Civil Action No. 20-1679-WCB, 2023 WL 4199413 (D. Del. June 22, 2023).

²⁷⁰ Id. at *17–*18.

^{271 81} F.4th 1362 (Fed. Cir. 2023).

²⁷²81 F.4th at 1366.

²⁷³ Civil Action No. 18-cv-12029-ADB, 2023 WL 6282898 (D. Mass. Sept. 26, 2023).

²⁷⁴ Id. at *22.

²⁷⁵ Id. at *24.

²⁷⁶ Civil Action No. 21-0091-RGA, 2023 WL 5748755 (D. Del. Sep. 6, 2023).

²⁷⁷ Id. at *7.

²⁷⁸ Id. at *3.

^{279 230} F.3d 1320 (Fed. Cir. 2000).

^{280 230} F.3d at 1326-1327.

Amgen involved an invalidity argument by a defendant in a patent infringement suit. Its potential impact is considerably broader. The reasoning of the case logically applies to the conjoint interpretation of sections 102, 103, and 112 when prior art is mobilized to block the issuance of a patent. To what extent must prior art enable something to be practiced before it blocks a patent for an invention by anticipating it or by making it obvious?

In a January, 2024 notice, ²⁸¹ the USPTO said that *Amgen* does not disturb its application of factors identified by the Federal Circuit in *In re Wands*,²⁸² to determine whether undue experimentation is required, thus negating enablement. Those factors are:

- (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.²⁸³

Just as *Amgen* did not change the standards for enablement in the patent-validity context, it does not, by implication, change the standards for assessing whether prior art is enabling. *Amgen* does, however, reinforce the need for a rigorous assessment of enablement, especially when prior art describes a genus without giving much detail about particular species within the genus.

B. Implications for Prior Art

The facts of *Amgen* put the Supreme Court in the position of deciding whether enablement of a handful of species within a broad genus enables the entire genus. The Supreme Court said, "no," thus embracing, according to his critics, a fullscope enablement requirement. If an applicant claims the genus the entire genus, the Supreme Court said it must enable all that it claims.

Amgen is likely to have considerably more impact in the biotech arena than in the mechanical and electrical arts. Gene Quinn, criticizing the Morse analogy, notes that the patent invalidated for lack of enablement in *Amgen* included 26 antibody examples, 400 pages of detailed instructions for generating additional antibodies within the genus, and a CDROM of the x-ray crystallography coordinates of Amgen's "anchor" antibodies.²⁸⁴ Mechanical and electrical patents, in contrast, are more likely to involve genera with only a few species. Therefore, Amgen's requirement for "full-enablement" will be easier to satisfy outside the biotech arena.²⁸⁵

²⁸¹ USPTO, Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. v. Sanofi, 89 Fed. Reg. 1563 (Jan. 10, 2024) (reiterating the appropriateness of the eight Wands factors in evaluating enablement in applications), citing *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

^{282 858} F.2d 731 (Fed. Cir. 1988).

^{283 858} F.2d at 737.

²⁸⁴ Gene Quinn, SCOTUS Ushers in a New Era of Enablement Law in Amgen Ruling, IPWATCHDOG (May 18, 2023) (excoriating Amgen decision).

²⁸⁵ But see Hyatt v. Iancu, 332 F. Supp. 3d 83, 106–107 (D.D.C. 2018) (rejecting genus claims for insufficient specificity; patent application for video processing and associated computing and memory architectures).

Amgen itself is anticlimactic. It affirmed what PTAB and the Federal Circuit were already doing with respect to enablement analysis, and, if USPTO's Federal Register notice is correct, did not change anything in the factors the Office applies to evaluate enablement. So, with respect to section 112 itself, *Amgen* is a non-event. But the decision has invited renewed attention to the enablement requirement and, thus, provides an opportunity to reconsider what might be called inverse enablement—the requirement that prior art must be enabling if it is to be anticipatory.

Amgen involved an invalidity argument by a defendant in a patent infringement suit,²⁸⁶ but the reasoning of the case logically applies to the conjoint interpretation of sections 102, 103, and 112 when prior art is mobilized to block the issuance of a patent. To what extent must prior art enable something to be practiced before it blocks a patent for an invention by anticipating it or by making it obvious?

As the Federal Circuit pointed out before the case got to the Supreme Court, "if another party invents a species not described or enabled by a first inventor, and hence not able to be encompassed by a properly enabled generic claim, that party has promoted the progress of the useful arts."²⁸⁷

VI. APPLYING THE LAW TO THE HYPOTHETICALS

The introduction offered four hypothetical situations in which fanciful, non-patent prior art was offered as anticipating an invention and thus defeating the novelty required for patenting. This section applies the law developed in the article so far to the facts of those hypotheticals.

