RETHINKING NOVELTY IN PATENT LAW

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ABSTRACT

The novelty requirement seeks to ensure that a patent will not issue if the public already possesses the invention. Although gauging possession is usually straightforward for simple inventions, it can be difficult for those in complex fields like biotechnology, chemistry, and pharmaceuticals. For example, if a drug company seeks to patent a promising molecule that was disclosed but never physically made in the prior art, the key possession question is whether a person having ordinary skill in the art (PHOSITA) could have made it at the time of the prior disclosure. Put differently, could the PHOSITA rely on then-existing knowledge in the field to fill in any missing technical details from the prior disclosure? This Article argues that existing novelty jurisprudence mishandles the possession question in two ways. First, it tends to overestimate the PHOSITA's then-existing knowledge by failing to fully appreciate the complex nature of certain technologies. Second, the current examination framework vitiates the presumption of novelty by placing proof burdens on the would-be inventor that can thwart innovation and frustrate important objectives of the patent system. To resolve these problems and to fill a gap in patent scholarship, this Article proposes a new paradigm that reframes the novelty inquiry during patent examination. Its implementation will not only improve the quality of issued patents, but also make the patent literature a more robust source of technical information. This Article contributes to broader policy debates over patent reform and joins a larger effort to bridge the disconnect between patent law and the norms of science.

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INTRODUCTION

The U.S. patent system is a pendulum. It swings back and forth, attempting to balance the need to reward inventors for their work against the need to foster innovation through the dissemination of

technical knowledge.[1] When the pendulum swings too far in one direction, the courts,[2] Congress,[3] and even the U.S. Patent and Trademark Office (Patent Office)[4] seek to make adjustments through patent reform. Perhaps due to criticisms that the system has become too "pro-patent,"[5] reform efforts in recent years have led to the scaling back of patent rights.[6] Some of these reforms have tightened the standards for patentability.[7] Indeed, patentability has become a

1. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that the information disclosed in the patent adds to the public storehouse of knowledge); Brenner v. Manson, 383 U.S. 519, 533 (1966) ("It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions."); 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); Blanchard v. Sprague, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1518) ("Patents for inventions are . . . a just reward [for ingenuity], and . . . highly beneficial to the public, not only by holding out suitable encouragements to genius and talents and enterprise; but as ultimately securing to the whole community great advantages from the free communication of [knowledge], which may be most important to all the great interests of society . . . .").

2. *See infra* notes 8–9 and accompanying text.

3. *E.g.*, Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009) (as introduced by Rep. Conyers, Mar. 3, 2009), 155 CONG. REC. H2923 (daily ed. Mar. 3, 2009); Patent Reform Act of 2009, S. 515, 111th Cong. (2009) (as introduced by Sen. Leahy, Mar. 3, 2009), 155 CONG. REC. S2691, S2706–16 (daily ed. Mar. 3, 2009); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007) (as passed by House, Sept. 7, 2007), 153 CONG. REC. H10,307 (daily ed. Sept. 7, 2007); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007) (as introduced by Sen. Leahy, Apr. 18, 2007), 153 CONG. REC. S4675, S4685–92 (daily ed. Apr. 18, 2007).

4. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, 2010–2015 STRATEGIC PLAN 10–25 (2010), *available at* http://www.uspto.gov/about/stratplan/USPTO_2010-2015_Strategic_Plan.pdf (describing several initiatives that will improve examination timelines and patent quality); Press Release, U.S. Patent & Trademark Office, USPTO Will Begin Study of Patent Examiners' Production Goals (Oct. 4, 2007), *available at* http://www.uspto.gov/news/pr/2007/07-42.jsp (predicting that the study will lead to changes in the Patent Office that will "motivate employees, improve [the] work environment, and enhance the quality and efficiency of the patent examination process").

5. *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 98–107 (2004) (exploring trends in the Federal Circuit toward strengthening patentees' rights); William M. Landes & Richard A. Posner, *An Empirical Analysis of the Patent Court*, 71 U. CHI. L. REV. 111, 128 (2004) (concluding that the "pro-patent leanings" of the Federal Circuit have "had a significant effect on patent activity").

6. *See infra* notes 8–9 and accompanying text.

