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Reinvention

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REINVENTION

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ABSTRACT

It is axiomatic that once an invention has been patented, it cannot be patented again. This aligns with the quid pro quo theory of patents—the public would receive nothing new in exchange for the second patent. Enforcing this rule is done through the novelty requirement, which bars a patent if the invention is already known. But the rule is hard to justify if the original patentee reneged on the quid pro quo by inadequately disclosing how to make and use the invention. The inadequate disclosure suggests that the original inventor did not invent anything and the public received no benefit from the original patent. Nevertheless, the current novelty rules prevent the subject matter from being patented again, even if a subsequent researcher can figure out how to make, use, and possibly commercialize it. This novelty bar might destroy the incentive to engage in research and development—an outcome that would ultimately deprive the public of a potential benefit (which, as in the case of a drug, could be enormous). In sum, the current novelty rules prevent many socially valuable inventions from reaching the public.

To remedy this problem, this Article proposes a new novelty paradigm. It draws attention to a situation where a subsequent inventor—the reinventor—seeks to claim subject matter identical to that claimed by another in an expired patent. If the reinventor can prove that the subject matter was inadequately disclosed in the earlier patent, that disclosure will not have a novelty-defeating effect. So the reinventor will be allowed to (re)claim the subject matter absent any other patentability hurdles. While the public would pay for the invention twice, it would ultimately benefit from the second period of exclusivity by obtaining an invention that it might otherwise not have received, a technically robust disclosure, and full possession of the invention at the end of the reinventor's patent term. Thus, reinvention promotes the patent system's fundamental goals of encouraging investment, innovation, and the full public disclosure of new inventions.

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INTRODUCTION

A bedrock principle of patent law is that the same invention cannot be patented twice.[1] Although improvements and modifications of the original invention can be patented, the identical subject matter cannot be claimed again.[2] For example, consider aspirin—acetylsalicylic acid—patented by Bayer in 1900.[3] Over a century later aspirin-related patents abound (including those for a nasal spray, chewing gum, and even a new method of making the drug).[4] But acetylsalicylic acid itself is no longer patentable—not by Bayer or any other party.[5] It has become public property.[6]

As a theoretical matter, this rule makes sense. The essence of the U.S. patent system is a quid pro quo between the patentee and the public.[7] The basic idea is that in order to promote the full disclosure of information about the invention to the public, the patentee must be given something in return.[8] What the patentee gets is the limited period of exclusivity conferred by the patent grant.[9] The public gets detailed knowledge about the invention as soon as the patent document is published[10] and possession of it at the end of the patent term.[11] So if an invention has already been disclosed in a prior patent, a subsequent inventor cannot give anything to the public that it did not already possess.[12]

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1 Miller v. Eagle Mfg. Co., 151 U.S. 186, 197 (1894) (noting "the well-settled rule that two valid patents for the same invention cannot be granted either to the same or to a different party"). If the second patent issues, it is invalid. *Id.* at 200.

2 *Id.* at 197.

3 Acetyl Salicylic Acid, U.S. Patent No. 644,077 (filed Aug. 1, 1898) (issued Feb. 27, 1900).

4 *See, e.g.*, Novel Method of Administering Aspirin and Dosage Forms Containing Same, U.S. Patent No. 4,885,287 (filed Aug. 9, 1988) (issued Dec. 5, 1989); Pharmaceutical Chewing Gum Containing Acetylsalicylic Acid, U.S. Patent No. 5,922,347 (filed Jan. 29, 1993) (issued July 13, 1999); Synthetic Procedure for the Manufacture of Aspirin, U.S. Patent No. 6,278,014 (filed June 6, 2000) (issued Aug. 21, 2001).

5 *Miller*, 151 U.S. at 197.

6 As the Supreme Court stated long ago, "It is self evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted." Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185 (1896).

7 Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974); Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945).

8 *Kewanee*, 416 U.S. at 480–81.

9 *Id.* at 480 ("In return for the right of exclusion—this 'reward for inventions'—the patent laws impose upon the inventor a requirement of disclosure." (citation omitted)).

10 *See id.* at 481 (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development).

11 Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . [so that] its benefits may be fully enjoyed by the public, after the patent expires.").

12 Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 23 (1829).

Indeed, a fundamental principle of patent law is that a patent cannot issue if it would remove subject matter that is already in the public domain.[13] Patent law requires novelty;[14] meaning that an invention "must be *new*, that is, bestowed for the first time upon the public by the patentee."[15] So if the subject matter has previously been disclosed, the inventor has not invented anything and the public would receive no benefit from the patent.[16]

But the theoretical rationale for the proscription against repatenting rests on a crucial assumption—that the original patentee adequately disclosed the invention in the original patent. The patent statute requires that an invention be disclosed in sufficient detail to enable a person having ordinary skill in the art (PHOSITA)[17] to make and use the full scope of all that is claimed without undue experimentation.[18] The enablement requirement lies at the heart of the quid pro quo theory of patents because it ensures that (1) the applicant's disclosure sufficiently enriches the public storehouse of knowledge in exchange for the exclusionary right;[19] and (2) the public will get complete possession of the invention at the end of the patent term.[20] So when an invention is inadequately disclosed, the quid pro quo failed—the original patentee received a patent yet the public was deprived of an enabling disclosure.

Unfortunately, current novelty rules render an invention that was nonenabled in a prior patent unpatentable by a subsequent inventor who tries to claim it, even if the subsequent inventor has figured out how to make and use it.[21] This is true even though noncompliance with the enablement requirement is a persistent problem in patent law.[22] Policing enablement,

13 Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147–48 (1989); Graham v. John Deere Co., 383 U.S. 1, 5–6 (1966).

14 Novelty is the statutory requirement that an invention be new. *See* 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter . . . may obtain a patent . . . ." (emphasis added)). For a detailed discussion of novelty, see *infra* Section III.A.

15 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 305 (1890).

16 GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA § 292, at 394 (2d ed. 1854).

17 The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987) (explaining that a PHOSITA is "not unlike the 'reasonable man' and other ghosts in the law"). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made. Envtl. Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 696 (Fed. Cir. 1983).

18 *See* 35 U.S.C. § 112(a); *infra* Section I.B.

19 Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed. Cir. 1999). For a discussion of the public storehouse of knowledge, see *infra* subsection I.A.2.

20 *See supra* note 11 and accompanying text.

21 *See infra* Section III.A.

22 *See infra* subsection I.B.2.

admittedly, is no easy task; rejecting a patent claim for nonenablement might be the most formidable task that a patent examiner can undertake.[23] It is no secret that the U.S. Patent and Trademark Office ("Patent Office") routinely issues patents with nonenabled claims.[24] And when one considers the universe of millions of expired patents,[25] there is every reason to believe that some of them—perhaps many of them—contain nonenabled claims. Particularly suspect are patents emerging from fields like chemistry, biotechnology, and pharmaceuticals where a single patent claim can easily cover a large number of compounds.

This Article draws attention to a situation where a subsequent inventor—the *reinventor*—seeks to claim subject matter identical to that claimed by a third party in an expired patent. Under current patent law, the expired patent presumably issued with enabled claims.[26] I argue that if the reinventor can prove that the earlier claim to the subject matter was nonenabled (and thus invalid when the original patent issued),[27] the reinventor should be allowed to claim the identical subject matter in a new patent.[28]

To illustrate, consider the following hypothetical. Suppose that pharmaceutical company AcmePharma seeks to obtain a patent on a promising compound, *X*—a fibrate that effectively lowers cholesterol in humans.[29] At the time that AcmePharma files its patent application in 2015, *X* is, as far as AcmePharma knows, previously unknown. But when the patent examiner searches the "prior art" (preexisting knowledge and technology already available to the public)[30] to assess novelty,[31] the examiner finds an expired drug patent filed in 1980 that listed *X* by name and structure and claimed it along

23 *See infra* Section I.B.

24 For commentary on the problem, see JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 66–67 (2008); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848–49 (1990).

25 An expired patent is one whose term of exclusivity has run. Inventions covered by an expired patent have become public property—at least in theory. Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 13 (1829). As of 2015, the Patent Office has granted just under nine million utility patents (covering electrical, mechanical, and chemical inventions) since 1836. U.S. PATENT & TRADEMARK OFFICE, TABLE OF ISSUE YEARS AND PATENT NUMBERS, FOR SELECTED DOCUMENT TYPES ISSUED SINCE 1836 (Feb. 18. 2016), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/issuyear.htm.

26 *See infra* subsection I.B.2.

27 Promega Corp. v. Life Techs. Corp., 773 F.3d 1338, 1349 (Fed. Cir. 2014); MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012).

28 *See infra* Part III.

29 A fibrate is "[a]ny of a class of carboxylic acid compounds commonly used as lipid-lowering medications . . . that primarily reduce levels of triglycerides" and "have a minor impact on low-density and high-density lipoprotein cholesterol." TABER'S CYCLOPEDIC MEDICAL DICTIONARY 923 (Donald Venes ed., 22d ed. 2013).

30 Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966) (defining prior art)). Documents like issued patents and printed publications are common sources of prior art. *See* 35 U.S.C. § 102(a) (2012) (setting forth the documents and activities that can serve as prior art).

with ninety-nine other compounds. But the original patentee's disclosure merely speculated about *X*'s effectiveness as a drug[32] and offered no details about how to make *X*. But this inadequate disclosure of *X* was of no import to the original patentee who made a business decision not to pursue *X*—perhaps because it would be too costly to develop or another claimed compound proved to be safe, effective, and profitable.[33] Yet while *X* was discarded by the original patentee, the Patent Office did not give *X* much (if any) scrutiny during the original examination, thereby allowing the nonenabled compound to slip through the cracks[34] and to be covered by a presumptively valid (now expired) patent.[35] Importantly, *X* has never been commercialized; and other than the expired patent, no mention of *X* appears in the technical literature. Simply put, *X* was not *invented* until AcmePharma came along.[36]

Nonetheless, two major hurdles prevent the reinventor from obtaining a patent for *X*, even if the reinventor can actually develop and commercialize it.[37] First, the same invention cannot be claimed again in a later patent.[38] This double-patenting prohibition rests on the presumption that the original patent issued with valid (and thus enabled) claims. Second, the Patent Office can reject AcmePharma's claim to *X* for a lack of novelty despite its inadequate disclosure in the expired patent.[39]

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31 *See supra* notes 14–16 and accompanying text. Determining novelty requires a comparison of the invention that the applicant seeks to patent with the prior art. *In re* Cruciferous Sprout Litig., 301 F.3d 1343, 1350 (Fed. Cir. 2002).

32 A patent applicant must assert a utility for each claimed invention. 35 U.S.C. § 101. The Patent Office must presume that the asserted utility is correct unless it can prove otherwise. *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

33 *See infra* note 140 and accompanying text.

34 For a discussion of why this happens, and particularly when the issue is enablement, see *infra* subsection III.D.1.

35 *See infra* Section II.C (discussing the presumption of patent validity).

36 The inventive process requires two acts—conception and reduction to practice. ROBINSON, *supra* note 15, at 26. In the chemical arts, conception requires knowledge of both the compound's chemical structure *and* an operative method of making it. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991). Reduction to practice occurs when the inventor either makes the invention and establishes that it works for its intended purpose or files a patent application that describes the invention in sufficient detail to satisfy the "how to make" prong of enablement. *In re* Borst, 345 F.2d 851, 855 (C.C.P.A. 1965). The U.S. Court of Customs and Patent Appeals was a five-judge Article III appellate court. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). The Federal Circuit adopted C.C.P.A. decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

37 *See infra* Section III.A.

38 *See supra* notes 1–2 and accompanying text.

39 *See supra* note 25. The novelty requirement safeguards the public domain by denying a patent for identical subject matter that the public already possesses. *See infra* note 80, 195 and accompanying text.