The analysis that follows in this section presupposes that "all of the elements of the claimed invention" are present in the prior art reference. In most cases, including the hypotheticals, it will be open to the applicant to challenge that proposition, thus negating the predicate for the presumption.²⁸⁸ Section 2121(I) of the MPEP imposes a presumption of enablement only when all elements are present. But, even if the applicant argues that not all elements are present, the doctrine of inherency may trip him up.²⁸⁹

Or worse, the PTAB may ignore the prerequisites to the presumption. In *Ex Parte William Kress Bodin, Jesse Redman, and Derral Charles Thorson*,²⁹⁰ the PTAB said that the applicant failed to rebut the presumption of enablement:

Appellants do not point to any facts evincing Duggan is non-enabling, but simply rely on the argument that 'Duggan does not disclose each and every element and limitation of the independent claim.' That argument, however, relates to anticipation, not enablement. As such, Appellants have failed to carry their burden.²⁹¹

²⁸⁶ 598 U.S. at 599 (describing procedural history).

²⁸⁷ Amgen. Inc. v. Sanofi, Aventisub LLC, 850 F.App'x 794, 797 (Fed. Cir. 2021) (aff'd 598 U.S. 594 (2023)).

²⁸⁸ See Ex Parte Sarbajit Banerjee, Luisa Whittaker-Brooks, Christopher J. Patridge, and Peter Marley, Appeal 2020-004119, Application 13/632,674, 2021 WL 3784325 at *3 (PTAB Aug. 25, 2021) (declining to sustain examiner's objection based on presumption of enablement; none of the prior art references include all of the limitations).

²⁸⁹ See § II.C, discussing inherency.

²⁹⁰ Appeal 2011-001823, Application 11/041,922, 2013 WL 3289118 (PTAB May 30, 2013).
²⁹¹ Id. at *4.

The enablement question is part of the anticipation question, and disclosure of each and every element is the predicate for application of the presumption. This aspect of the *Ex Parte Bodin* decision is simply wrong.

Enablement is most likely in the cooking recipe hypothetical. There, whether the disclosure is enabling depends quite a lot on what is to be cooked. If it is a cake, undue experimentation likely would be required to determine the portions of flour, eggs, fat, sugar, salt, liquid, and leavening agents such as baking soda²⁹² and further to determine cooking temperatures.²⁹³ Cooking times are less of a problem because one can experiment simply by examining the cake periodically while it is in the oven.

On the other hand, if the recipe is for chili or an omelet, the proportions of ground beef, beans, tomatoes and spices do not much matter for acceptable chili; neither do the proportions of eggs, cheese and vegetables much matter for an omelet. Cooking temperatures are not particularly critical, and cooking times easily can be determined by inspection. The degree of experimentation required to turn a list of ingredients into successful chili or a successful omelet is modest.

The prior art reference in each of the other hypotheticals may turn out to be enabling or not, depending on the point in time at which a PHOSITA is defined.

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.²⁹⁴

Hindsight bias is not only a problem with obviousness assessment under section 103, but prior-art enablement evaluation under section 102. Gregory Mandel observes, based on his experimental data,²⁹⁵ that hindsight bias invalidates prior-art enablement determinations because the level of skill of a PHOSITA changes between the time a patent application is filed and prior art enablement is evaluated, and in technologies that are advancing the fastest.²⁹⁶

Enablement is least likely in the telepathy example, but whether it exists is highly dependent on the time at which PHOISITA knowledge is assessed.²⁹⁷ Telepathy was a common theme of science fiction writing in the late 1940s and early

²⁹² See Dede Wilson, The Importance of Baking Proportions, BAKEPEDIA, Jan. 28, 2014, https://www.bakepedia.com/tipsandtricks/baking-proportions/.

²⁹³ See Andy Connelly, *The science of cake*, THE GUARDIAN (Jun. 9, 2010), https://www.theguardian.com/science/ blog/2010/jun/09/science-cake-baking-andy-connelly (providing detailed instructions on proportions, mixing, and cooking temperatures).

²⁹⁴ In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (internal quotations and citations omitted).

²⁹⁵ Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 Ohio St. L. J. 1391, 1394–1395 (2006) (analyzing experimental evidence of hindsight bias and concluding that it infects enablement determinations, as well as doctrine of equivalents, claim construction, the on-sale bar).

²⁹⁶ 67 Оню St. L. J. at 1442–1443.

²⁹⁷ See § IV.C, analyzing time at which enablement is assessed.

1950s.²⁹⁸ According to what was known at the time, telepathy seemed about as practicable as perpetual motion, and perpetual motion has always been the paradigm of impossibility in patent law.²⁹⁹

But if enablement of telepathy is assessed in 2024, after the Neuralink success³⁰⁰ was publicized, the likelihood is much greater that one skilled in the art would know how to make a telepathy device without undue experimentation.

Dick Tracy's 1946 version of the two way wrist radio is very unlikely to be enabling if the time to assess PHOSITA is 1946. To make a two-way wrist radio resembling the Apple watch back then would have required a person reading the comic strip to develop the whole universe of post-World War II electronic technology, including the transistor and other semiconductors, miniaturization, integrated circuits, and exploitation of UHF frequencies. The degree of experimentation to accomplish all of this in a reasonable period time would be insuperable. On the other hand, if one takes a snapshot of a PHOSITA in 2024, any reasonably sophisticated engineer could construct something resembling a two-way wrist radio after being prompted by the comic strip.

Whether patents associated with Elon Musk's Starlink satellites are anticipated by Arthur C. Clarke's 1945 article³⁰¹ depends on timing as well. If the relevant art is that of 1945, the article is not enabling. If relevant art is assessed as of 2019, when the first Starlink satellite was launched, the article may be enabling.