7. The conditions for patentability are found in Title 35 of the United States Code. In short, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–103 (2006). In addition, § 112, ¶ 1, requires that the application adequately describe, enable, and set forth the best mode of carrying out the invention; and § 112, ¶ 2, requires that the application conclude with claims that delineate the invention with particularity.

hot topic as reform-minded courts, in a series of landmark decisions, have relied on narrowing it to trim the scope of patent-eligible subject matter[8] and to make patents harder to obtain (and easier to invalidate) based on obviousness.[9]

These reform efforts have rekindled broader discussions about other patentability requirements. One that has received relatively little attention in recent commentary is novelty, which is the statutory requirement that an invention be new.[10] Determining novelty requires a comparison of the invention that the applicant seeks to patent with the "prior art," which refers to preexisting knowledge and technology already available to the public.[11] Documents like issued patents and printed publications are common sources of prior art.[12] A document asserted against the invention that the applicant seeks to patent is called a prior art reference.[13]

To qualify as *novelty-defeating* prior art, the reference must satisfy three conditions.[14] First, it must predate the applicant's invention or have existed more than one year before the applicant's filing date.[15] Second, every element of the claimed invention[16] must be identically disclosed or described within the four corners of the prior

8. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (holding that claims relating to a method of hedging risks are unpatentable).

9. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit's rigid test for nonobviousness due to its inconsistency with the "expansive and flexible" approach set forth in Supreme Court precedent).

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

11. 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)).

12. *See* 35 U.S.C. § 102 (defining the documents and activities that can serve as prior art).

13. HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 18 (3d ed. 2001).

14. Prior art is also used to determine whether an invention is obvious. *See* 35 U.S.C. § 103(a) (providing that an invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains"). For a discussion of obviousness and its relationship to novelty, see *infra* notes 104 and 170.

15. Prior art provisions fall into two main categories: (1) the novelty provisions of §§ 102(a), (e), and (g), which depend on the invention date; and (2) the loss-of-right provisions of § 102(b), which depend on the applicant's filing date. *See* 2 R. CARL MOY, MOY'S WALKER ON PATENTS § 8:1 (4th ed. 2009) (explaining § 102 of the Patent Act).

16. A patent claim must define "the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. A claim element further limits the breadth of the claim. 1 DONALD S. CHISUM, CHISUM ON PATENTS, at Gl-3 (2009). For an illustration, see *infra* note 19 and accompanying text.

art reference.[17] This is referred to as the "strict identity" requirement.[18] So, for example, if an applicant seeks to claim a paper clip made with titanium and nickel, the reference must also disclose a paper clip made with titanium and nickel.[19] Third, the reference must be enabling.[20] This means that the reference must disclose the subject matter in sufficient detail to enable a person having ordinary skill in the art (PHOSITA)[21] to make it without undue experimentation.[22] If a reference meets all three criteria, it "anticipates" the claim[23] and

17. *In re* Skvorecz, 580 F.3d 1262, 1266 (Fed. Cir. 2009); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the patent claim."); *see also* Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984) (explaining that another reference or knowledge in the art cannot supply missing elements).

18. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296 (Fed. Cir. 2002) (noting the "strict identity" test for novelty); *see also* Jamesbury Corp. v. Litton Indus. Prods., Inc., 756 F.2d 1556, 1560 (Fed. Cir. 1985) (explaining that "a prior art disclosure which is only 'substantially the same' as the claimed invention" is insufficient to defeat novelty).

19. In this hypothetical, titanium and nickel are claim elements. *See supra* note 16.

20. Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1306 (Fed. Cir. 2006) ("In order to anticipate, a prior art reference must not only disclose all of the limitations of the claimed invention, but also be enabled."); Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 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.").

21. 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 "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983).

22. Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008). For a discussion of what constitutes undue experimentation, see *infra* Part I.B.2.

23. *See* W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1554 (Fed. Cir. 1983) ("Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration."); *see also* Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). "In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning . . . , and identify corresponding elements disclosed in the allegedly anticipating reference." Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984) (citing Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983), *overruled by* SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107 (Fed. Cir. 1985) (en banc); SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 377 (Fed. Cir. 1983)).

renders it unpatentable (or invalid) for lack of novelty[24] because the subject matter is considered to be in the public's possession.[25]

Although the foregoing analysis tends to be simple for paper clips, it can be difficult for more-complex subject matter. For example, consider an inventor at a drug company who seeks to obtain a patent on a promising compound, *X*. At the time of filing, *X* is, as far as the inventor knows, previously unknown. Yet, during patent examination, the examiner uncovers a third-party patent[26] that discloses, but does not claim, *X* and makes a few speculative statements about how compounds like *X* might be made.[27] Is this modicum of disclosure sufficiently enabling to anticipate? If it offers no more than a starting point for further experimentation, the answer

24. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003); *see also* 1 CHISUM, *supra* note 16, at G1-14 (defining novelty as a basic patentability requirement that "precludes any claim that is anticipated by any single reference in the prior art"). Though § 102(b) is technically not a novelty provision, "[i]t is clearly established that *novelty* is lacking . . . when the [§ 102(b)] prior art product or process is identical to that of the inventor's product or process." 2 CHISUM, *supra* note 16, § 6.02[3].

25. Akzo N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1479 (Fed. Cir. 1986). As a general matter, patent applicants aggressively seek to limit the universe of prior art that can be asserted against them during examination. The easiest way to accomplish this is to show that a particular reference cannot serve as prior art because of its publication date. For example, an applicant facing a lack-of-novelty rejection based on a journal article published the day after the applicant's filing date can simply identify the date discrepancy and compel the Patent Office to remove the reference and withdraw the rejection. This is true even if the reference discloses an identical paper clip made with titanium and nickel. The analysis is simple and objective because § 102 determines when references become available as prior art. Nonetheless, applicants have an incentive to ensure that the examiner considers all potentially patent-defeating prior art. *See* Jurgens v. McKasy, 927 F.2d 1552, 1558 (Fed. Cir. 1991) (explaining that an accused infringer may invalidate a patent more easily if the examiner never considered the asserted prior art).

26. It is often forgotten that the patent document serves several key roles in the patent system. Most prominently, the claims establish the boundaries of the patentee's right to exclude, 35 U.S.C. § 112, ¶ 2 (2006), which expires twenty years from the earliest effective filing date, *id*. § 154(a)(2). But in addition, the disclosure (the written description and the drawings) of a patent or published patent application can serve as prior art. *Id.* § 102(a), (b), (e). A patent is effective as prior art as of its filing date and remains so forever (just like a book, a magazine, or any other printed publication). *See id.* § 102(e)(2) (providing that an invention is not patentable if it is described in "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent"); *In re* Giacomini, 612 F.3d 1380, 1385 (Fed. Cir. 2010) (explaining that § 102(e) "codified the history of treating the disclosure of a U.S. patent as prior art as of the filing date of the earliest U.S. application to which the patent is entitled" (emphasis and internal quotation marks omitted)).

27. For a discussion of why patentees might disclose subject matter but not claim it, see *infra* notes 124–29, 230–35 and accompanying text.

should be no.[28] Regardless, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) has held that, for the sake of expediency, the examiner is allowed to presume that the third-party patent is enabling.[29] In practical terms, this means that the subsequent inventor bears the affirmative burden of proving that the third-party patent is not enabling.[30]

This paradigm raises significant issues, some of which have received little attention in patent scholarship.[31] First, as a substantive matter, in certain fields a PHOSITA needs actual experimental details to make the invention without undue experimentation.[32] Second, placing the burden on the inventor to prove that a prior art reference is nonenabling vitiates the presumption of patentability that applicants should enjoy during examination.[33] Third, given these first two points, it is not uncommon for patentees "to pad the patent

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28. In the words of Judge Learned Hand,

> If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, if it does not inform the [PHOSITA how to make] the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation.

Dewey & Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 989 (2d Cir. 1942).

29. *See infra* Part II.A. Documentary sources that may serve as prior art include patents and scientific journal articles. *See supra* text accompanying note 11. Regarding the latter category, the Federal Circuit has not decided whether nonpatent references are entitled to a presumption of enablement. *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 n.22 (Fed. Cir. 2003) ("We note that by logical extension, our reasoning here *might* also apply to [nonpatent] prior art printed publications as well, but as Sugimoto is a patent we need not and do not so decide today." (emphasis added)).

30. *See infra* Part II.A.2.

31. Scholarship that addresses enablement in the prior art context is limited. *See, e.g.*, Donald S. Chisum, *Anticipation, Enablement and Obviousness: An Eternal Golden Braid*, 15 AIPLA Q.J. 57, 63 (1987) ("A reference that was not enabling upon its publication can become enabling and therefore an anticipation at a later time when additional prior art becomes available—showing, for example, a method of making the disclosed invention."); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 171–73 (2006) (arguing that the Federal Circuit's "motivation to combine" doctrine incorporates an enablement standard into the obviousness determination); Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1131–54 (2008) (arguing that courts should apply a heightened enablement standard when making inherent anticipation determinations); Alan W. White, *The Novelty-Destroying Disclosure: Some Recent Decisions*, 12 EUR. INTELL. PROP. REV. 315, 316–19 (1990) (exploring British cases that address enablement based on prior disclosures).