To qualify as novelty-defeating prior art, the expired patent must satisfy three conditions.[40] First, it must predate the reinventor's filing date.[41] Second, the subject matter that the reinventor seeks to patent (X) must be identical to that disclosed in the prior patent (the "strict identity" requirement).[42] Third, and very importantly, the asserted prior art reference must be enabling.[43] This means that as of the reinventor's filing date, a PHOSITA could have combined the teachings of the expired patent with preexisting knowledge in the field to make X without undue experimentation.[44] If the expired patent meets all three criteria, it "anticipates" the reinventor's claim and renders it unpatentable for a lack of novelty because X is considered to be in the public's possession.[45] The U.S. Court of Appeals for the Federal Circuit[46] has held that, for the sake of expediency, the examiner is allowed to presume that prior art references are enabling.[47]

Thus, the reinventor's patentability hurdles are tied to enablement—a presumption that the expired patent issued with *enabled claims* and a presumption that the expired patent has an *enabling disclosure*. But the latter completely subsumes the former—if X is not enabled later in time when the reinventor files, it was not enabled earlier in time when claimed in the original patent.[48] Thus, I argue that if the reinventor can prove that the expired patent was nonenabling for prior art purposes, that proof rebuts *both* presumptions. The double-patenting problem disappears because the original, nonenabled patent was technically invalid.[49] The novelty problem disap-

40 Prior art is also used to gauge nonobviousness. *See* 35 U.S.C. § 103 (2012). For discussion of the role of nonobviousness in the reinvention paradigm, see *infra* Section III.C.

41 35 U.S.C. § 102(a)(1) (denying patentability if "the claimed invention was patented . . . before the effective filing date of the claimed invention"); *id.* § 102(a)(2) (denying patentability if "the claimed invention was described in a patent . . . [that] names another inventor and was effectively filed before the effective filing date of the claimed invention").

42 Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296 (Fed. Cir. 2002) (noting the "strict identity" test for novelty).

43 *In re* Antor Media Corp., 689 F.3d 1282, 1289 (Fed. Cir. 2012); *see also* Elan Pharm., Inc. v. Mayo Found., 346 F.3d 1051, 1054 (Fed. Cir. 2003) ("To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.").

44 *In re* Morsa, 713 F.3d 104, 108–09 (Fed. Cir. 2013); Impax Labs., Inc. v. Aventis Pharm. Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008); *see also infra* notes 199–201 and accompanying text.

45 Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

46 The Federal Circuit has jurisdiction over appeals from the Patent Office and district court cases arising under the patent laws. The court was created by the Federal Courts Improvement Act of 1982. *See supra* note 36.

47 *See infra* subsection III.B.1.c.

48 This is because the PHOSITA's knowledge and skill evolve over time. Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1486 (2016). While what was nonenabling earlier in time can become enabling later in time, what is nonenabled later in time could not have been enabled earlier in time. *See infra* subsection III.B.2.

49 *See supra* note 27.

pears because a nonenabled reference does not qualify as anticipatory prior art.[50] Thus, AcmePharma can claim *X* in its own patent.[51]

The reinvention paradigm clearly aligns with broader goals of the patent system. A basic purpose of the patent system is to encourage investment in the research, development, and commercialization of socially valuable inventions that firms would not otherwise make.[52] Indeed, the possibility of reinvention—and ultimately securing a patent—might accelerate innovation by leading firms to engage in socially-productive races to figure out how to make and use the claimed-but-nonenabled subject matter contained in the universe of expired patents.[53] Returning to AcmePharma, it has determined *X* has value. If the firm is willing to invest time and money to prove that the original claim to *X* was nonenabled, AcmePharma will probably commercialize it. So reinvention would not only allow AcmePharma to recoup its research and development (R&D) costs,[54] but the public would finally get its end of the patent bargain—an adequate disclosure of *X* (which would hopefully spur more innovative activity during the patent term[55]) and possession of *X* when the patent expires.[56] Yet if a patent is unavailable, AcmePharma has little incentive to invest in the development of *X*.[57] AcmePharma and other firms may simply ignore *X*, thereby resulting in its ultimate loss to the public (which, in the case of a drug, could be enormous).[58] That the current novelty rules can actually deprive the public of socially beneficial inventions is cause for concern and merits attention.

The Article proceeds as follows. Part I explores the link between disclosure and possession in patent law. It explains that if *X* was inadequately disclosed in the original patent, the original patentee never possessed it; thus,

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50 Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003); CURTIS, *supra* note 16, § 292, at 395 (noting that if the description in the allegedly anticipatory reference is nonenabling, "it cannot be said that a knowledge of that thing is in the possession of the public").

51 *See infra* subsection III.B.2.

52 FRITZ MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM: STUDY OF THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE COMMITTEE ON THE JUDICIARY, S. DOC. NO. 85-15, at 36 (1958); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 247 (1994).

53 John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 443 (2004); Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1062 (2005). "A patent race is a race among competing firms to be the first to discover and patent some new idea having commercial potential." WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 300 (2003).

54 LANDES & POSNER, *supra* note 53, at 294.

55 *See infra* note 61 and accompanying text.

56 *See infra* note 91 and accompanying text.

57 For a discussion of the incentives for pharmaceutical companies to engage in costly drug development, see sources cited *infra* note 325. As a general matter, "individuals will not generally invest in invention or creation unless the expected return from doing so exceeds the cost of doing so—that is, unless they can reasonably expect to make a profit from the endeavor." Lemley, *supra* note 53, at 1054.

58 *See infra* Section III.D.

the public never gained possession of *X* when the original patent expired. Part II draws attention to squandered patent claims, which are a direct result of inadequate disclosure in the original patent. It explains how squandered subject matter is essentially lost unless and until it is reinvented. This Part explores why squandered claims proliferate in patent law, the challenges in solving the problem, and the consequences for the patent system. Finally, Part III proposes the reinvention paradigm. It begins by describing how the current novelty rules can defeat a later claim to *X* even though it was inadequately disclosed in the earlier patent. This Part then explores the theoretical underpinnings, mechanics, and normative justification for the reinvention paradigm and explains how it would solve the squandering problem. After discussing limits and responding to potential criticisms, this Part concludes by discussing how reinvention aligns with broader policy goals of the patent system.

I. DISCLOSURE AND POSSESSION IN PATENT LAW

An oft-touted justification for the patent system is that society will get some benefit from the invention's disclosure.[59] In theory, the statutory disclosure requirements[60] ensure that the public can use the technical details disclosed in the patent document to improve upon the invention, to design around it, or to engage in other innovative activities during the patent term[61] and gain full possession of it at the end of the patent term.[62] This Part explores the intricate link between disclosure and possession and the costs to the public and the patent system when the disclosure function fails.

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59 *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that the federal government "is willing to pay the high price" of exclusivity conferred by a patent for its disclosure, which, "it is assumed, will stimulate ideas and the eventual development of further significant advances in the art").

60 The patent statute sets forth three disclosure requirements:

> The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor . . . of carrying out the invention.

35 U.S.C. § 112(a) (2012) (emphasis added).

61 As Judge Giles Rich once explained, "even if [the invention] does not go into the public domain during the patent term, the public gets the advantage of knowing what the invention is and how to practice it." Janice M. Mueller, *A Rich Legacy*, 14 BERKELEY TECH. L.J. 895, 900 (1999) (quoting E-mail from Giles S. Rich, Circuit Judge, U.S. Court of Appeals for the Fed. Circuit, to Janice M. Mueller, Assoc. Professor, John Marshall Law Sch. (Aug. 16, 1997)).

62 *See supra* note 20 and accompanying text.

A. Patents and Knowledge Transfer

Fostering innovation through information dissemination is a basic goal of the patent system.[63] The exclusory right conferred by the patent is the inventor's reward for fully disclosing technical information about the invention.[64] This Section explains how the inventor's disclosure is the key benefit that the public receives from the patent bargain.

1. The Quid Pro Quo Theory of Patents

A fundamental goal of the patent system is to encourage the dissemination of technical knowledge.[65] As soon as a patent document publishes, there is hope that the public will use the technical details disclosed therein to improve upon the invention, design around it, or simply learn from it.[66] Although the patentee maintains the right to "exclude others from practicing the invention until the patent term expires, the technical information disclosed in the patent document has potential immediate value to the public, which can use the information for any purpose that does not infringe upon the claims."[67] This supports the patent system's broader mission to promote scientific progress and extend knowledge.[68]

Perhaps the most basic strategy for promoting disclosure is to give the inventor something in return—a quid pro quo. The inventor's incentive for full disclosure of the invention is the limited period of exclusionary rights provided by the patent,[69] which allows the inventor to recoup R&D expendi-

63 Patent law "seeks to foster and reward invention" with the hope that the disclosure will "stimulate further innovation and . . . permit the public to practice the invention once the patent expires." Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

64 *See* Graham v. John Deere Co., 383 U.S. 1, 9 (1966) (describing a patent as "a reward, an inducement, to bring forth new knowledge"); Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 19 (1829) (recognizing that the patent system seeks to promote the progress of the useful arts and to reward inventors).

65 Brenner v. Manson, 383 U.S. 519, 533 (1966).

66 MICHAEL A. GOLLIN, DRIVING INNOVATION: INTELLECTUAL PROPERTY STRATEGIES FOR A DYNAMIC WORLD 15–19 (2008).

67 Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 624 (2010) (footnote omitted) (citing Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. [2004] UKHL 46, [2005] R.P.C. 9 ¶ 77 (appeal taken from Eng.)); *see also supra* note 61.

68 This goal emanates from the Intellectual Property Clause of the Constitution: "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." U.S. CONST. art. I, § 8, cl. 8; *see also* Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) (observing that "the primary purpose of our patent laws . . . is 'to promote the progress of science and useful arts'" (quoting U.S. CONST. art. I, § 8, cl. 8)).

69 *See* J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974))); *Kewanee Oil Co.*, 416 U.S. at 480–81 (describing the quid pro quo that supports the patent grant as a constitutional objective).

tures.[70] The public benefits from the exchange by obtaining valuable technical information about the invention, which can be used to make improvements to the invention, design around it, or spur the development of new technologies.[71] This paradigm not only discourages trade secrecy,[72] but provides technical information about "non-self-disclosing" inventions like complex chemical compounds or industrial processes—things that a PHOSITA cannot easy replicate or reverse engineer.[73] Thus, the quid pro quo promotes the disclosure of information that the public might not otherwise get.[74]

2. What Is the Public Storehouse of Technical Knowledge?

The inventive act produces *two* things that are potentially useful to the public: the invention itself, which will be defined here as the subject matter claimed in the patent (i.e., machine, product, process, composition of matter),[75] and the *disclosure*, which furnishes technical details about the invention (i.e., how to make it, how to use it)[76] and becomes a part of the technical literature. Though the claimed invention is probably the first thing that comes to mind when patents are discussed, the importance of the disclosure cannot be overlooked.[77]

The disclosed information enters what patent law calls the public storehouse of technical knowledge.[78] The courts have stated that the disclosure must actually enrich the public storehouse;[79] meaning that a patent cannot

70 LANDES & POSNER, *supra* note 53, at 294.

71 *See infra* subsection I.A.2.

72 *See* Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1622 (2011) ("[T]rade secrecy protection can theoretically provide even more powerful incentives than patents because trade secrecy rights are potentially infinite in duration."); J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 923–27 (2011) (exploring the patent versus trade secret distinction).

73 Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 83. For such inventions, "the disclosure of the invention in the patent [document] is valuable to society . . . because it adds something the inventor could have kept secret to the store of public technical knowledge." *Id.* at 105–06.

74 EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE 143 (2002).

75 *See* 35 U.S.C. § 101 (2012) (defining patent-eligible subject matter).

76 *See supra* note 60.

77 The Supreme Court has stated that "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

78 *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge"); *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that the full disclosure of how to make and use the invention "adds a measure of worthwhile knowledge to the public storehouse").

79 Graham v. John Deere Co., 383 U.S. 1, 6 (1966) ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system

issue if the disclosure is not new[80] or is a trivial extension of what is already present.[81] In addition, a patent can neither remove extant knowledge from the public storehouse nor limit free access to it.[82]

It is often forgotten that the inventive process furnishes technical information to the public storehouse not at the end of the patent term, but as soon as a patent document publishes.[83] Patent theory contemplates that the early entry reduces R&D waste,[84] spurs creativity,[85] leads others "to climb onto the patentee's shoulders in seeking improvements or wholly new inventions,"[86] and, of course, promotes technological progress.[87]

B. The Primacy of Enablement

Enablement is the patentability requirement that "lies at the heart of the patent bargain."[88] By compelling an applicant to prepare a written descrip-

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which by constitutional command must 'promote the Progress of . . . useful Arts.'" (alteration in original) (quoting U.S. CONST. art. I, § 8, cl. 8)).

80 *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 64 (1998) (noting that section 102 "exclud[es] ideas that are in the public domain from patent protection"); *Bonito Boats*, 489 U.S. at 148 (explaining that granting a patent for an invention that lacks novelty "injure[s] the public by removing existing knowledge from public use").