The analysis of all of the hypotheticals indicates that evaluation of enablement is quite fact sensitive in all of them and equally sensitive to the legal rules for inherency and timing. Given its likely outcome-determinative effect in determining anticipation, all of the facts determining enablement should not be obscured by an automatic presumption.

VII. SHOULD ENABLEMENT BE PRESUMED?

Assuming that a prior-art reference is enabling has been a feature of patent law for decades. It originated for patent prior-art, where the rationale is clear: a patent examiner has determined, at least implicitly, that the specification in the patent meets the requirements of section 112, and is thus enabling. It more recent years, the presumption has been extended to published patent applications that have not been examined and to non-patent publications which will never be examined. The following sections consider the arguments for and against retaining the presumption.

To be sure, MPEP § 2121 does not make a reference identifying all of the elements *per se* enabling; instead, it establishes a rebuttable presumption of enable-

³⁰¹ See note 12, supra.

²⁹⁸ Telepathy, The Encyclopedia of Science Fiction (Feb. 2, 2021), https://sf-encyclopedia.com/entry/telepathy (reporting on popularity of telepathy in science fiction of the 1950s).

²⁹⁹ "[I]t is well established that fantastic or impossible inventions are not considered useful under Title 35 and so they are not patentable. Although the courts have determined that perpetual motion machines are not patentable because they are impossible and individuals can therefore not use them as required under § 101," Bailey Gallagher, *The Singularity Is Near: Implications for Patent and Copyright Law in the Age of Whole Brain Emulation*, 26 FED. CIR. BAR J. 1, 20 (2016).

³⁰⁰ See § supra (discussing Neuralink experiment).

ment. But rebuttable presumptions are hard to rebut, and it is not clear why the burden with respect to prior art enablement should be shifted to the applicant instead of the examiner.

A. Arguments for Retaining the Presumption

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.,*³⁰² the court explained in a footnote why district courts should be relieved of the burden of adjudicated prior art enablement in every case:

Additionally, we think it unwise as a matter of policy to force district courts to conduct a mini-trial on the proper claim construction of a prior art patent every time an allegedly anticipating patent is challenged for lack of enablement. As we frequently revisit district courts' determinations in matters of claim construction and validity, we are certainly aware that such a task can occupy a great deal of a court's resources. In any event, because the presumption outlined here does not rely on § 282, we see no reason to impose these burdens on litigants and the district courts.³⁰³

The same rationale can be extended to the Patent Office, which should not have to shoulder the burden of evaluating enablement for every anticipatory reference.³⁰⁴

This argument treats enablement of prior act as a collateral issue and argues that that patent prosecution or infringement litigation should not get embroiled in controversies over collateral issues. But whether a reference counts as prior art and anticipates is hardly a collateral issue. It well may be outcome determinative.

The Patent Office offered a somewhat different justification for retaining the presumption in its brief before the Federal Circuit in *Finjan*:³⁰⁵

Permitting examiners and the Board to continue this practice makes good sense from a policy perspective. Examiners are reviewing hundreds of thousands of applications a year, often relying on non-patent literature. Usage of such literature would be severely curtailed if an examiner had to prove in the first instance that every non-patent reference was enabling. Additionally, applicants are in a better position than examiners to marshal evidence to explain why a particular reference is not enabling for what it discloses. *See Therasense, Inc. v. Becton, Dickinson and Co.,* 649 F.3d 1276, 1314 (Fed. Cir. 2011) (en banc) ("[A] patent applicant is often in a better position than the examiner to know of relevant art or potentially invalidating circumstances, such as prior use."); *see also In re Huang*, 100

^{302 314} F.3d 1313 (Fed. Cir. 2003).

³⁰³ 314 F.3d at 1355 n.21.

³⁰⁴ See generally Holbrook, 65 EMORY L. J. at 1018 (describing motivation to create end run around enablement analysis because it involves complicated facts).

³⁰⁵ Brief for Appellee Director of the United States Patent and Trademark Office, *In re* Finjan, Inc., No. 2011-1542, 2012 WL 831197 (Fed. Cir. Filed Feb. 13, 2012).

F.3d 135, 139-40 (Fed. Cir. 1996) (in response to an obviousness rejection, the applicant bears the burden of showing "hard evidence" of commercial success because the "the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion[s]").³⁰⁶

Presuming enablement and shifting the burden to contest its existence results in an adversarial presentation of evidence more robust than if the starting point is an examiner's articulation of a *prima facie* case of non-enablement. If the applicant or patent defender is burdened to rebut a presumption, the amount and quality of evidence presented will be considerably greater than if the examiner unilaterally, as a part of the examination process, must articulate the basis for a *prima facie* case of lack of enablement. If the examiner finds lack of enablement during prosecution, the applicant will be pleased, the examiner will be satisfied with his own conclusions, and no one will be motivated to contest the relatively simple articulation of the *prima facie* case.

B. Nevertheless, the Presumption Should Be Eliminated

The presumption of prior-art enablement is applied beyond its rationale, in disregard of its prerequisites, with considerable hindsight bias, to allow speculators about technology to deprive real innovators of an incentive to invent. The Patent Office is established to scrutinize the basis for patents, and it should not be able to escape its responsibility when the effect of prior art is at issue.