32. *See infra* Part I.B.2.

33. *See infra* notes 93–94 and accompanying text.

literature with chaff, presumably to muddy the waters in a defensive or nuisance maneuver" to thwart subsequent, deserving inventors.[34]

Finally, and perhaps most importantly, the current paradigm has a potential negative effect on innovation. Suppose *X* in the previous example is a drug molecule. In their recent comprehensive study of the U.S. patent system, Professors James Bessen and Michael Meurer show empirically that over two-thirds of the value of worldwide patents accrues to chemical and pharmaceutical firms, and that more than half accrues to a small number of large pharmaceutical firms.[35] They conclude that chemical and pharmaceutical patents are "substantially more valuable than other patents overall."[36] Why is this so? First, given that the claims often depict discrete molecular structures, the boundaries are clearly defined and thus easier to police.[37] Second, these patents tend to be broad in scope.[38] Third and

34. David S. Wainwright, *Patenting Around Nuisance Prior Art*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 221, 221–22 (1999). For a further discussion of the tactic of disclosing subject matter to deliberately thwart a subsequent inventor's claim, see *infra* notes 124–29.

35. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 109 (2008). The researchers define "value" as the private value of the relevant patent, which derives from the right to exclude. *Id.* at 97. This value "is measured relative to the alternative means an innovator has for profiting from her invention," including trade secrecy and profits on complementary goods. *Id.* at 98. Unlike most other industries, the pharmaceutical industry views patents as the most effective means of profiting from inventions. *See* OLIVER GASSMANN, GERRIT REEPMEYER & MAXIMILIAN VON ZEDTWITZ, LEADING PHARMACEUTICAL INNOVATION: TRENDS AND DRIVERS FOR GROWTH IN THE PHARMACEUTICAL INDUSTRY 133–34 (2d ed. 2008) ("[Patent] protection is crucial in the pharmaceutical industry as otherwise nobody would invest in expensive and long-term drug development."); *see also* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 tbl.1 (1986) (reporting that 65 percent of products from the pharmaceutical industry would not have been brought to market without patent protection, which contrasts with considerably lower numbers for products from other industries). Indeed, "it is well known that pharmaceutical companies generally refuse to develop new drugs unless they have strong patent protection over them." Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 513 (2009).

36. BESSEN & MEURER, *supra* note 35, at 107. The payoff is important because pharmaceutical companies need to recoup their research and development investments. *See* Roin, *supra* note 35, at 510 & n.21 (collecting sources which estimate that pharmaceutical companies spend an average of at least $800 million to bring a new drug to market).

37. *See* Jonathan M. Barnett, *Private Protection of Patentable Goods*, 25 CARDOZO L. REV. 1251, 1279 (2004) (observing that it is easier to detect and show infringement in discrete technologies); Richard C. Levin, Alin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 798 (arguing that patents are particularly effective in the chemical arts because relatively clear standards can be applied to assess validity and to defend against infringement); *see also* Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 18–20 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000),

relatedly, it is often difficult for competitors to "invent around" the compound of interest.[39] These qualities can converge to produce a so-called blockbuster drug patent.[40] A single compound (X) can thus generate billions of dollars in annual revenue.[41] And perhaps not

available at http://www.krannert.purdue.edu/faculty/smartin/courses/590/NBER7552.pdf (exploring cross-industry differences in patenting).

38. In preparing the claims, a savvy drafter often includes a broad claim encompassing a large number—frequently millions—of individual compounds, which serves as a "net" to ensnare everything using the basic concept of the patentee. *See* HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY CHEMICALS & PHARMACEUTICALS § 87, at 114 (2d ed. 1994) ("Claims of varying scope should be provided to take advantage of the multiple claim system. A broad 'claim 1' is fine as a net to try to capture everyone using the basic concept of the patentee." (citation omitted)). For an extreme example, see U.S. Patent No. 5,422,351 (filed June 21, 1991). This particular patent includes a structural formula in claim 1 that encompasses at least one novemdecillion (10^{60}, or one followed by sixty zeroes) chemical compounds. *Id.* cols. 133–34. Given that a pharmaceutical patent application is often filed at an early stage of research and development when end results or uses remain uncertain, the resulting patent is like an expensive lottery ticket with the hoped-for payoff being the substantial revenue generated by at least one claimed molecule. Jonathan A. Barney, *A Study of Patent Mortality Rates: Using Statistical Survival Analysis to Rate and Value Patent Assets*, 30 AIPLA Q.J. 317, 328 n.30 (2002) (using a lottery analogy); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1548 (2005) (same).

39. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1616–17 (2003) (explaining that pharmaceutical patents must be broad enough to prevent invent-arounds). In addition to the possibility of infringement, the unpredictable nature of chemistry hinders the development of successful invent-arounds because "even a minute change to a chemical molecule results in an entirely non-substitutable product." Barnett, *supra* note 37, at 1279.

40. The pharmaceutical industry defines a blockbuster drug as one that generates at least $1 billion in annual revenue. RONALD J. VOGEL, PHARMACEUTICAL ECONOMICS AND PUBLIC POLICY 25 (2007). This payoff is important because pharmaceutical companies need to recoup their research and development investments. *See* Roin, *supra* note 35, at 510 & n.21 (collecting sources that estimate that pharmaceutical companies spend an average of at least $800 million to bring a new drug to market).

41. Many pharmaceutical companies rely on a few blockbuster drugs to recoup their investment in innovation and to cover the costs of failed products. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 5 (2003); *see also* Roin, *supra* note 35, at 510 & n.21 ("Pharmaceutical companies on average spend upwards of $800 million on R&D for each new drug that reaches the market."). A pharmaceutical company may screen hundreds of thousands of chemical compounds as likely candidates for development, but for "every 10,000 compounds that are evaluated in animal studies, 10 will make it to human clinical trials in order to get 1 compound on the market." RICHARD B. SILVERMAN, THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION 8 (2d ed. 2004). In addition, bringing a new drug to market can take twelve to fifteen years and can cost over $800 million. *Id.*; *see also* Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420, 424 (2006) (estimating a total cost of $868 million per approved drug); Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (estimating the total research and development cost per drug as $802 million). To appreciate the amount of revenue that a

surprisingly, the blockbuster drug usually spawns significant research activity aiming to produce competitive or follow-on products.[42] The ability to derive these rewards from *X*, however, is jeopardized if the compound is deemed unpatentable because of a prior disclosure of its name or structure. Denying a patent to someone who can actually enable *X* can frustrate both the economic and innovation-related goals of the patent system.[43]

This Article attempts to address these issues and explore a new analytical framework for gauging novelty for complex inventions. For concreteness, the Article focuses on the common scenario described in the foregoing discussion: when a third party's patent is asserted as novelty-defeating prior art against a would-be inventor.[44] This Article

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blockbuster drug can generate, consider the cholesterol-lowering drug Lipitor—the best-selling drug of all time—which generated over $13.6 billion in revenue for Pfizer in 2006. *See* GASSMANN ET AL., *supra* note 35, at 7 tbl.2 (analyzing blockbuster drug data); *see also* Matthew Herper & Peter Kang, *The World's Ten Best-Selling Drugs*, FORBES.COM (Mar. 27, 2006, 6:00 AM ET), http://www.forbes.com/2006/03/21/pfizer-merck-amgen-cx_mh_pk_0321topdrugs.html (revealing that Lipitor's annual sales are more than twice as high as its closest competitor). The Lipitor patent expires in June 2011. *See* U.S. Patent No. RE40,667 (filed Jan. 16, 2007) (reissue patent); U.S. Patent No. 5,273,995 (filed Feb. 26, 1991) (original patent); *see also* Susan Decker, *Pfizer Wins New Lipitor Patent Expiring in June 2011 (Update2)*, BLOOMBERG (Jan. 6, 2009, 4:46 PM EST), http://www.bloomberg.com/apps/news?sid=aNSygEPe7QWw&pid=newsarchive (discussing the reissue of Pfizer's patent on Lipitor's key ingredient after the company modified "inconsistent language" that an appellate court had found rendered the patent invalid).

42. *See* STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 51 (2d ed. 2007) ("[Biotechnology firms that] are able to generate revenue . . . typically reinvest in their products (and in follow-on products in the pipeline) in hopes of discovering yet another new drug, perhaps a spin-off of the earlier one.").