81 *See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453–54 (Fed. Cir. 1984) (defining "prior art" as "knowledge that is available, *including what would be obvious from it*, at a given time, to a [PHOSITA]" (emphasis added)). Sometimes an inventor can obtain a patent for seemingly obvious inventions, such as when it exhibits an unexpected property. *See In re* Papesch, 315 F.2d 381, 386–87 (C.C.P.A. 1963); *see also Graham*, 383 U.S. at 17–18 (discussing objective indicia of nonobviousness).

82 *Graham*, 383 U.S. at 6; *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("[T]he stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.").

83 Patent documents include issued patents and published patent applications. Since 1999, most patent applications publish eighteen months after the earliest effective filing date. 35 U.S.C. § 122(b)(1)(A) (2012). Once a patent application publishes, the information it discloses is considered known to the public. *See id.* § 102.

84 Dam, *supra* note 52, at 267 n.79.

85 *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974); GOLLIN, *supra* note 66, at 15–19.

86 Dam, *supra* note 52, at 264; *cf.* Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 400 (1960) ("The literature of the art is enriched, another way of doing something is made known and even if it be inferior to the means already known, there is no telling when it may give another inventor an idea or when someone will improve on it in such a way as to surpass all that is known.").

87 Rich, *supra* note 86, at 400 ("Whenever novel subject matter, unobvious to the workers of ordinary skill in an art, is published, progress in the art is promoted.").

88 3 DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 7.01, at 7-9 (2010); *cf.* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (describing enablement as the essential aspect of the patent bargain).

tion of the invention[89] sufficient to teach a PHOSITA how to make and use it without undue experimentation,[90] enablement ensures that the applicant's disclosure sufficiently enriches the public storehouse of technical knowledge and that the public will get complete possession of the invention once the patent expires.[91] It polices claim scope[92] and safeguards patent law's disclosure function.[93]

1. The Disclosure Standard

Enablement is a standard.[94] Determining whether a disclosure in an expired patent is enabling is a legal conclusion that rests on underlying factual inquiries.[95] The Federal Circuit set forth several factors relevant to the enablement analysis in *In re Wands*.[96] They are: (1) the amount of direction or guidance presented in the disclosure; (2) the existence of working examples; (3) the nature of the invention; (4) the predictability or unpredictability of the art; (5) the PHOSITA's level of skill; (6) the state of the prior art; (7) the breadth of the claims; and (8) the quantity of experimentation necessary to practice the claimed invention.[97] While not mandatory,[98] the *Wands* factors are ubiquitous in evaluating enablement[99]—probably because they touch on issues that are important in virtually all enablement determina-

89 The written description is the part of the patent document that completely describes the invention. 35 U.S.C. § 112(a)–(b) (2012). "Disclosure" and "specification" are also used to refer to the written description.

90 *Id.* § 112(a). Although "[t]he term 'undue experimentation' does not appear in the statute . . . it is well established that enablement requires that the [patent document] teach those in the art to make and use the invention without undue experimentation." *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

91 *See supra* note 11 and accompanying text.

92 Claim scope is the "technological territory" that the inventor claims to control. Merges & Nelson, *supra* note 24, at 844. The enablement provided serves as a constraint on claim scope. Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999).

93 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 4, at 3–4 (2003) [hereinafter FTC REPORT], https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf (explaining that enablement plays a central role in "safeguard[ing] the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others . . . can learn").

94 *See* Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 130 (2008).

95 Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999–1000 (Fed. Cir. 2008).

96 *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

97 *Id.* (factors reordered from original text).

98 Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the *Wands* factors are illustrative and not mandatory).

99 *See* CHISUM, *supra* note 88, § 7.03, at 7-15–7-16 (collecting cases).

tions.[100] These include issues related to the technical scope and substance of the disclosure (factors one and two),[101] the nature of the technology (factors three and four),[102] the PHOSITA's knowledge and skill (factor five),[103] and the scope of the claim sought (factor seven).[104]

Gauging compliance with the enablement requirement is easiest when the applicant actually makes the invention before filing and discloses the technical details in the patent application.[105] But unlike mainstream science, which requires a description of every experimental detail of work actually performed as a prerequisite for publication,[106] an applicant can obtain a patent with no (or very little) actual proof of concept or pre-filing experimentation.[107] Indeed, the patent system values the concept more than physical activity[108] and "explicitly assumes the need for more experimentation *after* filing to actually implement the invention."[109]

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100 The factors are interrelated. For example, if the PHOSITA is really smart (factor five), an applicant need not disclose what the PHOSITA can easily figure out (factors one and two). *See* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987).

101 The two factors are clustered together because working examples are a form of guidance. Seymore, *supra* note 67, at 641–46.

102 One way to determine the requisite amount of teaching is to ask whether the technology is "unpredictable" or "predictable." The courts refer to chemistry, biotechnology, and related experimental fields as "unpredictable" because PHOSITAs in these fields often cannot predict whether a reaction protocol that works for one embodiment will work for others. Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997). Applied technologies like electrical and mechanical engineering are often regarded as "predictable" arts because they are rooted in well-defined, predictable factors. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991). For a deeper exploration of the predictable-unpredictable dichotomy, see Seymore, *supra* note 94, at 136–39.

103 This factor is receiving more attention from the courts. *See, e.g.*, ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 941–42 (Fed. Cir. 2010) (holding that the district court properly determined the PHOSITA's level of skill and did not err in giving less weight to a witness who analyzed an issue using the wrong level of skill).

104 Enablement places an outer limit on claim scope. *See supra* note 92.

105 *Cf.* Seymore, *supra* note 67, at 652–53 (advocating a working example requirement for complex technologies that would, among other things, simplify the enablement analysis).

106 *See* Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 114 (2011) ("[A] scientific publication typically has to describe an actually completed experiment, while a patent specification does not.").

107 *See In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."); Karschtedt, *supra* note 106, at 114.

108 Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60–61 (1998).

109 Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 93 (2009) (emphasis added) (citing Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314–15 (Fed. Cir. 2008)). For a critique of this approach, see Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1172–74 (2016).

2. Technical Complexities

Inventions disclosed in a patent application, including those not physically made at the time the application was filed, enjoy a presumption of enablement.[110] This means that an examiner who doubts enablement must build a prima facie case of nonenablement, which must be supported with documentary evidence.[111] The applicant can rebut the prima facie case with persuasive argument or proof.[112] The burden of production may continue to shift as each side presents new evidence;[113] however, the examiner carries the ultimate burden of persuasion with a preponderance of the evidence as the standard of proof.[114]

While this presumption might not be a cause for concern for simple inventions like paper clips or chopsticks,[115] it becomes more dubious for more complex inventions like chemical compounds and sophisticated devices.[116] An enabling disclosure is crucial for complex inventions because the PHOSITA must rely heavily, if not exclusively, on the instruction provided within the four corners of the patent document in order to practice the invention.[117] However, all too often the examiner lacks the time, incentive, or facilities to adequately evaluate enablement.[118] It is also very hard to prove that something *cannot* be done.[119] This means that the examiner must often accept any assertions made by the applicant that cannot be disproved by promptly identifiable documentary evidence.[120]

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110 *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995); *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971).

111 *See Marzocchi*, 439 F.2d at 224; *see also In re* Brebner, 455 F.2d 1402, 1405 (C.C.P.A. 1972) (holding that the Patent Office must provide a factual basis for a lack of enablement rejection rather than conclusory statements).

112 *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

113 When the applicant submits rebuttal evidence, the examiner must "start over" and "consider all of the evidence anew." *Id.* at 1472 (internal quotation marks omitted) (quoting *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976)).

114 *In re* Oetiker, 977 F.2d 1443, 1449 (Fed. Cir. 1992).

115 *See* Seymore, *supra* note 67, at 644 (arguing that a PHOSITA can make simple inventions with a minimal amount of teaching from the inventor).

116 *See id.* at 644–45.

117 Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1528 (2011). Thus, the lack of a detailed teaching means that a PHOSITA will probably need to engage in undue experimentation to practice the full scope of the invention. *Id.* at 1530.

118 Examiner incentives are complicated; certain application-related activities "count" more for production goals, promotion, and bonus decisions than others. Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. & STAT. 817, 818 (2012).

119 Arthur Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763, 764 (1967).

120 FTC REPORT, *supra* note 93, ch. 5, at 9; *cf.* Beckman Instruments, Inc. v. Chemtronics, Inc., 439 F.2d 1369, 1378–79 (5th Cir. 1970) (noting that in the absence of its own testing facilities, the Patent Office must rely on information presented to it).

So it is not surprising that nonenabled patents slip through the cracks. And while some enablement defects are innocent,[121] savvy patentees take advantage of the presumption and strategically draft claims that deliberately cover undeveloped or underdeveloped subject matter.[122] Regardless, it is hard to overstate that these nonenabled patents create problems and frustrate many important goals of the patent system. They contribute to the well-known patent quality problem,[123] add little or nothing to the public storehouse of knowledge,[124] supply little technical fodder for follow-on researchers to build upon,[125] and create roadblocks for subsequent inventors who *can* enable the claimed subject matter.[126]

C. Evincing Possession

The enablement requirement of section 112(a) of the Patent Act compels the inventor to disclose in writing how to make and use the claimed subject matter.[127] The claim scope sought dictates how much information the inventor must disclose.[128] Society must pay for this information; it does so with the twenty years of exclusory rights conferred by the patent grant.[129]

Providing a full, enabling disclosure at the application stage confers two benefits to society that can be described in terms of possession. First, the public gains immediate possession of the technical information disclosed in the patent document upon publication and can use it for any purpose that does not infringe upon the claims.[130] Second, the public gains possession of the invention itself at the end of the patent term.[131] When a nonenabled patent issues, however, the public might be deprived of *both*.[132]

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121 For instance, so-called "nuisance" prior art describing an unworkable invention "can . . . be generated as a result of a bona fide attempt at a constructive reduction to practice that for some unexpected reason fails to work as disclosed." David S. Wainwright, *Patenting Around Nuisance Prior Art*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 221, 223–24 (1999). Innocuously disclosed information has the same effect. *See id.* at 222, 223 n.3.

122 BESSEN & MEURER, *supra* note 24, at 67.

123 *See infra* subsection III.D.1.

124 *See supra* subsection I.A.2.

125 In other words, the disclosure lacks sufficient technical detail to be helpful. It does little to advance technological progress, which the Constitution requires. Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

126 *See* Seymore, *supra* note 67, at 660.

127 35 U.S.C. § 112(a) (2012).

128 *See supra* note 92 and accompanying text.

129 Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974); Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L.J. 369, 379 (2013).

130 Seymore, *supra* note 67, at 624.

131 *See supra* notes 11, 20 and accompanying text.

132 Recall in the reinvention paradigm, there has been no intervening disclosure, commercialization, or interest in the subject matter between the time of the expired patent and the reinventor's patent application. So any benefit to the public will come from reinvention. *See supra* text accompanying notes 36–39. But one can imagine a scenario where the public might (eventually) gain possession of the nonenabled subject matter

So how does an inventor show complete possession of an invention in a patent document? According to the Federal Circuit, "a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention."[133] Thus, the question of possession is really one of enablement.[134]

What makes possession challenging is that the invention is not necessarily a particular embodiment but more of an intangible idea.[135] And the inventor is required to fully disclose the intangible idea in the patent document. Demonstrating the possession of an intangible idea is difficult because one can describe an idea but not necessarily possess it.[136] A good example is an idea about reversing the hands of time by controlling the aging process in humans. An idea about how to control the aging process does not mean that a patent applicant possesses a method of doing it.[137] As Timothy Holbrook explains, "[T]he key aspect of possession is whether or not the [researcher] can actually make a functioning device. Thus, the best evidence of possession would be either the inventor physically creating the invention or, at least, providing a description that is clear enough to enable someone else to build it."[138]

Thus, enablement limits permissible claim scope to what the inventor actually invented and taught, even if the inventor tries to claim far more broadly.[139]

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because the PHOSITA's knowledge and skill evolves over time, allowing the invention to be practiced without undue experimentation. *See supra* note 48.

133 LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005).

134 It is important to note that another disclosure requirement also implicates possession. The "written description" requirement of section 112(a) compels the applicant to "convey with reasonable clarity to [a PHOSITA] that, as of the filing date sought, he or she was in possession *of the invention*." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). In the chemical context, the question is whether the compound at issue was specifically disclosed by name or chemical structure. Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993). Since *X* is specifically described in the expired patent, the written description requirement is met.

135 *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 S.M.U. L. REV. 123, 146 (2006).