Presumed enablement extends a rationale developed for patent prior art to non-patent prior art, where it is a non-sequitur.

Five types of prior art exist: patents, published patent applications, other publications, public use, and public sale. The presumption of enablement is appropriate only with respect to the first of these. When a patent is issued, a patent examiner has concluded that the enablement requirement of section 112 has been satisfied. Otherwise, she is not authorized to approve issuance of a patent. The Federal Circuit acknowledged the difference in *Impax Laboratories v. Aventis Pharmaceuticals, Inc.*,³⁰⁷ "An issued patent enjoys a presumption of validity. Thus, a party challenging patent validity has the burden to prove its case with clear and convincing evidence. When the examiner considered the asserted prior art and basis for the validity challenge during patent prosecution, that burden becomes particularly heavy."³⁰⁸

Examination has not occurred with respect to most published applications, and other publications have not been submitted for examination. What if enablement is denied in the prosecution process, but the published application is then offered as prior art and enablement is presumed? Consider *Amgen* itself. In that situation, the rationale for the presumption would be turned on its head. Enablement was, indeed, already adjudicated, and it was found lacking. Yet the presumption would supply it in a subsequent prosecution.

³⁰⁶ Id. at *16–*17.

^{307 548} F.3d 1312 (Fed. Cir. 2008).

^{308 545} F.3d at 1314.

Public sale and use present a somewhat different situation. Examination has not occurred, but the use and the presence in the marketplace indicate enablement. Something that cannot be reduced to practice cannot be in use, and it is unlikely that sale will be offered of something that is not functional.

Section 2121 refers to MPEP § 716.07, which justifies the presumption in favor of the operability of a reference by the presumption of validity of a patent. This logic collapses when the reference is not a patent.

With patents, affording the prior examination results the status of a presumption that is a weak form of non-mutual collateral estoppel. The same issue, enablement, exists that was decided before, but the parties are different. Whether enablement was expressly decided in the prior application depends on what the file wrapper history reveals. If it was not explicitly decided, the common-law doctrine of collateral estoppel is unavailable. If it was, the presumption reflects the "deference that is due to a qualified government agency presumed to have properly done its job."³⁰⁹

But PTAB is unwilling to defer to its own earlier findings of non-enablement. In *Ex Parte Mahalaxmi Gita Bangera, Muriel Y. Ishikawa, Edward K.Y. Jung, Nathan P. Myhrvold, Elizabeth A. Sweeney, Richa Wilson, and Lowell L. Wood Jr.,³¹⁰ the Board found a prior art reference enabling under the presumption, even though an examiner had found the reference not to be enabling during its prosecution, reasoning that the earlier determined related to the claims and that the question of anticipation relied on the entire reference.³¹¹*

For the other categories of private prior art, either the presumption is entirely unjustifiable, or it must be justified by some rationale other than having been already adjudicated. One possibility is allocating the burdens of proof to the party to most likely to be in possession of the relevant evidence. It is the new applicant for a patent who is best able to understand how he went beyond what was already known in the art. He is in the best position to explain how the prior art did not enable what he has done; how if he had merely followed the directions implicit in the prior art his inventive effort would have failed. Justification for shifting the burden to the patent applicant is that the patent applicant is in the best position to explain why his invention is beyond the scope of what is enabled by the prior art reference for example, the applicant can present expert testimony by one skilled in the art that she, instructed by the reference, would never have thought of doing what the applicant did, and if she had, she would not have expected success.

Nevertheless, presumed enablement is inappropriate for non-patent references for a number of reasons. First of all, as Judge Newman points out in her dissent in *Morsa II*,³¹² the doctrine of section 102 anticipation has drifted so as to conflate anticipation with obviousness, supplying missing terms from prior art references by inference from what would be obvious to one skilled in the art. Making it easier to find that all the elements in the application exist in a prior art reference lowers the threshold for triggering the presumption of enablement.

³⁰⁹ Alza Corp. v. Milan Laboratories, Inc., 388 F. Supp. 2d 717, 734 (N.D. W. Va. 2005) (rejecting claim of anticipation explicitly considered and rejected in prosecution), quoting Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed.Cir.1984).

³¹⁰ Appeal 2014-002957, Application 11/728,950, 2017 WL 913818 (PTAB Feb. 24, 2017).

³¹¹ Id. at *12.

^{312 803} F.3d 1374, 1377 (Fed. Cir. 2015). See notes 319-321, supra and accompanying text.