43. *See infra* Part III.B.4.

44. *See supra* text accompanying notes 26–30. This is a common scenario because examiners in the Patent Office are familiar with patents and have easy access to them. Thus, most prior art rejections are likely to involve patent documents. *See* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 101–02 (2002) (presenting empirical findings on references to prior art); *see also* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2120 (2000) ("The predominance of U.S. patents [as cited prior art] may . . . reflect the limitations of the [Patent Office] systems for searching: the [Patent Office] is much more likely to find documents that it itself has generated."). This Article does not explore scenarios in which the inventor's own prior activities or disclosure can serve as novelty-defeating prior art, although such scenarios can be problematic, particularly in the academic and drug-discovery contexts. *See* Roin, *supra* note 35, at 527–31 (discussing the difficulty of satisfying the novelty requirement in university and drug-development contexts because of the possibility of premature disclosure); Sean B. Seymore, *The "Printed Publication" Bar After* Klopfenstein*: Has the Federal Circuit Changed the Way Professors Should Talk About Science?*, 40 AKRON L. REV. 493, 495 (2007) ("*Klopfenstein* is particularly important in the realm of academic science because it suggests that under certain circumstances a run-of-the-mill research talk can become a § 102(b) 'printed publication' and trigger the one-year clock.").

fills a gap in patent scholarship and contributes to broader policy debates over patent reform. It is part of a larger project to bridge the disconnect between patent law and the norms of science.[45]

The Article proceeds as follows. Part I presents the basic novelty question, which is whether the public already possesses the invention. It explores the technical difficulties that arise in answering this question for inventions in unpredictable fields like chemistry, biotechnology, and pharmaceuticals.[46] After briefly describing the current examination framework, Part II turns to what is perhaps the most important unresolved issue in the law of anticipation: whether and under what circumstances the appearance of a chemical name or structure in the prior art anticipates a subsequent inventor's claim for the compound. Although the Patent Office and the courts have wrestled with the "quintessential novelty problem" since the earliest days of the chemical era, this Part contends that current anticipation doctrines and vestiges of older ones often produce paradoxical

45. *See generally* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127 (2008) [hereinafter Seymore, *Heightened Enablement*] (proposing a new approach for examining patent applications in unpredictable technologies which, by requiring applicants to disclose actual experimental results, resolves a striking incongruity between patent law and the experimental sciences); Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185 (2009) [hereinafter Seymore, *Serendipity*] (arguing that although accidental discoveries pervade science, inventors who invent by accident can be unjustly deprived of patents because such discoveries do not mesh with the substantive law of invention); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010) [hereinafter Seymore, *Teaching Function*] (proposing a disclosure regime that would allow patents to compete with other forms of technical literature as a source of substantive technical information).

46. The courts refer to chemistry, biotechnology, and related experimental fields as "unpredictable" because skilled artisans 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) (explaining that in the chemical arts, "a slight variation . . . can yield an unpredictable result or may not work at all"). On the other hand, 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). But enablement depends on the facts in a given case because, for example, a mechanical device can have unpredictable features. *See In re* Bowen, 492 F.2d 859, 861–62 (C.C.P.A. 1974) (criticizing the dichotomy and advocating an alternative classification). For a deeper exploration of the predictable/unpredictable dichotomy, see Seymore, *Heightened Enablement*, *supra* note 45, at 136–39; and Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282–84 (2008). The U.S. Court of Customs and Patent Appeals (C.C.P.A.) was a predecessor to the Federal Circuit. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal Circuit adopted the C.C.P.A. decisional law as binding precedent. South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

outcomes seemingly incongruous with basic principles of patent law. To that end, Part III offers a new patent examination framework that reframes the novelty inquiry. By eliminating presumptions and shifting burdens of proof, the new paradigm will at last resolve the quintessential novelty problem, foster innovation, and promote other goals of patent policy. Finally, in response to some of the concerns that accompany the new paradigm, this Part explores how it will improve the quality of both issued patents and the patent literature.