136 *Id.*

137 In *In re Eltgroth*, the applicant claimed a method of influencing the age of a living organism by modifying the abundance of chemical isotopes in the bloodstream through the addition of certain chemical compounds. *In re* Eltgroth, 419 F.2d 918, 918–19 (C.C.P.A. 1970). The C.C.P.A. upheld a nonenablement rejection because the applicant's written description failed to disclose any details regarding specific isotopes and how to alter their abundance. *Id.* at 921. Rather, the disclosure was simply "a speculative theory or hypothesis" requiring undue experimentation to make it work. *Id.*

138 Holbrook, *supra* note 135, at 147.

139 Rantanen, *supra* note 129, at 374. The Federal Circuit has also held that a patent claim cannot be construed to literally cover later-developed technologies that were not enabled at the time the patent application was filed. *See* Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339–42 (Fed. Cir. 2003); *cf.* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1262–63 (Fed. Cir. 2004) (Bryson, J., concurring) (explaining that

II. The Proliferation of "Squandered" Patent Claims

The lax enforcement of the enablement requirement can lead to much mischief in patent law. Many problems can be tied to the proliferation of what I call *squandered* claims. After defining the term, this Part explores the proliferation of squandered claims and their negative impact on the patent system. It also shows that much subject matter that a reinventor would seek to claim was squandered in an earlier, expired patent.

A. The Breadth of the Problem

When one considers the universe of millions of expired patents, there is probably an incalculable amount of claimed-but-nonenabled subject matter. Most of this subject matter was discarded by the original patentee—perhaps because it would be too costly to develop or other claimed embodiments proved to be more promising or profitable.[140] And there has been no subsequent commercialization, use, or disclosure of it in the technical literature. It is as if the claimed-but-nonenabled subject matter never existed.[141] But since the current novelty rules prevent it from being claimed again, it has been *squandered.* No one can derive a benefit from claimed-but-nonenabled subject matter unless and until it is (re)invented.

Squandering can occur in any patent; however, it is particularly problematic in chemical and pharmaceutical patents because of the way that chemical moieties are typically described and claimed. The claims may encompass hundreds, thousands, even millions of potential compounds, "the vast majority of which have never been synthesized or tested and whose very existence may only be theoretical."[142] And to the extent that some of the claimed compounds are nonenabled, the stage is set for squandering.

To illustrate, I will build on the hypothetical introduced earlier.[143] Consider a drug company that finds that two closely related compounds show promising pharmacological activity. It files a patent application in 1980 that does not merely disclose and claim the two compounds actually tested;[144] rather it discloses and claims the entire class of 100 compounds by name and

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claims cannot be construed "broadly enough to encompass technology that is not developed until later and was not enabled by the original application"). *Id.* at 1262.

140 This is not unexpected. *See* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 Berkeley Tech. L.J. 577, 603 (1999) (stating most patented technologies "will not be economically viable or commercially successful"). The original patentee might have claimed broadly to "hedge [its] bets" if it was uncertain about which claimed subject matter was likely to prove valuable. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1505 (2001).

141 *See supra* note 36.

142 Tony Ellery & Neal Hansen, Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand 96–97 (2012).

143 *See supra* text accompanying notes 29–36.

144 For an explanation, see *infra* text accompanying note 171.

structure. The compounds share a core structure; they differ in the number and identities of chemical functional groups.[145]

The question is whether the ninety-eight unmade compounds have been squandered. To answer this question, suppose the now-expired patent is subjected to an enablement analysis. The question is whether all 100 were enabled as of the reinventor's filing date. After construing the claim, assessing the PHOSITA's level of skill, and evaluating the teaching provided in the patent document, the decisionmaker determines it enabled a PHOSITA to practice *ten compounds, not 100.* Support for the nonenablement determination is based on the finding that:

> [R]eplacing a functional group on a chemical compound can often have highly unpredictable results. . . . [E]ven a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group . . . could result in either a significant improvement or reduction in the activity of the compound against a particular biological target.[146]

The point here is that a PHOSITA could not extrapolate a result from the two compounds actually made across all 100 compounds claimed with a reasonable expectation of success.[147] Thus, a PHOSITA would have had to engage in undue experimentation to practice its full scope.

The inadequate disclosure in the now-expired patent is costly for the patent system and the public. Even if none of the ninety claimed-but-nonenabled compounds has been commercialized or disclosed in the technical literature, their prior disclosure in the earlier patent defeats novelty and prevents them from being patented again.[148] This is true even though the

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145 A functional group is "[a]n atom or group of atoms within a molecule that shows a characteristic set of physical and chemical properties." WILLIAM H. BROWN ET AL., ORGANIC CHEMISTRY G-4 (6th ed. 2012). A functional group represents a potential reaction site in a compound, and thus determines a compound's chemical reactivity. RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS: A GUIDE TO FUNCTIONAL GROUP PREPARATIONS (2d ed. 1999).

146 Singh v. Brake, 317 F.3d 1334, 1344 (Fed. Cir. 2003).

147 In chemistry, results are often unpredictable because researchers often must engage in trial and error to figure out what works and what does not. Thus, a PHOSITA cannot predict if a reaction protocol that works for one compound will work for others. *See supra* note 102; *see also In re* Prutton, 200 F.2d 706, 712 (C.C.P.A. 1952) (holding that claims to a class of chemical compounds, which were sufficiently broad to involve some speculation, lacked enablement despite the presence of operative specific examples within the class).

148 Throughout this Article, I have drawn attention to a scenario where *X* is specifically disclosed and claimed in the expired patent. But one can imagine a scenario where *X* is not specifically recited by name or structure but rather is disclosed (and claimed) as part of a genus in a generic chemical formula. It is true that sometimes a generic chemical formula is disclosed so broadly that it is insufficient to anticipate a species. *See, e.g.*, Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999 (Fed. Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus."); *In re* Ruschig, 343 F.2d 965, 974 (C.C.P.A. 1965) (determining that the disclosed genus did not anticipate everything within its scope because the description of the genus would not lead a PHOSITA to a "small recognizable class with common properties"). If a PHOSITA can "at once envisage" the specific compound at

ninety compounds never entered the public domain because of their inadequate disclosure in the earlier patent.[149] Nonetheless, the current patent laws provide little or no incentive for subsequent inventors to develop them.[150] Thus, the ninety claimed-but-nonenabled compounds have been squandered.[151] This outcome harms the public[152] and frustrates basic goals of the patent system.[153]

B. Mixed Signals from the Courts

Given that squandered claims are technically invalid for nonenablement, one may wonder why they proliferate. It would seem that the Patent Office and the courts would demand a tight correspondence between the scope of the enablement provided and the scope of the claim ultimately granted. Indeed, there is a so-called "commensurability" requirement;[154] however, enforcing it is complicated.

Recall that enablement is a standard that affords the decisionmaker a fair amount of discretion.[155] Given that enablement is judged by the state of the relevant technology and the PHOSITA's knowledge and identity at a specific point in time, the analysis is inherently flexible—requiring a case-by-case treatment of the relevant issues.[156] A flexible, fact-sensitive enablement doctrine also allows patent law to accommodate different technologies, new technologies, and old technologies that evolve over time.[157]

But flexibility need not implicate the *threshold* for enablement, which can be set uniformly high (or low) by the decisionmaker. To be sure, the

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issue within the generic chemical formula in the prior art reference, the compound is anticipated. *In re* Petering, 301 F.2d 676, 681 (C.C.P.A. 1962). A PHOSITA must be able to draw the structural formula or write the compound's name. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2131.02 (9th ed. 2014) [hereinafter MPEP] (citing *In re* Schaumann, 572 F.2d 312, 316–17 (C.C.P.A. 1978)). Again, the reinvention paradigm does not pose a *Ruschig* problem because *X* is specifically disclosed.

149 *See supra* note 39 and accompanying text.

150 *See infra* note 178.

151 *See infra* Section II.D.

152 *See supra* Section II.A (first paragraph).

153 *See supra* Part I.

154 Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed. Cir. 1999) ("The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.").

155 *See supra* note 94 and accompanying text. A standard can be defined as a "legal directive" that "giv[es] the decisionmaker more discretion" by "collaps[ing] decisionmaking back into the direct application of the background principle or policy to a fact situation," thereby "allow[ing] the decisionmaker to take into account all relevant factors or the totality of the circumstances." Kathleen M. Sullivan, *The Justices of Rules and Standards*, 106 HARV. L. REV. 22, 58–59 (1992).

156 AK Steel Corp. v. Sollac, 344 F.3d 1234, 1245 (Fed. Cir. 2003); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

157 *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1191 (2002).

threshold can be set sufficiently high to render any claim covering nonenabled subject matter invalid. Although the Federal Circuit has not gone that far, recently it has been touting a "full scope" enablement requirement;[158] meaning that "[c]laims are not enabled when, at the effective filing date of the patent, [a PHOSITA] could not practice their *full scope* without undue experimentation."[159]

Of course, full scope enablement and squandering are mutually exclusive. So one might think that a robust, full scope enablement requirement would solve the squandering problem.[160] But the story is not so simple. There is an enablement subdoctrine—the inoperative embodiments doctrine[161]—which renders a claim not necessarily invalid if some of the subject matter fails to work as described.[162] The Federal Circuit has stated that the patentee need not guarantee that everything claimed actually works.[163] This means that a patentee will not be limited to those embodiments specifically exemplified in the patent document[164] or shown to actually work for their intended purpose.[165]

The inoperable embodiments doctrine is patentee-friendly. The cases make clear that the claims need not specifically exclude possible inoperative

158 *See, e.g.*, Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008).

159 Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1384 (Fed. Cir. 2013) (emphasis added) (citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380–81 (Fed. Cir. 2012)).

160 *Cf.* James Farrand et al., *"Reform" Arrives in Patent Enforcement: The Big Picture*, 51 IDEA 357, 415–17 (2011) (describing the full scope enablement doctrine and noting that it "can invalidate many existing broad patent claims, particularly if it continues to be applied as broadly as it is being stated"). *Id.* at 417.

161 Although the doctrine has existed for quite some time, Jeffrey Lefstin named it the "'inoperative embodiments' doctrine." *See* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1178 (2008).

162 *See In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971); *In re* Sarett, 327 F.2d 1005, 1019 (C.C.P.A. 1964) (noting that the mere inclusion of inoperative embodiments in a claim will not defeat patentability). Only "if the number of inoperative [embodiments] becomes significant, and in effect forces [a PHOSITA] to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); *cf. In re* Kamal, 398 F.2d 867, 871 (C.C.P.A. 1968) ("Whether a disclosure gives reasonable assurance that all of the compounds embraced by the claims would be useful for the purposes intended must be determined by the particular circumstances of each case, including the nature of the compounds per se and the supporting disclosure." (quoting *In re* Riat, 327 F.2d 685, 686 (C.C.P.A. 1964))).

163 Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1189 (Fed. Cir. 2014) (citing Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 61 (1998)).

164 *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) ("It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art."); SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (explaining that the law does not require that an applicant describe every conceivable embodiment of the invention).

165 *Alcon Research Ltd.*, 745 F.3d at 1189.

substances.[166] And if the applicant had to demonstrate that everything claimed actually worked, "the research to do this would quite evidently be endless."[167] So the traditional evidentiary rules apply—namely, a presumption in both the Patent Office and the courts that the full scope of a claim is enabled.[168] The burden rests with the party challenging enablement to prove unpatentability or invalidity, respectively.[169]

Thus, the inoperative embodiments doctrine vitiates full scope enablement. Again, full scope enablement means that a PHOSITA should be able to read the patent's written description of the invention and—combined with the PHOSITA's own knowledge—make and use *everything* that is claimed. So if the patent covers 100 chemical compounds that purportedly have a specific pharmacological activity, the PHOSITA should be enabled to make and use *each of them.* The inoperative embodiments doctrine, however, raises doubts about this expectation.[170]

And while the doctrine essentially guarantees squandering (because it allows for some inoperable embodiments in the scope of the claim), it finds considerable support in patent law. Robert Merges and Richard Nelson argue that requiring a tighter connection between the disclosure and the claims would lead to (narrow) patents of little value because an imitator could find minor variations over the embodiments specifically exemplified or actually reduced to practice.[171] Thus, the doctrine seemingly adds value to patent claims.[172] Proponents would assert that it encourages early disclo-

166 *Atlas Powder Co.*, 750 F.2d at 1576 (quoting *In re* Dinh-Nguyen, 492 F.2d 856, 858–59 (C.C.P.A. 1974) (emphasis omitted)).

167 *In re Sarett*, 327 F.2d at 1019.