Judge Newman dissented challenged the majority for confusingly conflating novelty under section 102 and obviousness under section 103.³¹³ She argued that the press release did not mention all of the steps and limitations of the claims in the application.³¹⁴ She criticized the board for taking official notice that a person skilled in the art would know how to fill in the gaps. "[W]e are directed to no disclosure in the prior art of all the claim elements and steps. 'Anticipation' is not established in accordance with law."³¹⁵

"'Official Notice' is not anticipation," she said.³¹⁶

The question on the *Morsa I* remand was whether the subject matter of the press release is enabled by the description in the press release: '[The] reference must . . .enable one skilled in the art to make the anticipating subject matter.' *PPG Indus., Inc. v. Guardian Indus. Corp.,* 75 F.3d 1558, 1566 (Fed.Cir.1996). My colleagues use the information in the Morsa specification to enable the press release. That is improper. The gaps in the prior art cannot be filled by the invention at issue; it is improper to transfer Mr. Morsa's teachings into the press release in order to enable the press release.³¹⁷

"These flaws confound the laws of anticipation and obviousness and enablement, defying precedent, and adding to the complexities of patenting. The issues should be decided on the correct law."³¹⁸

To revisit the hypothetical in the introduction involving a recipe: it could be argued that proportions, temperatures, and durations constitute elements of the invention missing from the prior art reference, thus not triggering the presumption of enablement under MPEP § 2121, but the approach criticized by Judge Newman's dissent could supply those, applying the reference without then and then using a combination of inherency and skill in the art to supply them.

In its petition for a *writ of certiorari*,³¹⁹ in *Finjan*, *Inc. v. United States Patent and Trademark Office*,³²⁰ Finjan challenged the USPTO presumption of enablement in non-patent prior art. The petitioner explained the rationale for presuming enablement when the prior art is a patent: the patent has been examined and necessarily found to be enabling; otherwise, it could not have issued. That rationale is entirely lacking, Finjan argued, when the prior art is a non-patent publication.³²¹

In *Matsushita Elec. Indus. Co., Ltd. v. Samsung Electronics Co.,*³²² the district court resolved an argument over how presumed enablement should work with respect

^{313 803} F.3d at 1378 (Newman, J., dissenting).

^{314 803} F.3d at 1379 (Newman, J., dissenting).

^{315 803} F.3d at 1380 (Newman, J., dissenting).

³¹⁶803 F.3d at 1380 (Newman, J., dissenting).

 ³¹⁷ 803 F.3d at 1380-1381 (Newman, J., dissenting).
 ³¹⁸ 803 F.3d at 1381 (Newman, J., dissenting).

³¹⁹2013 WL 1650538 (filed April. 11, 2013).

³²⁰No. 12-1245 (U.S. cert. denied Oct. 7, 2013).

³²¹*Id.* at *3–*4.

³²² Ltd. Civ. No. 02-336 (GEB). 2006 WL 1794768 (D. N.J. June 26, 2006).

to a non-patent publication. To resolve it, the court had to interpret the 2003 *Amgen* case.³²³ It noted that the *Amgen* court did not decide whether its presumption, while applicable in both prosecution and infringement contexts, applied to non-patent publications.³²⁴ "Without further guidance by the Federal Circuit, and in light of the accused infringer's heavy burden with regard to invalidity, the Court declines to shift the burden of proving [non-enablement] to Samsung, the patentee."³²⁵ It found that Samsung had introduced sufficient evidence of enablement to withstand a motion for summary judgment.³²⁶

Prophesies make the pernicious effects of the presumption worse

Janet Freilich³²⁷ acknowledges that prophetic examples benefit patent applicants, because they permit earlier applications, given that writing a prophetic example is quicker than conducting even simple experiments. Prophetic examples present no risk of not working, necessitating delays for developing new test protocols. They permit broader claims without the expect of having to conduct more experiments.³²⁸

But she criticizes the practice of allowing prophetic examples, arguing that

may hinder innovation because they prevent others from conducting their own experiments—even after the patent has expired and even if the prophetic example is incorrect. Prophetic examples also hopelessly confuse scientists—99% of scientific articles that cite to prophetic examples incorrectly cite them as if they contained factual information—which means that made-up results from patents may contaminate the scientific literature.³²⁹

She advocates a change in terminology, more accurately calling prophetic examples, "hypotheses."³³⁰ More significantly, she urges reversal of the presumption of enablement and written description.

"They should be presumptively non-enabled, meaning that the burden would be on the patentee to prove that the prophetic example was enabled. Patents should include evidence for why a prophetic example would work—*i.e.*, the reasoning and calculations behind the prediction. Patent examiners should determine how much credit to give prophetic examples based on that reasoning. There could also be benefits after patent grant. If prophetic examples were presumptively non-enabled, it might reduce the chilling effect and encourage others to conduct experiments in these areas.³³¹

³²³ Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed.Cir.2003).

³²⁴ Id. at *4.

³²⁵*Id.* At *5.

³²⁶ Id. at *5.

³²⁷ Janet Freilich, Prophetic Patents, 53 U.C. DAVIS L. REV. 663 (2019).

³²⁸53 U.C. DAVIS L. REV. at 682–683.

^{329 53} U.C. DAVIS L. REV. at 664-664.

³³⁰53 U.C. DAVIS L. REV. at 721.

^{331 53} U.C. DAVIS L. REV. at 722.

She limits this recommendation, however, to the section 112 inquiry in patent prosecution context and does not extend it to the presumption of enablement in the section 102 anticipation context.