I. NOVELTY AND POSSESSION

A. Does the Invention Already Belong to the Public?

A bedrock principle of patent law is that a patent cannot issue if it would remove technology that is already in the public domain.[47] The corollary is that inventions "must be *new*, that is, bestowed for the first time upon the public by the patentee."[48] As nineteenth-century legal historian George Ticknor Curtis wrote in his famous treatise on patent law, when the invention has already been described in the prior art,

> the public have acquired nothing from the [disclosure] of the patentee[] which they did not possess before, and . . . the patentee has invented nothing, which he, as one of the public, could not have derived from the means of knowledge which the public before possessed. Hence it is, that the production of a prior description, which was in the possession of the public, negatives the title of the patentee as the first inventor.[49]

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47. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147 (1989) (noting that Thomas Jefferson, the "driving force behind early federal patent policy," believed that "a grant of patent rights in an idea already disclosed to the public [i]s akin to an *ex post facto* law, 'obstruct[ing] others in the use of what they possessed before'" (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* 13 THE WRITINGS OF THOMAS JEFFERSON 326, 327 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1903))); Graham v. John Deere Co., 383 U.S. 1, 5–6 (1966) (explaining that it would be unconstitutional for Congress to authorize the issuance of patents that would remove existing knowledge from the public domain); Max Stul Oppenheimer, *In Vento Scribere: The Intersection of Cyberspace and Patent Law*, 51 FLA. L. REV. 229, 236–42 (1999) (exploring the constitutional basis and statutory background for prohibiting the granting of patents that would remove technology from the public domain).

48. 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 305 (Boston, Little, Brown & Co. 1890).

49. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES § 292 (Boston, Little, Brown & Co. 2d ed. 1854) (footnote omitted); *cf.* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent*

To allow otherwise would not only add nothing to the sum of human knowledge,[50] but "would in fact injure the public by removing existing knowledge from public use."[51] Thus, novelty serves to safeguard the public's right to enjoy what it already possesses.[52]

B. The Enablement Question

Anticipation requires, first, strict identity between the previously disclosed and the now-claimed subject matter;[53] and, second, an enabling disclosure.[54] Although checking for strict identity is often

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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.").

50. *See* United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933) ("An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge."); *see also* 1 ROBINSON, *supra* note 48, at 305 ("If the same [knowledge] has been already made accessible to [the public] by the inventive genius . . . no benefit results to them from his inventive act and there is no consideration for his patent.").

51. *Bonito Boats*, 489 U.S. at 148. Therefore, 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." Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 12–13 (1992).

52. As the late Judge Giles S. Rich once wrote about knowledge already present in the public domain, "Society, speaking through Congress and the courts, has said 'thou shalt not take it away.'" Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453–54 (Fed. Cir. 1984).

53. Anticipation occurs if the prior art discloses what the applicant seeks to claim. *See supra* notes 17–18 and accompanying text.

54. In other words, the prior art reference must disclose the subject matter in sufficient detail to enable a PHOSITA to make it without undue experimentation. *See supra* notes 20–25 and accompanying text. The requirement that an anticipatory reference contain an enabling disclosure can be traced back to *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516 (1870). In that case, an accused infringer attempted to use a foreign publication to invalidate the patent-at-issue. *Id.* at 554. Finding the publication's disclosure inadequate, the Supreme Court stated,

> Patented inventions cannot be superseded by the mere introduction of [the reference], though of prior date, unless the description . . . contain[s] . . . a substantial representation of the patented improvement, in such full, clear, and exact terms as to enable any person skilled in the art or science to which it appertains, to make, construct, and practice the invention to the same practical extent as they would be enabled to do if the information was derived from a prior patent. Mere vague and general representations will not support such a defence . . . .

Id. at 555; *cf.* Cohn v. U.S. Corset Co., 93 U.S. 366, 370 (1876) ("It must be admitted that, unless the earlier [reference] does exhibit the later patented invention in such a full and intelligible manner as to enable persons skilled in the art to which the invention is related to comprehend it without assistance from the patent, or to make it, or repeat the process claimed, it is insufficient to invalidate the patent."). In support of its holding, the *Seymour* Court cited the Curtis treatise, 78 U.S. (11 Wall.) at 555 n.*, which states that

> the description [in the allegedly anticipatory reference] must be such as to give the public the means of knowledge, or, in other words, must of itself *enable* the public to

quite easy, gauging enablement is not. This last point is particularly important because the question of whether the public already possesses the claimed subject matter often reduces to a question of enablement.[55]

1. *Defining the Standard.* Enablement questions typically arise in two contexts in patent law. Section 112, ¶ 1, of the Patent Act[56] compels a patent applicant to submit a written description[57] that enables a PHOSITA to make and use the full scope of the claimed invention without undue experimentation.[58] This "statutory" or patent-supporting form of enablement places an outer limit on the scope of the claims.[59] By contrast, the form pertaining to prior art references discussed earlier is referred to as "anticipatory" or patent-defeating enablement, because it is used to demonstrate that a PHOSITA could use preexisting knowledge to make the invention.[60]

> practise the invention. It is not necessary that the invention should have been reduced to practice, but, unless the description would *enable* the public, without further invention, to put the thing in practice, it cannot be said that a knowledge of that thing is in the possession of the public.