168 *See* ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("Because patents are presumed valid, lack of enablement must be proven by clear and convincing evidence."); *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining the presumption and placing the burden on the examiner to prove nonenablement).

169 *See supra* note 168; *see also* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (holding that a patent was enabling because the challenger did not prove that undue experimentation would be required to practice the undescribed embodiments).

170 In unpredictable fields like chemistry, there is a real danger that claimed subject matter not specifically exemplified or actually reduced to practice cannot be made or work as intended. *PPG Indus., Inc.*, 75 F.3d at 1564; Seymore, *supra* note 67, at 631–32.

171 Merges & Nelson, *supra* note 24, at 845; *see also* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005) (arguing that narrow patent rights become worthless as new modes of practicing the invention develop).

172 It is true that claims are of little value unless they can ensnare a potential infringer. Patentees achieve this goal by obtaining broad claims that cover "all expected and unanticipated [variants] that competitors and others may later develop . . . which embody the inventor's concept." ROBERT C. FABER, FABER ON MECHANICS OF PATENT CLAIM DRAFTING § 10:1.1 (6th ed. 2014).

sure,[173] gives the patentee an edge over competitors,[174] and prevents patent documents from becoming overly thick.[175]

C. *Consequences*

Consider again the incalculable number of claimed-but-nonenabled compounds that exist in the universe of expired patents. Assuming that they were never commercialized and—other than the expired patent—have not been described in the technical literature, these compounds have been essentially lost.[176] Nothing about them has entered the public storehouse of knowledge,[177] and the public has derived no benefit from them. There might be little or no economic incentive for others to research or develop these compounds since they cannot be patented again.[178] The expired patent creates roadblocks for other inventors,[179] including the ability to dominate other technological innovations that only subsequent workers in the field can actually enable.[180]

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173 *See* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1568 (Fed. Cir. 1990) (quoting *In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977)) (arguing that limiting the scope of the claims to the specific embodiments disclosed is a poor way to stimulate invention and discourages early disclosure).

174 *See* Edlyn S. Simmons, *Prior Art Searching in the Preparation of Pharmaceutical Patent Applications*, 3 DRUG DISCOVERY TODAY 52, 52 (1998) (explaining the importance of drafting broad generic claims that include hypothetical compounds in order to prevent competitors from developing them).

175 *See* N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed. Cir. 1990) ("It is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification.").

176 *Cf.* Seymore, *supra* note 67, at 656 (explaining that since many patentees do not disclose technical information about their inventions in another medium, much technical information not disclosed through the patent system never enters the public storehouse of knowledge and will likely be lost).

177 *Id.* at 666.

178 This is certainly the case for costly new drugs. *See supra* note 57 and accompanying text; *infra* note 325.

179 BESSEN & MEURER, *supra* note 24, at 67; *see also* Frank B. Killian & Co. v. Allied Latex Corp., 188 F.2d 940, 942 (2d Cir. 1951) (explaining that unknown and unexploited patents stand on the same footing as other novelty-defeating prior art).

180 Seymore, *supra* note 67, at 660. Another commentator elaborates on the scope and consequences of the problem:

> The further a patent moves away from a requirement that the inventor actually have a complete and operative invention [at the time of filing], the broader the patent's scope and the greater potential that the [claims] will protect speculative ideas . . . . With just a little time, money, and imagination, one may . . . without inventing anything . . . [obtain a patent with] claims that are broad enough to [encompass] technology developed for the first time years after the inventor first files an application. . . . [This can have] an undue chilling effect on the behavior of later scientists [and] researchers . . . who (sometimes many years later) through their own experimentation, hard work, and trial and error succeed in [creating] a bona fide product or process that actually works.

Another roadblock is the presumption of patent validity. When a patent issues, it is presumed valid.[181] This applies to everything claimed, including each of the numerous compounds under discussion. The rationale is that "a government agency such as the . . . Patent Office [is] presumed to do its job."[182] This allows the patentee to benefit from *double deference*—that the patent application as filed presumptively complied with the statutory patentability requirements, including enablement (the presumption of enablement),[183] *and* that the Patent Office did its job to only issue valid patents (the presumption of patent validity).[184] This presumption creates a formidable hurdle for challengers, who must prove that the contentious subject matter was nonenabled.[185]

The preceding discussion suggests two things. First, from a patentee's perspective, there is little downside to squandering.[186] Second, it is nearly impossible for a subsequent inventor to patent previously claimed-but-nonenabled subject matter.

III. The Reinvention Paradigm

In this Part, I propose the reinvention paradigm and explain how it helps solve the squandering problem. I focus on the quintessential reinvention scenario discussed above—and specifically on the hypothetical set forth in the Introduction—where a reinventor seeks to claim a chemical moiety, *X*,

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Christopher A. Harkins, *Fending Off Paper Patents and Patent Trolls: A Novel "Cold Fusion" Defense Because Changing Times Demand It*, 17 Alb. L.J. Sci. & Tech. 407, 453 (2007).

181 35 U.S.C. § 282 (2012).

182 Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984), *accord* K/S Himpp v. Hear-Wear Techs., LLC, 751 F.3d 1362, 1369 (Fed. Cir. 2014) ("The assumption that PTO examiners will use their knowledge of the art when examining patents is the foundation for the presumption in 35 U.S.C. § 282(a) that issued patents are valid."). Doug Lichtman and Mark Lemley posit a theoretical justification that "patent examiners have expertise when it comes to questions of patent validity, and if patent examiners have decided that a given invention qualifies for protection, judges and juries should not second-guess the experts." Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 Stan. L. Rev. 45, 47 (2007).

183 *See supra* subsection I.B.2.

184 *See supra* notes 181–182 and accompanying text.

185 In litigation, a challenger must prove invalidity with clear and convincing evidence. Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2251 (2011). The America Invents Act created several post-issuance, non-litigation-based mechanisms including inter partes review (IPR), 35 U.S.C. §§ 311–19, and post-grant review (PGR), *id.* §§ 321–29—trials conducted by the Patent Trial and Appeal Board. In both proceedings the petitioner need only prove patent invalidity by a preponderance of evidence. *Id.* § 316(e); § 326(e). However, both mechanisms are quite limited. For example, for both IPR and PGR, the petition must be filed within nine months of patent issuance. *Id.* § 311(c); § 321(c). For IPR, only novelty and nonobviousness may be challenged. *Id.* § 311(b).

186 *See* Graham Dutfield, Intellectual Property Rights and the Life Science Industries: Past, Present and Future 46 (2d ed. 2009) ("Firms may deliberately file excessively broad patent claims in the hope that at least some of these will slip through the examination system and be allowed.").

that was claimed but nonenabled (squandered) in an earlier, now expired patent.[187]

A. *Theoretical Underpinnings*

The reinvention paradigm is founded on a straightforward theoretical basis. The universe of expired patents is full of squandered compounds like *X*. And since squandered subject matter was nonenabled,[188] any claim to *X* in an expired patent is technically invalid.[189] The original inventor never possessed *X*; thus, the public never gained possession of it at the end of the patent term.[190] And assuming that *X* has not been disclosed, used, or commercialized, it is still unknown. I contend that the new patent should be granted if the reinventor can: (1) establish that the disclosure in the expired patent did not enable *X*; and (2) satisfy enablement and the other patentability requirements for *X*.

The key patentability hurdle that the reinventor must overcome is *novelty*—the statutory requirement that *X* is new.[191] If the identical subject matter has been "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,"[192] it is anticipated by the prior disclosure and is unpatentable.[193] Novelty is a rigid rule—perhaps unduly so.[194] The theoretical basis for novelty rests on the assumption that the invention's prior disclosure gave the public access to it; thus, a patent is not required as an incentive to invent.[195] And if a patent is not needed as an inducement, the costs to the

187 *See supra* notes 29–36 and accompanying text.

188 *See supra* Section II.A.

189 *See supra* note 27.

190 *See supra* Section I.C.

191 "Whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter . . . may obtain a patent . . . ." 35 U.S.C. § 101 (2012) (emphasis added).

192 *Id.* § 102(a)(1).

193 The patent statute provides a grace period for certain prior disclosures that came directly or indirectly from the inventor. *See id.* § 102(b).

194 The novelty rules protecting the public domain are

> so solicitous of preserving access to the prior art that they can seem almost absurd. There is no inquiry into [ ] the practical accessibility of the prior art; once it is public, even marginally, and only in one obscure place or one obscure form, the game is over—no patent. Period.

ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 143 (2011).

195 RONALD A. CASS & KEITH N. HYLTON, LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS 64 (2013); *see also* Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 12–13 (1992) ("The logic behind [the novelty requirement] is fairly straightforward . . . . [Because if] information is already in the public domain when the 'inventor' seeks to patent it[,] society has no need to grant a patent to get this information.").

public (who would no longer have free access to the invention) would outweigh any benefit of patent protection.[196]

At this point it is necessary to say more about enablement as it pertains to prior art. The Introduction discussed how the reinventor would have to face two enablement hurdles. Section 112(a) of the Patent Act compels a patent applicant to submit a written description that enables a PHOSITA to make and use the full scope of the claimed invention without undue experimentation.[197] While a "statutory" or patent-supporting form of enablement places an outer limit on claim scope,[198] the form pertaining to prior art references is referred to as "anticipatory" or patent-defeating enablement because it is used to demonstrate that a PHOSITA could use preexisting knowledge to make *X* without undue experimentation.[199] Unlike the statutory form, anticipatory enablement is a narrower doctrine because there is no requirement that a prior art reference disclose how to use *X*.[200] A prior art reference need only enable a PHOSITA to make *X* and nothing more.[201]

Finally, if the expired patent is nonenabling, it does not qualify as prior art.[202] And to be clear, it is not that the expired patent has somehow lost its status as prior art over time—it *was never prior art* because of the inadequate (nonenabling) disclosure.[203]

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196 CASS & HYLTON, *supra* note 195, at 64; Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2088 (2000) ("Granting patents on technologies that are not new would impose the social costs of monopolies without the countervailing benefits of promoting development and introduction of welfare-enhancing inventions.").

197 *See supra* note 90 and accompanying text.

198 *See supra* Section I.B.

199 Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1355 (Fed. Cir. 2005); *In re* Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985) ("Such possession is effected if [a PHOSITA] could have combined the publication's description of the invention with his own knowledge to make the claimed invention."). "Enablement" does not appear in the text of section 102. Thus, the doctrine is the result of a "judicially imposed limitation" on section 102 that the description of the subject matter in the reference must be an enabling description. *In re* LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962).

200 Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325 (Fed. Cir. 2005) ("[S]ection 112 'provides that the specification must enable one skilled in the art to "use" the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure.'" (quoting *In re* Hafner, 410 F.2d 1403, 1405 (C.C.P.A. 1969))).

201 Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).

202 *See supra* note 50 and accompanying text.

203 In patent law, the courts recognize the "lost art" doctrine, which holds that prior knowledge or use of an invention cannot anticipate a subsequent claim to the invention if the details from the first invention have been completely lost. Gayler v. Wilder, 51 U.S. (10 How.) 477, 497–98 (1850) (applying the doctrine after determining that the first invention had been completely forgotten and essentially abandoned). The first invention does not qualify as prior art because it is no longer accessible to the public. *Id.* at 497. In contrast to the reinvention paradigm, the "lost art" *was* or *could have been* prior art but no longer qualifies because it is no longer publicly accessible. *See* ROBINSON, *supra* note 15, at 442 ("An invention, once in use, is considered as inaccessible to the public when it has been abandoned and forgotten, and can no longer be completely known, by [a PHOSITA],

B. A New Novelty Framework

Obtaining a reinvention patent for *X* would follow the typical patent prosecution rubric.[204] As I describe below, prosecution is driven by evidentiary mechanisms that include presumptions and shifting burdens of proof.

1. Presumptions and Burdens of Proof

a. Overview

At the time of filing, the reinventor's patent application presumably complies with each of the statutory patentability requirements,[205] including novelty.[206] Accordingly, the initial burden of proof rests with the examiner to build a prima facie case of *X*'s unpatentability.[207] Once made, the burden shifts to the reinventor to rebut the prima facie case with persuasive argument or proof.[208] While the burden of production may shift back and forth during prosecution, the ultimate burden of persuasion is on the Patent Office.[209] Whether a prior art reference is enabling is a question of law based on underlying factual inquiries.[210] On appeal, the question of whether a reference is enabling is reviewed de novo, and the underlying factual inquiries are reviewed deferentially.[211] Whether a reference anticipates is a question of fact.[212]

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from anything which still remains in the possession of the public." (citing *Gayler*, 51 U.S. at 496)).