In a subsequent study, she determined that ninety percent of the experiments described in patents cannot be replicated: they do not work.³³²

Jorge Contreras argues that prophetic examples allows patents for fakes, fictions, and mistakes.³³³ He speculates that allowing patent scope to be energized prophetic examples might have allowed Lilienthal, Chanute, Maxim, or Langley to patent the idea of fixed-wing piloted aircraft, thereby blocking the Wright Brothers practical demonstration.³³⁴ He criticizes "lenient" application of the enablement requirement (without focusing on the MPEP § 2121 presumption), prophetic examples, and constructive reduction to practice.³³⁵ He recommends a new procedure for applicant certification of enablement.³³⁶

The technical literature is full of prophetic speculation about where it would be nice to take new technologies. To allow these prophecies and fantasies to preempt the patent field would allow a mere hopeful speculation to push aside concrete innovation, to the detriment of the public. Magazine covers and II blogs are full of prognostications about personal aircraft in suburban home garages, automatic refrigerator-to-stove food preparation, and various communications modes that never saw the light of day.

If one includes the vastly larger realm of science fiction and other non-technical literature, the realm of prophetic fantasy is even wider.

It is not necessary, nor does this article suggest, that prophetic examples should be disallowed. They are necessary and appropriate in rapidly developing technologies. Requiring every inventor to conduct the experiments necessary for working examples would impose an unacceptable burden on the patenting process.

Instead, a finding of enablement should be less likely when the reference contains mainly prophetic examples and few working ones. Such content suggests speculation rather than success in reducing an idea to practice.

Hindsight bias makes the enablement presumption irrational

Allowing post-publication technology development to show enablement makes the problem worse. The loose way the Office and the Board employ the presumption of enablement suggests that hindsight bias operates strongly. This is consistent with Professor Mandel's experimental findings about hindsight bias.³³⁷

³³² Jane Freilich, The Replicability Crisis in Patent Law, 95 IND. L.J. 431, 434 (2020).

³³³ Jorge L. Contreras, *Patent Reality Checks Eliminating Patents on Fake, Impossible and Other Inoperative Inventions*, 102 J. PAT. & TRADEMARK OFF. SOC'Y 2, 4-7 (2021) (citing Theranos patents as indication that prophetic examples allow patents for nonexistent or inoperable inventions).

³³⁴102 J. Pat. & Trademark Offi. Soc'y at 9.

³³⁵102 J. Pat. & Trademark Offi. Soc'y at 10–13.

³³⁶102 J. Pat. & Trademark Offi. Soc'y at 13–14.

³³⁷ See text and note 296 supra. See also Holbrook, 65 EMORY L. J. at 1026–1027 (recognizing that enablement increases over time as technology advances); Alan L. Durham, *Patent Scope and Enablement in Rapidly Developing Arts*, 94 N.C. L. Rev. 1101, 1136 (2016) (discussing role of after-filing-date technology advances with respect to enablement generally).

The presumption and its application are irrational, and irrational presumptions are arbitrary and capricious and violate the Administrative Procedure Act

The Office and the Board apply the presumption of enablement even when it is not warranted under USPTO's own policy.

Defense of the presumption would be more credible if the Office and the PTAB applied it rationally and correctly; but they do not. They ignore the articulated prerequisites for the presumption, they inexplicably claim that the enablement inquiry is distinct from the anticipation inquiry, and they ignore their own examiners' findings of inoperability.

In *Ex Parte William Kress Bodin, Jesse Redman, and Derral Charles Thorson,*³³⁸ PTAB rejected the applicant's effort to avoid the presumption of prior-art enablement where the reference did not contain all of the elements of the claim, saying that anticipation is a different question from enablement. That is wrong. Enablement in the context was part of the anticipation analysis. Even if a reference is offered to show that a particular aspect of an invention was known in the art, it is not "known" unless it was enabled.

In *Ex Parte Mahalaxmi Gita Bangera, Muriel Y. Ishikawa, Edward K.Y. Jung, Nathan P. Myhrvold, Elizabeth A. Sweeney, Richa Wilson, and Lowell L. Wood Jr.*,³³⁹ the Board found a prior art reference enabling under the presumption, even though an examiner had found the reference not to be enabling during its prosecution, reasoning that the earlier determined related to the claims and that the question of anticipation relied on the entire reference.³⁴⁰ The elements of collateral estoppel were established, and the earlier examiner finding at least should have lifted the presumption for a full exploration of enablement.

Irrational presumptions are arbitrary and capricious under the Administrative Procedure Act³⁴¹ and violate due process. Cases finding presumptions applied by administrative agencies to be arbitrary and capricious or to deny dues process are rare,³⁴² but they exist.³⁴³

Relaxed timing rules undermine the enablement requirement for non-patent prior art.

Tim Holbrook suggests that evolving knowledge of a PHOSITA represents an additional exception to the single-reference rule for anticipation.³⁴⁴ Allowing anticipation to be judged from the perspective of art at the time of a new application make it more likely that any prior art reference will be enabling.

³³⁸ Appeal 2011-001823, Application 11/041,922, 2013 WL 3289118 (PTAB May 30, 2013).

³³⁹ Appeal 2014-002957, Application 11/728,950, 2017 WL 913818 (PTAB Feb. 24, 2017).

³⁴⁰ Id. at *12.

^{341 5} U.S.C. § 552.

³⁴² Compare Johnson v. Morales, 946 F.3d 911, 926 (6th Cir. 2020) (rejecting claim that presumption in city restaurant regulation violated due process; split panel) *with id.* at 935, 937 (White, J., concurring); *see* Solar Energy Industries Assoc. v. Federal Energy Reg. Comm'n, 80 F.4th 956, 987 (9th Cir. 2023) (upholding energy regulatory presumption about avoidable costs).