204 The process of obtaining a patent—where the inventor or his or her agent or attorney files an application with the Patent Office—is called patent prosecution. ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 37 (4th ed. 2013).

205 *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

206 *In re* Wilder, 429 F.2d 447, 450 (C.C.P.A. 1970).

207 *Oetiker*, 977 F.2d at 1445; *In re* King, 801 F.2d 1324, 1327 (Fed. Cir. 1986) (noting that the Patent Office must establish a prima facie case before any burden shifting occurs). According to federal regulation:

> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with [what is described in the patent application], and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b)(2)(ii) (2014).

208 *Oetiker*, 977 F.2d at 1445.

209 *Id.* at 1449 (Plager, J., concurring); *In re* Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967).

210 Impax Labs., Inc. v. Aventis Pharm. Inc., 545 F.3d 1312, 1315 (Fed. Cir. 2008).

211 For appeals from the Patent Office, the Federal Circuit reviews the factual underpinnings for substantial evidence. *In re* Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Appellate courts review lower courts' factual findings in bench trials for clear error. *Impax Labs.*, 545 F.3d at 1315.

212 *In re* Hyatt, 211 F.3d 1367, 1371 (Fed. Cir. 2000).

b. The Prima Facie Case

The key procedural role for the prima facie case is to establish the examiner's initial burden of production.[213] The reinvention paradigm retains the prima facie case in its current format for three reasons. First, in ex parte matters, it serves as an orderly mechanism for initially producing evidence[214] and developing a written record of the proceedings before the Patent Office.[215] Second, it prevents the reinventor (or any applicant) from having to guess why the examiner believes a claim is unpatentable.[216] Third, the prima facie case reduces arbitrariness to the extent that it requires the Patent Office to come forward with a sufficient factual basis for denying a patent.[217]

The prima facie case, however, does much more than determine who goes first. The substantive basis for a prima facie case often rests on presumptions that raise interesting and important questions crucial to patentability. In a reinvention scenario, recall that novelty reduces to the question of anticipatory enablement, which asks if the disclosure in the expired patent would have enabled a PHOSITA to make *X* without undue experimentation.[218] For reasons that will be explained shortly, the Federal Circuit has held that "an examiner is entitled to reject claims as anticipated by a prior art publication or patent *without conducting an inquiry into whether or not that prior art reference is enabling.*"[219]

c. The Presumption of Enablement

The U.S. Court of Customs and Patent Appeals[220] articulated a burden-shifting framework to handle anticipatory enablement issues that arise during patent examination.[221] As a starting point, at the time of filing, 35 U.S.C. § 102 affords the applicant a presumption of novelty because the statute states that "a person shall be entitled to a patent *unless*" one of the statutory exclusions is shown.[222] This means that the examiner has the initial burden

213 *In re* Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

214 *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

215 *Morris*, 127 F.2d at 1054.

216 *In re* Oetiker, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (Plager, J., concurring).

217 *Id.*

218 *See supra* note 199 and accompanying text.

219 *In re* Antor Media Corp., 689 F.3d 1282, 1289 (Fed. Cir. 2012) (emphasis added). The presumption of enablement also applies in district court proceedings. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003).

220 *See supra* note 36.

221 *See In re* Sasse, 629 F.2d 675, 681–82 (C.C.P.A. 1980) (explaining that anticipatory-enablement issues are governed by a burden-shifting regime); *In re* Wilder, 429 F.2d 447, 450–52 (C.C.P.A. 1970) (outlining the burden-shifting process for the anticipatory-enablement inquiry).

222 *Wilder*, 429 F.2d at 450 (quoting 35 U.S.C. § 102 (2006)). As former Chief Judge Paul Michel once explained, "If the claimed invention is patentable, the applicant is *entitled* to a patent (because [section 102 of] the statute says so)—not eventually, but as soon as patentability can be determined." Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1249 (1994).

of coming forward with evidence of anticipation;[223] yet the examiner can make a prima facie case whenever a reference specifically describes *X* by name or structure.[224] Importantly, the examiner can reject the applicant's claim to *X* for anticipation without conducting an inquiry into whether the asserted prior art reference enables the subject matter.[225] Put simply, the expired patent enjoys a presumption of enablement.[226]

From a technical standpoint, the presumption rests on shaky ground. In unpredictable fields, it can be hard to believe that all asserted prior art is enabling. However, the Federal Circuit's rationale for the presumption is not based on the technical robustness of the disclosure:

> [I]t is procedurally convenient to place the burden on an applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not enabling . . . . It would be overly cumbersome, perhaps even impossible, to impose on the [Patent Office] the burden of showing that a cited piece of prior art is enabling. The [Patent Office] does not have laboratories for testing disclosures for enablement.[227]

So it seems that the presumption is based on the practical realities of patent examination. Nonetheless, it allows a cursory disclosure in a prior art reference—which would be inadequate to enable *X* for patent-obtaining purposes—to potentially defeat a later claim of novelty by a subsequent inventor.[228]

The next question is whether the presumption of enablement should apply to *X* in the reinvention paradigm. To be sure, squandered subject matter like *X* is by definition nonenabled. In the case of previously *disclosed but unclaimed* subject matter, a patent asserted as prior art should not enjoy a presumption of enablement if it discloses no substantive technical information about the subject matter at issue.[229] A typical situation is where the asserted prior art is a "shotgun" reference—a document that discloses, but does not claim, millions of chemical compounds.[230] Importantly, the Patent

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223 *Wilder*, 429 F.2d at 450; *accord In re* Sun, No. 93-1261, 22 F.3d 1102, 1993 WL 533128, at *2 (Fed. Cir. Dec. 23, 1993) ("The examiner bears the burden of presenting at least a prima facie case of anticipation.").

224 *Wilder*, 429 F.2d at 451.

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

226 *Id.*; *see In re* Antor Media Corp., 689 F.3d 1282, 1287–88 (Fed. Cir. 2012).

227 *Antor Media*, 689 F.3d at 1288; *see also In re* Morsa, 713 F.3d 104, 110 (Fed. Cir. 2013) (reaffirming the procedural basis for the presumption); *Amgen*, 314 F.3d at 1355 n.21 (further elaborating on the policy basis for the presumption).

228 *Cf. In re* Hafner, 410 F.2d 1403, 1405 (C.C.P.A. 1969) (noting that a disclosure sufficient to anticipate for patent-defeating purposes may be insufficient to support the patentability of a claim under section 112 of the Patent Act).

229 Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 959 (2011).

230 *See In re* Schoenewaldt, 343 F.2d 1000, 1002 (C.C.P.A. 1965) (defining a "shotgun" reference). One reason for shotgunning is defensive disclosure—deliberately creating prior art problems for subsequent inventors. Douglas Lichtman et al., *Strategic Disclosure in the Patent System*, 53 VAND. L. REV. 2175, 2175–76 (2000); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 927 (2000). A typical strategy is to disclose millions of chemi-

Office does not conduct a section 112 enablement analysis on unclaimed subject matter disclosed in an application.[231]

The reinvention paradigm is different because the compound at issue (*X*) was actually *claimed* in the expired patent. In theory, the examiner examined *X* and concluded (albeit wrongly) that the claim to it was supported by an enabling disclosure. Nevertheless, the presumption is somewhat defensible since the Patent Office is presumed to do its job.[232]

d. The Reinventor's Rebuttal Evidence

At this point the burden shifts to the reinventor to rebut the presumption of enablement.[233] This is the most crucial step in the paradigm, because failing to rebut the presumption will result in a patent denial.[234] The reinventor must show, through persuasive argument or proof, by a preponderance of the evidence, that the asserted expired patent is nonenabling with respect to *X* and therefore insufficient to have placed *X* in possession of the public.[235] Facts such as actual experimental data or affidavits from experts in the field are often "highly probative."[236] However, a successful challenge can be lodged without resort to expert assistance "[w]hen a reference appears to not be enabling on its face"[237] buttressed by "specific, concrete reasons" to support the contention of nonenablement.[238]

Nevertheless, proving that *X* was nonenabled in the expired patent can be difficult because "[i]t is actually very difficult to offer rigorous proof that something cannot be done."[239] This brings to the fore the potential for hindsight bias.[240] In the enablement context, hindsight bias would lead the

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cal structures in a patent application with one that is actually enabled. Then, the applicant can "claim that enabled compound and get a patent issued on that compound and have the rest of the [disclosed but unclaimed] structures become enabled prior art . . . ." CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION GUIDE TO PATENT LAW 170 n.4 (2010).

231 *See* MPEP, *supra* note 148, § 2164.08 ("All questions of enablement are evaluated against the claimed subject matter."); *see also* Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1531 (Fed. Cir. 1991) ("Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless, and the pitfalls endless.").

232 *See supra* note 182 and accompanying text.

233 *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

234 *In re* Spada, 911 F.2d 705, 707 n.3 (Fed. Cir. 1990).

235 *In re* Antor Media Corp., 689 F.3d 1282, 1287–88 (Fed. Cir. 2012) (citing Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003)).

236 *In re* Payne, 606 F.2d 303, 315 (C.C.P.A. 1979).

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

238 *Id.*

239 Kantrowitz, *supra* note 119, at 764.

240 Hindsight bias is the cognitive limitation that prevents persons from disregarding their knowledge of an outcome in assessing past events. Baruch Fischhoff, *For Those Condemned to Study the Past: Heuristics and Biases in Hindsight*, *in* JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 335, 341 (Daniel Kahneman et al. eds., 1982). Hindsight reasoning is impermissible in assessing patentability or claim validity. *See, e.g.*, KSR Int'l Co. v.

examiner to overestimate the PHOSITA's level of skill, since subsequent advances in the field might suggest that *X* could have been made without undue experimentation.[241]

When the reinventor submits rebuttal evidence, the examiner must "start over"[242] and "consider all of the evidence anew."[243] The burden of production may continue to shift as each side presents new evidence;[244] but again, the examiner carries the ultimate burden of persuasion.[245] If the examiner fails to carry the burden, and absent any other grounds for unpatentability, the reinventor is entitled to the patent.[246]

2. Illustration

To illustrate how the paradigm would work, I return to the hypothetical discussed thus far throughout this Article.[247] Recall that AcmePharma, the reinventor, files a patent application claiming *X*, a fibrate compound that it has made and found to effectively lower cholesterol in humans.[248] At the time of filing *X* is, as far as AcmePharma knows, previously unknown since the compound has not been commercialized and nothing about it has been disclosed in the technical literature.

Upon receipt of the application, the examiner searches the prior art and rejects *X* for a lack of novelty.[249] The asserted prior art reference is an expired drug patent filed in 1980 that discloses and claims (the chemical structures of) 100 compounds, including *X*. The exemplification section[250] begins with the following boilerplate language:

> The invention will be more readily understood by reference to the examples below. The embodiments specifically exemplified are included merely for the purposes of illustration and are not intended to limit the invention. *Those skilled in the art will recognize, or be able to ascertain using no more than*

Teleflex Inc., 550 U.S. 398, 421 (2007) (noting that factfinders should be aware of the "distortion" caused by hindsight bias).

241 Burk & Lemley, *supra* note 157, at 1199; *see also* R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PA. L. REV. 159, 205 (2002) ("[In considering] enablement, which is measured through the lens of the knowledge of the relevant field as of the filing date of the patent application[, a]s the filing date becomes distant, the potential for . . . hindsight bias[ ] increases." (footnote omitted)).

242 *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (quoting *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976)).

243 *Id.*

244 *In re* Sasse, 629 F.2d 675, 681–82 (C.C.P.A. 1980).

245 *See supra* note 209.

246 *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re* Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967); *see also In re* Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994).

247 *See supra* text accompanying notes 29–36, 143–52.

248 *See supra* note 29.

249 *See supra* subsection III.B.1.a.

250 This is the portion of the written description that includes working examples—technical details about embodiments of the invention that have actually been made.

routine experimentation, how to make embodiments not specifically exemplified herein.[251]

The document then provides full technical details about how to make and use two of the 100 compounds disclosed and claimed.[252] Importantly, it provides no specific details about how to make *X*. Nonetheless, the examiner can make a prima facie case of anticipation because (1) the subject matter that AcmePharma seeks to claim (*X*) is identical to that disclosed in the expired patent (*X*); and (2) the expired patent presumably enables a PHOSITA to make *X*.[253]

At this point, the burden shifts to AcmePharma to rebut the prima facie case.[254] Since strict identity is not an issue, the novelty question reduces to one of anticipatory enablement. AcmePharma must establish by a preponderance of the evidence that as of its filing date (2015), the expired patent's teachings combined with extant knowledge in the field could not have enabled a PHOSITA to make *X* without undue experimentation.[255]

AcmePharma responds to the rejection with argument and proof. Pointing to the *Wands* factors,[256] AcmePharma argues that given the nature of *X* (factor three), the unpredictability of organic chemistry[257] (factor four) and the lack of teaching provided about how to make *X* or compounds like *X* (factors one and two), and the current level of skill in fibrate chemistry (factor five), undue experimentation would be required (factor eight).[258] Thus, the cursory disclosure in the expired patent was nothing more than an "invitation to experiment."[259] A reference that merely "provides a starting point from which [a PHOSITA] can perform further research in order to [make *X*], but . . . is not adequate to constitute enablement"[260] and does not qualify as prior art for novelty purposes.[261]

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251 Such language is ubiquitous in patent documents. *See, e.g.*, Method of Preparing Dry Powder Inhalation Compositions, U.S. Patent No. 8,075,873 (filed May 6, 2009) (issued Dec. 13, 2011).

252 *See supra* text accompanying note 144.

253 *See supra* notes 41–43 and accompanying text.

254 *See supra* subsection III.B.1.c.

255 *See supra* note 44 and accompanying text.

256 Recall that the Federal Circuit has set forth several factors relevant to the enablement inquiry. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); *see* Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1315 (Fed. Cir. 2008) (applying the *Wands* factors in the anticipatory enablement context).

257 For an instance of the Federal Circuit opining on the unpredictability of organic chemistry, see Singh v. Brake, 317 F.3d 1334, 1344 (Fed. Cir. 2003); *see also supra* text accompanying note 146.

258 *Wands*, 858 F.2d at 737.

259 *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

260 Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1198 (Fed. Cir. 1999) (citing Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

261 *See supra* note 50 and accompanying text; *see also* Gillman v. Stern, 114 F.2d 28, 31 (2d Cir. 1940) (Hand, J.) (explaining that when considering whether a prior disclosure is anticipatory, "what ha[s] not in fact enriched the art, should not count [as prior art]"). As

To support its argument, AcmePharma adduces evidence to show the *current* state of the art of fibrate chemistry. This is because "it is conceivable that a prior art reference that was not enabled as of its effective prior art date *could become* enabled over time as the knowledge of the PHOSITA expands."[262] AcmePharma offers an article, *Fifty Years of Fibrate Chemistry*, published in a 2015 issue of *Chemical Reviews*. The article reveals that fibrates like *X* with multiple cyclopropyl functional groups[263] have proven elusive. Based on this information, AcmePharma argues that as of the application's filing date, undue experimentation would have been required for a PHOSITA to make *X*. (Note that unlike the PHOSITA, the inventor is one of *extraordinary* skill.)[264]

Upon reconsideration, after weighing all of the evidence, the examiner withdraws the novelty rejection because the expired patent is nonenabling.[265] But overcoming the novelty rejection does not guarantee a patent because AcmePharma must still satisfy other patentability requirements. For example, to the extent that fibrate chemistry has advanced over the past thirty-five years, a PHOSITA might now find that *X* looks obvious in light of those scientific advances.[266] As discussed below, this would create another ground of unpatentability.

C. The Role of Nonobviousness

AcmePharma's ability to prove that the expired patent's disclosure of *X* was nonenabling removes the reference from the prior art for novelty purposes. Thus, *X* is new; meaning that AcmePharma should be allowed to claim *X* in its own patent.

It might appear that implementing the proposal might open the floodgates to reinvention claims, thereby sending a shockwave through the patent system. This is highly unlikely since the reinventor must satisfy other patenta-

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to whether the expired patent can serve as prior art for the nonobviousness inquiry, see *infra* Section III.C.

262 Holbrook, *supra* note 48, at 10 ("Because enablement is based not only on the prior art disclosure but also on the knowledge of the PHOSITA, the teaching of a prior art reference is an ever-moving target, as the PHOSITA's knowledge grows over time.").

263 A cyclopropyl group is comprised of three carbons that form a strained, three-membered ring. JONATHAN CLAYDEN ET AL., ORGANIC CHEMISTRY 369 (2d ed. 2012).

264 *See* Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985) ("Inventors . . . possess something . . . which sets them apart from the workers of ordinary skill . . . ."); Burk & Lemley, *supra* note 157, at 1189 (explaining that the inventor "almost by definition is presumed to be one of extraordinary skill").

265 Once the applicant provides rebuttal evidence, the examiner "must then weigh all the evidence . . . including the [written description] . . . [and] any new evidence supplied by [the] applicant [with the] evidence and[/or] scientific reasoning previously presented in the [initial] rejection and then decide whether the claimed invention is enabled." MPEP, *supra* note 148, § 2164.05.

266 *See infra* subsection III.C.2.

bility requirements. Chief among them is nonobviousness, which has been called "[t]he fundamental gatekeeper to patenting."[267]

The nonobviousness requirement, embodied in section 103(a) of the patent statute,[268] denies patents for trivial extensions of what is already in the public domain.[269] It does not target inventions that are identically disclosed in the prior art,[270] but rather those that are sufficiently close to the prior art and within the PHOSITA's technical grasp at the time of filing.[271] The idea is that even if the claimed invention is new and enabled, a fact-intensive evaluation of its technical merit might suggest that a patent should not issue because the potential benefit that society might derive from the invention and its disclosure does not justify the costs of granting a patent.[272] This is because the invention does not differ substantially from what is already known. Thus, nonobviousness "creates a 'patent-free' zone around the state of the art,"[273] allowing the PHOSITA to substitute materials, streamline processes, and "[make] the usual marginal improvements which occur as a technology matures."[274] If an invention is obvious, it would have inevitably come about through routine advances; so the inducement of a patent is thought to be unnecessary.[275]

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267 John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 789 (2003); *cf.* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 812 (1988) (describing nonobviousness as the "final gatekeeper of the patent system").

268 The statute reads in relevant part:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a [PHOSITA] to which the claimed invention pertains.

35 U.S.C. § 103(a) (2012).

269 *See* John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 6–7 (2007) (exploring the wisdom of denying patents for trivial inventions).

270 This is the role of the novelty requirement. *See supra* notes 14–16 and accompanying text.

271 35 U.S.C. § 103(a).

272 Abramowicz & Duffy, *supra* note 72, at 1594; *cf.* Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 62 (2008) ("The nonobviousness requirement protects society against the social costs both of denying a deserving patent and of granting an undeserving monopoly.").

273 MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 295 (4th ed. 2015); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("[T]he stringent requirements for patent protection . . . assure that ideas in the public domain remain there for the free use of the public.").

274 ADELMAN ET AL., *supra* note 273, at 295.

275 ALAN DEVLIN, FUNDAMENTAL PRINCIPLES OF LAW AND ECONOMICS 261 (2014); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 886 (2004).

Nonobviousness is a standard. Like novelty, it requires a comparison of the invention that the applicant seeks to patent with the prior art.[276] In *Graham v. John Deere Co.*, the Supreme Court articulated the basic framework for determining nonobviousness.[277] It is a question of law based on the following pertinent underlying facts: (1) the scope and content of the relevant prior art; (2) the differences between the prior art and the claimed invention; (3) the PHOSITA's level of skill; and (4) secondary considerations that provide objective proof of nonobviousness, such as showing that the invention fulfilled a long-felt but unsolved need.[278] The flexible nature of the nonobviousness inquiry allows modulation of the standard to optimize incentives[279] and encourage investment and innovation in uncertain and perhaps costly research fields.[280]

While novelty ensures that an invention is new,[281] nonobviousness ensures that an invention is "new enough" to warrant a patent.[282] Even if an inventor has done something novel, that is not enough—nonobviousness requires that it be "significantly new, nontrivially new" to justify a patent.[283]

In some cases a lack of nonobviousness could defeat patentability in the reinvention paradigm.[284] For example, undertaking the factual findings set

276 *See supra* note 30 and accompanying text.

277 Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

278 *Id.* at 17–18. Subsequent caselaw has established that a conclusion of obviousness must be supported by clearly articulated reasoning. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007); *see also* MPEP, *supra* note 148, § 2141(III) (listing rationales that examiners can use to support a conclusion of a lack of nonobviousness).

279 DEVLIN, *supra* note 275, at 261; Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1634 (2003).

280 *See* Burk & Lemley, *supra* note 279, at 1581–82 (discussing modulation in the field of biotechnology).

281 *See supra* notes 14–16 and accompanying text.

282 CHISUM, *supra* note 88, § 3.01, at 3-9 (2013); *see also* Joseph Scott Miller, *Nonobviousness: Looking Back and Looking Ahead*, *in* 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE 1, 2 (Peter K. Yu ed., 2007) ("[N]onobviousness divides the patentably new from the unpatentably new.").

283 MERGES, *supra* note 194, at 143.

284 For nonobviousness, it is contemplated that the PHOSITA will combine and modify the teachings of multiple sources to arrive at the claimed invention. 35 U.S.C. § 103(a) (2012); *see also* Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1364 (Fed. Cir. 2008) ("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."). One question that arises is whether the examiner can assert the expired patent as prior art for nonobviousness. The answer is no—an examiner cannot rely on section 103 to circumvent the requirement for enabling prior art. *In re* Hoeksema, 399 F.2d 269, 274–75 (C.C.P.A. 1968). As Judge Rich once explained:

> [A] reference which merely describes a thing . . . without telling how to make it . . . [will] not support a holding of anticipation unless "[a PHOSITA] could take its teachings in combination with his own knowledge of the particular art and be in possession of [it]," or [will] not support a holding of obviousness unless "there is some known or obvious way" to make the thing . . . .

forth in *Graham*[285] could reveal that *X* is very similar in structure and efficacy to a fibrate compound that is already known. This could lead the examiner to conclude that it would have been obvious for a PHOSITA as of the effective filing date of the claimed invention to make *X*.[286] If the structural differences between *X* and the prior art compound are minor, a PHOSITA would expect them to have similar properties[287] and a reasonable expectation of success in independently arriving at the claimed invention.[288] Relatedly, a PHOSITA seeking to design a fibrate requiring a lower effective dosage would ordinarily contemplate tweaking known compounds "to try to obtain compounds with improved properties."[289]

Here it is worth reiterating the main point. Although the reinvention paradigm would allow a reinventor to overcome novelty hurdles in previously squandered subject matter, that would not guarantee that the reinvention is patentable. Other patentability hurdles like nonobviousness may still bar the reinventor's claim.

D. Policy Considerations

The reinvention paradigm fulfills the fundamental purpose of the substantive patentability requirements because it allows the reinventor to reclaim (squandered) subject matter that should never have been patented. While this clearly benefits the reinventor, it is important to explore the paradigm's potential impact on the public and the extent to which it aligns with broader goals of the patent system.

In re Collins, 462 F.2d 538, 542–43 (C.C.P.A. 1972) (emphasis omitted) (citation omitted) (first quoting *In re* LeGrice, 301 F.2d 929, 936 (C.C.P.A. 1962); and then quoting *Hoeksema*, 399 F.2d at 273); *see also* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 (Fed. Cir. 1985) ("The test of whether a particular compound described in the prior art may have been relied upon to show that the claimed subject matter at issue would have been obvious is whether the prior art provided an enabling disclosure with respect to the disclosed prior art compound.").

285 *See supra* notes 277–78 and accompanying text; *see also* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 399 (2007) (reaffirming the *Graham* framework for the nonobviousness inquiry).

286 The PHOSITA's level of skill (third *Graham* factor) can be found implicitly. MPEP, *supra* note 148, § 2141(II)(C).

287 For nonobviousness, "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship . . . to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Otsuka Pharm. Co., Ltd. v. Sandoz, Inc., 678 F.3d 1280, 1293 (Fed. Cir. 2012) (quoting Aventis Pharm. Deutschland v. Lupin, Ltd., 499 F.3d 1293, 1301 (Fed. Cir. 2007)).

288 *See In re* O'Farrell, 853 F.2d 894, 903–04 (Fed. Cir. 1988) ("Obviousness does not require absolute predictability . . . . [Just] a reasonable expectation of success.").

289 Procter & Gamble Co. v. Teva Pharm. USA, Inc., 566 F.3d 989, 995–96 (Fed. Cir. 2009) (quoting Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)); *see also KSR Int'l Co.*, 550 U.S. at 421 (explaining that an invention may be found obvious if it would have been obvious to a PHOSITA to try a course of conduct).