³⁴³ See Western & A. R.R. v. Henderson, 279 U.S. 639, 644 (1929) (finding presumption of accident causation based on operation of railroad was irrational and violated Fourteenth Amendment); Beriguete v. New York City Dept. of Educ., 36 N.Y.S.3d 556, 360 (N.Y. Sup. Ct. 2016) (finding application of presumption of teacher incompetence to be arbitrary and capricious); B.L. and R.W.H. v. Department of health and Rehabilitative Services, 545 So. 2d 289, 292 (Fla. Dist. Ct. App. 1989) (finding that presumption of abuse from duration of bruises would violate due process).

³⁴⁴Holbrook, 69 VAND. L. REV. 1459 at 1477-1479.

Presumed enablement enables inventors of specific innovations to sweep under their monopolies large swaths of future invention

Recalling Samuel FB Morse's claim to all forms of "motive power of electro-magnetism" to communicate information, as the Supreme Court did in *Amgen*,³⁴⁵ illustrates the policy considerations. To have allowed enforcement of Morse's broad generic claim would have preempted innovation in telegraphy—and maybe telephony—for the life of his patent.

If this patent had merely been used after its expiration as prior art with such broad anticipatory and obviousness interpretations, he would have deprived inventors in the telegraph, telephone, and, maybe, the radio³⁴⁶ industries of the incentive that Congress meant to provide them in the patent statutes and which the founders intended to provide through the Patents and Copyrights Clause of Article I of the Constitution.

Presumed enablement allows commentators who are not inventors to preempt innovation; merely describing a possibility is not a material contribution to the useful arts

Second, the presumption allows commentators who were not inventors to preempt the rewards for real innovation, perhaps intentionally seeking to remove potential advances in the art from patent eligibility. One can imagine anti-intellectual-property activists or activists concerned about new technologies such as artificial intelligence wishing to diminish economic incentives for their further development by writing articles that spin out various fantasies. Even innocent popular literature tends to hyperbolize the effects of new technologies.³⁴⁷

Imposing more rigorous enablement requirements has the effect of enlarging the scope of what is patentable and not anticipated or obvious. Relaxing prior-art enablement requirements has the effect of narrowing the university of patent eligibility. At the limit, it would allow actors to remove large swatches of knowledge from patent eligibility simply by writing an article that describes the field to be pre-empted from patenting.

Patent law consistently has sought to strike the right balance to promote innovation and enhancements to the public domain after a patent has expired. Merely describing a possibility in an article or a leaflet is not a contribution to the public domain unless it goes far enough in its specific detail to be enabling. Presumed enablement means that some disclosures that are not enabling in fact will be given anticipatory status, reducing contributions to the public domain through patent applications and patents. A true inventor fearful of the effect of presumed enablement will elect to keep his invention a trade secret, rather than risking the patent application process.

Presumed enablement opens the door to abuse by generative AI

In mid-2024 USPTO solicited input on the impact of generative AI on prior art under the patent statutes. The office published a request for information on April 30³⁴⁸ and held a public listening session on July 19.³⁴⁹

^{345 598} U.S. at 605-606.

³⁴⁶ Radio communication, after all, requires the use of the "motive power of electro-magnetism" to generate electromagnetic radiation. O'Reilly v. Morse, 15 How. 62 (1854).

³⁴⁷ See Henry H. Perritt, Jr., *Robot Regulations*, 75 S.C. L. Rev. 219 (2023) (noting exaggerations in literature on generative AI).

³⁴⁸USPTO, Impact of the Proliferation of AI on Prior Art and PHOSITA, 89 Fed. Reg. 34217 (April 30, 2024).

³⁴⁹ USPTO, Impact of the Proliferation of AI on Prior Art and PHOSITA: Public Listening Session, 89 Fed. Reg. 55588

Several commenters suggested that AI technology will increase the volume of prior art that needs to be analyzed and that the office should pay closer attention to enablement requirement for prior art,³⁵⁰ the thesis of this article.

AIPLA expressed concern about AI systems intended to generate prior art as barrier to patentability.

"the sheer number of these publications, and the resultant burden on a patent applicant to prove lack of enablement for large numbers of references, may have significant negative impact on the patent system . . . "³⁵¹

AIPLA recommended more rigorous application of the requirement that prior art be enabling.³⁵² The BSA Software Alliance agreed that robust scrutiny of enablement is critical to weed out irrelevant AI-generated or located references.³⁵³ IBM recommended against any presumption of enablement.³⁵⁴ IEEE suggested abandoning the presumption of enablement and perhaps substituting a presumption of non-enablement.³⁵⁵ Novartis suggested that the presumption of enablement should be easy to overcome.³⁵⁶

Presumed enablement makes patentability less predictable and less likely

Imposing more rigorous enablement requirements on prior art has the effect of enlarging the scope of what is patentable and not anticipated or obvious. Relaxing prior-art enablement requirements has the effect of narrowing the universe of patent eligibility. At the limit, it would allow actors to remove large swatches of knowledge from patent eligibility simply by writing an article that describes the field to be pre-empted from patenting.