1. Patent Quality and the Public Interest

Although the Patent Office has come under much fire in recent times for issuing patents of questionable quality,[290] this criticism is not new.[291] Patent quality can be defined as "the capacity of a granted patent to meet (or exceed) the statutory standards of patentability,"[292] or, more simply, "the likelihood that a court, applying correct standards of patentability and having knowledge of all relevant information, would find the patent valid if it were contested."[293] Aside from being technically invalid,[294] low-quality patents impose costs on the legal system, competitors, would-be inventors, and society.[295]

One cost of low-quality patents is the proliferation of squandered claims—the key problem that the reinvention paradigm seeks to address.[296] The extent of squandering in any expired patent, and thus its overall quality, is closely tied to the quality of the underlying examination.[297] As discussed earlier, the principal cause of squandering is noncompliance with the enable-

290 *See, e.g.*, ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 74 (2004) (describing what can happen when the Patent Office "falls down on the job"); Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181–82 (2008) (exploring criticisms).

291 *See, e.g.*, SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS, S. COMM. ON THE JUDICIARY, TO PROMOTE THE PROGRESS OF USEFUL ARTS: REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, S. DOC. NO. 90-5, at 32–33 (1st Sess. 1966) (concluding that raising the quality of issued patents should be a major objective of the patent system); P.J. Federico, *Adjudicated Patents, 1948–54*, 38 J. PAT. OFF. SOC'Y 233, 247–49 (1956) (finding that at least sixty-seven percent of litigated patents are invalidated); Bert Russell, *The Improvement of Our Patent System*, 15 J. PAT. OFF. SOC'Y 666, 677 (1933) (quoting an unprinted report to the Secretary of Commerce on the needs of the Patent Office indicating that improved quality is "fundamental and necessary" because the work of the Patent Office "is not sufficiently accurate and authoritative").

292 R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009).

293 Thomas E. Popovich, Comment, *Patent Quality: An Analysis of Proposed Court, Legislative, and PTO—Administrative Reform—Reexamination Resurrected (Part I)*, 61 J. PAT. OFF. SOC'Y 248, 248 n.2 (1979).

294 *Cf.* FTC REPORT, *supra* note 93, ch.1, at 5 ("A poor quality or questionable patent is one that is likely invalid or contains claims that are likely overly broad.").

295 *See, e.g.*, Lemley, *supra* note 140, at 1515 (noting that bad patents impose costs on licensees, potential competitors, and society); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 113–39 (2006) (making similar arguments); John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 731 (2002) (explaining that legal actors often must revisit the Patent Office's work to assess patent validity).

296 *See supra* Part II.

297 FTC REPORT, *supra* note 93, ch. 1, at 19. Of course, squandering in most if not all expired patents could have been avoided if the Patent Office had "paid closer attention to what the [first] inventor actually disclosed in his specification as an indicator of what the inventor actually achieved, and . . . restricted the allowed scope accordingly." Merges & Nelson, *supra* note 24, at 909.

ment requirement.[298] Recall that an examiner who wants to mount an enablement challenge bears the burdens of both building a prima facie case of nonenablement and carrying the ultimate burden of persuasion on the issue.[299] The examiner must afford every patent application a presumption of enablement even if there is minimal teaching disclosed therein.[300] For complex inventions like chemical compounds, the absence of a detailed teaching, combined with the information asymmetry,[301] makes it hard for examiners to gauge enablement adequately.[302] And when combined with the examiner's time pressures and incentives,[303] it is easy to see how dubiously-enabled patents can slip through the cracks. This, of course, leads to the proliferation of squandered claims.

While the reinvention paradigm cannot prevent the issuance of low-quality patents, it would do much to alleviate the harm caused by squandered claims. For the reinventor, the proposed novelty framework removes the expired patent from the universe of prior art, thereby allowing someone who can actually comply with the statutory patentability requirements to (re)claim squandered subject matter. Indeed, the possibility of reinvention might accelerate innovation by encouraging firms to engage in socially-productive races to figure out how to make and use the claimed-but-nonenabled subject matter.[304] For the public, the benefit is twofold. First, given the high likelihood that the reinventor will develop the (re)claimed subject matter into a commercializable product, the public will get the benefit of the invention itself. The benefit conferred could be enormous—such as when the invention is a costly new drug that would not have been developed but for the prospect of a patent.[305] Second, the public gets an enabling disclosure that actually puts useful information into the public storehouse of technical knowledge.[306] This is something that the original patentee did *not* do.

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298 *See supra* Section I.B.

299 *See supra* subsection I.B.2.

300 *See supra* text accompanying notes 106–09.

301 I have argued elsewhere that since the inventor knows more information about the invention than the examiner, this creates an information asymmetry that "inevitably allows bad patents to slip through the cracks and further contributes to the patent quality problem." Sean B. Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. 963, 991–92 (2016); *cf.* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 805, 818 (2011) (exploring the incentives for applicants to behave strategically and withhold certain information from the examiner, particularly in the absence of an adversarial check).

302 *See supra* note 117 and accompanying text; *see also* Seymore, *supra* note 94, at 143–54 (arguing that evaluating enablement has a strong pro-patent bias).

303 *See* JAFFE & LERNER, *supra* note 290, at 151–52 (noting that since rejections tend to be more time consuming than allowances, examiners have an incentive to "go easy" on applications and grant patents); *supra* note 118.

304 *See supra* note 53 and accompanying text.

305 *See supra* note 57 and accompanying text.

306 *See supra* subsection I.A.2.

2. Tradeoffs

One potential criticism about the reinvention paradigm is that the public would actually pay for the invention *twice*. It granted a patent to the original patentee and would do so again to the reinventor—thereby requiring the public to bear the costs of two periods of exclusivity. The first question is whether the reinvention paradigm passes constitutional muster; and the second is whether it makes good patent policy.

The Supreme Court has stated that the patent system must, by constitutional command, promote technological progress.[307] Patents cannot issue that would remove extant knowledge from the public domain.[308] Indeed, the statutory requirements of novelty and nonobviousness work in tandem to ensure that the constitutional mandate is met by denying patents that would impinge upon the public's right to unfettered access to technology already available.[309] Put simply, old or obvious inventions cannot be patented.[310] But the underlying tenet of the reinvention paradigm is that the previously claimed-but-nonenabled subject matter never entered the public domain because it was inadequately disclosed in the expired patent.[311] Moreover, there has been no subsequent disclosure, commercialization, or interest in the subject matter between the time of the expired patent and the reinventor's patent application.[312] Thus, there should be no constitutional objection to reinvention because the public is gaining access to technology that it did *not* previously possess.

The preceding discussion reveals why the reinvention paradigm makes good patent policy. First, the current novelty framework does not work—it allows a seemingly trivial disclosure in an expired patent to defeat a subsequent claim to the subject matter. But the public never benefitted from the first period of exclusivity since the expired patent's (inadequate) disclosure did not enrich the public storehouse of knowledge.[313] In other words, the quid pro quo failed because the public was shortchanged. Reinvention by contrast, would give the public a technically robust disclosure of the invention, a high likelihood of a commercializable product, and full possession of

307 *See supra* notes 68, 79.

308 *See supra* notes 13, 82.

309 Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989); *see also* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) ("[N]o patent should be granted which withdraws from the public domain technology already available to the public." (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966)).

310 Commentators agree that novelty is a constitutional requirement. *See* WALTERSCHEID, *supra* note 74, at 310–11 (2002) (citing *Graham*, 383 U.S. at 6). Nonobviousness has constitutional underpinnings in that some standard of creativity might be needed to support patentability. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007) (explaining that inventions that are "the results of ordinary innovation are not the subject of exclusive rights under the patent laws" (citing U.S. CONST. art. I, § 8, cl. 8)).

311 *See supra* text accompanying notes 36–51.

312 *See supra* Section II.C.

313 *See supra* subsection I.A.2.

the invention at the end of the reinventor's patent term.[314] So the public would benefit from the second period of exclusivity. Reinvention also solves the squandering problem[315] and promotes the patent system's fundamental goals of disseminating technical knowledge and fostering innovation.[316]

Second, the possibility of reinvention could encourage *original inventors* to postpone filing until the invention is "further down the technology development path."[317] Instead of claiming broadly at the time of filing and subsequently discarding the unpromising or unprofitable subject matter,[318] applicants may adopt patenting strategies that involve filing smaller, discrete applications.[319] From a policy perspective much good can come from delayed filing, including better inventions,[320] more efficient patent examination,[321] improved patent quality,[322] reduced uncertainty,[323] and better disclosure.[324]

Third, reinvention might be the *only* way for the public to ever benefit from *X*. If *X* is a drug, pharmaceutical companies need an adequate incen-

314 *See supra* note 131 and accompanying text.

315 *See supra* Section II.A.

316 *See supra* Section I.A.

317 Cotropia, *supra* note 109, at 122. It is also worth noting that reinvention would only be available to third parties to the original patent. Thus, original patentees would be estopped from asserting that the original patent was nonenabling. This would prevent evergreening—an attempt by patentees to refresh their expiring patents with new ones by making minor modifications to subject matter that should go to the public domain. Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 420 (2008).

318 *See supra* note 140 and accompanying text.

319 Seymore, *supra* note 67, at 643 n.108.

320 Further development and refinement of the invention "produce a better invention—whether it be safer, cheaper, more efficient, more durable, or more effective." *Id.* at 654.

321 For example, if the invention is actually reduced to practice at the time of filing, it is much easier for the examiner to gauge compliance with the enablement requirement. *Id.* at 653. Relatedly, the applicant's ability to provide more technical information about the invention allows for a more robust examination and mitigates the examiner's information deficit. *See supra* note 301.

322 That delayed filing allows the applicant to generate more technical information about the invention and allows for a more robust examination, which translates into improved patent quality. *See supra* subsection III.D.1.

323 As Christopher Cotropia explains:

> Additional technical information . . . reduce[s] the uncertainty surrounding the invention before examination begins. The inventor gains a better handle on whether the invention provides the wanted results. Furthermore, the additional time that passes while [development] is occurring produces more information of its own. This all places the actual examination forward in time, giving the inventor more certainty as to the invention's ultimate commercial worth.

Cotropia, *supra* note 109, at 123 (citing Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1075–76 (2007)).

324 Seymore, *supra* note 67, at 654.

tive to invest in its development.[325] Without the possibility of a patent, pharmaceutical companies may simply ignore *X*, which would ultimately deprive the public of its potential benefit (which could be enormous).[326] This should be a cause for concern given the tremendous benefits that new drugs provide to society.[327]

CONCLUSION

While many scholars have written about the ills of patenting underdeveloped technology,[328] they have all overlooked the squandering problem. Since the current novelty rules render squandered subject matter unpatentable, most of it is probably ignored by private firms that could actually figure out how to make and use it. As a result, many socially valuable inventions never reach the public. This alone should be a great cause for concern.

It is impossible to gauge precisely how much squandered subject matter exists in the universe of millions of expired patents. Since the squandered subject matter was not enabled in the expired patent and has not been subsequently disclosed in any other medium, it stands to reason that the subject matter was never *invented* in the past. And to be clear, this is not a situation where the trivial disclosure in the expired patent made the invention somehow inchoate—*it never existed* until reinvention. So there is no theoretical reason why the subject matter cannot be patented again.

Reinvention has a strong normative justification because the reinventor can actually fulfill the substantive requirements for patentability for subject matter that otherwise would be lost, forgotten, or overlooked. Thus, the reinvention paradigm would be a major triumph for the patent system because it solves the squandering problem, creates an incentive for firms to engage in socially beneficial research and development, and gives the public both a high likelihood of a commercializable product and a technically robust disclosure of the invention. It is for these reasons that the second period of exclusivity can be justified.

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325 JAFFE & LERNER, *supra* note 290, at 40–41 (explaining how patents provide the incentive for costly drug development that would not otherwise occur); BERNICE SCHACTER, THE NEW MEDICINES: HOW DRUGS ARE CREATED, APPROVED, MARKETED, AND SOLD 51–53 (2006) (explaining the business decision to develop a new drug); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 720–21 (2005) ("Patent law traditionally takes the lion's share of credit for motivating investments in drug development.").

326 *See supra* note 58 and accompanying text.

327 Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 569–70 (2009).

328 *See, e.g.*, Abramowicz, *supra* note 323, at 1090 (discussing how early filing increases the likelihood of underdevelopment); Cotropia, *supra* note 109, at 107–19 (same).