This treatment of the embodiment requirement and prior art is inconsistent with *Amgen*'s caution that the Patent Office must not be so relaxed about the enablement requirement is to read it out of the examination process.

No one should be able to remove large range of technology from inventor innovation backed up by patent simply by describing subject matter in a publication without providing sufficient detail to amount to enablement.

Any presumption that makes it more difficult to get a patent increases the cost of obtaining a patent by burdening the applicant with the expense of rebutting the presumption. At the margin, this means that fewer legitimate patent applications

⁽July 5, 2024) (announcing public listening session July 19, 2024).

³⁵⁰ See notes 349, 351–356, considering questions and comments on a possible flood of AI generated disclosures.

³⁵¹ Ann M. Mueting, President, American Intellectual Property Law Association, Comment Letter on AI and Inventorship RFC, Docket No. PTO-P-2023-0044 (July 29, 2024) at p4, https://www.regulations.gov/document/ PTO-P-2023-0044-0048 [hereinafter "AIPLA Comment"].

³⁵²AIPLA Comment at 7–9.

³⁵³BSA, BSA Response to USPTO Solicitation of Comments on AI and Patentability 2024-07-26 (July 26, 2024) at 5, https://www.regulations.gov/comment/PTO-P-2023-0044-0034 [hereinafter "BSA Comments"].

³⁵⁴ See Mark Valone & Lisa Ulrich, IBM Corporation, Comment Letter on AI and Inventorship RFC (July 29, 2024) at 5, https://www.regulations.gov/document/PTO-P-2023-0044-0042 (arguing that neither Ai-generated nor human-authored disclosures should be entitled to presumption of enablement).

³⁵⁵ Keith Moore, IEEE-USA President, Comment Letter on AI and Inventorship RFC (July 22, 2024), https://www.regulations.gov/document/PTO-P-2023-0044-0025.

³⁵⁶ See Novartis, Novartis Comments Re: Impact of AI on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Related Patentability Issues (Docket PTO–P–2023–0044, 89 FR 34217), July 26, 2024, at 4, https://www. regulations.gov/comment/PTO-P-2023-0044-0037 (recommending guidance to examiners allowing presumption of enablement to be overcome easily).

will be granted. Unless substantial justification exists for the presumption, this is an unwarranted tilting of the playing field against patent applicants.

Eliminating the presumption would impose no improper burdens on patent prosecution.

To be sure, it takes some effort for the Patent Office to evaluate patent applications to determine if they meet the statutory requirements for a patent. Inherent in this evaluation process is assessing whether prior-art references anticipate the invention. They do not anticipate the invention unless they are enabling. Obviousness requires a nuanced give and take between examiner and applicant, and the same kind of give-and-take is appropriate for questions of prior-art enablement.

Serious consideration of whether prior-art references *are* enabling is an essential part of examination. The Patent Office should not be able to remove a significant part of its duty by imposing unwarranted presumptions. Whatever burden may exist to consider the facts concealed by the presumption is an inherent part of Patent Office duty under the statutes.

VIII. CONCLUSION

A respectable body of commentary supports this article's argument that affording a presumption of enablement to non-patent prior art is irrational and undesirable. Finjin's petition for *certiorari* is most directly on point. It expresses the often-recognized point that the rationale for presuming enablement exists with respect to patents, which have been subject to USPTO review and approval, but not to other forms of prior art.³⁵⁷ Judge Newman, in her dissent in Morsa II, does not particularly focus on presumption of enablement, but she explains why the Federal Circuit has made it too easy for the Patent Office or an infringer to establish the prerequisites for the presumption of enablement by weakening the long-standing requirement that anticipation does not exist unless all elements of the new invention are disclosed in the prior art.³⁵⁸ Prof. Freilich similarly does not explicitly focus on the presumption of enablement, but she explains how prophetic examples in patent descriptions can be pernicious.³⁵⁹ The combination of prophetic examples and the presumption of enablement extends the reach of patent monopolies diminishes opportunities for true innovators to obtain patent protection, unwarranted by true inventive effort in the past.

Prof. Contreras jumps on the Freilich bandwagon and criticizes too-easy enablement findings with a broader brush.³⁶⁰

To be sure, much of this commentary aims at reducing rather than expanding patentability. The effect of accepting this article's arguments would be to expand patentability because more prior art references would be found not to be enabling.

So, at the most general level, whether one accepts this arguments articles depends on whether one favors an expanded role for patents or a contracted one.

³⁵⁷ See notes 322–324 supra and accompanying text.

³⁵⁸ See notes 314–321 *supra* and accompanying text; Holbrook, 65 EMORY L. J. at 1021–1025 (describing inherency doctrine as a way of weakening the strict requirements for anticipation and noting criticism).

³⁵⁹ See text accompanying notes 199–335 supra, discussing Freilich arguments.

³⁶⁰ See note 336 supra and accompanying text.

If one is neutral on that broad policy and economic question, it is hard to deny that the current presumption in MPEP § 2121 outruns its rationale when it goes beyond patents into other prior-art territory.

The increasing use of generative AI to synthesize and to generate references that may constitute prior art militates in favor of using enablement as a more effective screening device.