CURTIS, *supra* note 49, § 292 (emphases added).

55. *See* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987) ("Enablement looks to placing the subject matter of the claims generally in the possession of the public.").

56. 35 U.S.C. § 112 (2006).

57. The written description is the part of the patent (or patent application) in which the patentee discloses the invention. *See supra* note 26.

58. The statutory disclosure requirement has four parts, which appear in the first and second paragraphs of § 112:

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

35 U.S.C. § 112, ¶¶ 1–2 (emphases added). Although the term "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the [written description] 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).

59. The scope of the claims must "be less than or equal to the scope of the enablement." Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). The scope of enablement "is that which is disclosed in the [written description] plus the scope of what would be known to [a PHOSITA] without undue experimentation." *Id.*

60. *See* 2 CHISUM, *supra* note 16, § 3.04; F. SCOTT KIEFF, PAULINE NEWMAN, HERBERT F. SCHWARTZ & HENRY E. SMITH, PRINCIPLES OF PATENT LAW 413 (4th ed. 2008).

Although similar to its statutory cousin, anticipatory enablement is a narrower doctrine.[61] A prior art reference need not demonstrate utility in order to anticipate.[62] And an anticipatory reference need only enable what falls precisely within the scope of the claim-at-issue and nothing more.[63] By comparison, an enabling description for patent-supporting purposes must enable the full scope of the claimed subject matter.[64] These differing standards reveal a curious asymmetry: a description that is sufficient to anticipate a claim for patent-defeating purposes might be insufficient to enable a claim for patent-supporting purposes.[65]

2. *Technical Difficulties.* Although the patent statute does not distinguish between different fields of invention in setting and applying legal standards,[66] technology matters in patent law, particularly in the enablement context. Determining whether undue

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61. Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1337 (Fed. Cir. 2010) ("The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102 . . . differs from the enablement standard under section 112." (quoting Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325 (Fed. Cir. 2005))). "Enablement" does not appear anywhere within the text of § 102. Thus, the doctrine is the result of a "judicially imposed limitation" on § 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); *see also* Mueller & Chisum, *supra* note 31, at 1137–38 (comparing the two forms of enablement).

62. *In re* Gleave, 560 F.3d 1331, 1335 (Fed. Cir. 2009) (citing *Rasmusson*, 413 F.3d at 1326). In an earlier case, Judge Rich provided a statutory basis for the distinction, noting that § 112 provides that the written description "must enable [the PHOSITA] to 'use' the invention whereas § 102 makes no such requirement as to an anticipatory disclosure." *In re* Hafner, 410 F.2d 1403, 1405 (C.C.P.A. 1969). Thus, the "double standard" is "implicitly[,] if not explicitly, required by law." *Id*.

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

64. *See infra* note 219.

65. *See* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (recognizing the distinction); *In re* Lukach, 442 F.2d 967, 970 (C.C.P.A. 1971) (same).

66. The patent statute is essentially technology-neutral on its face, although several commentators argue that it is technology-specific in application. *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 59–65 (2009) (describing how the courts treat industries differently); Burk & Lemley, *supra* note 39, at 1654 (same); William A. Drennan, *The Patented Loophole: How Should Congress Respond to This Judicial Invention?*, 59 FLA. L. REV. 229, 323–28 (2007) (same). Congress added a technology-specific provision to the nonobviousness section of the statute in 1995. Act of Nov. 1, 1995, Pub. L. No. 104-41, § 1, 109 Stat. 351, 351 (codified as amended at 35 U.S.C. § 103 (2006)) (addressing biotechnology patent processes). Interestingly, technological distinctions are prohibited by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which states that patent rights shall be "enjoyable without discrimination as to . . . the field of technology." Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, 108 Stat. 4809, 869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

experimentation is required to make what is disclosed in the prior art, and thus whether the reference is enabling, is a fact-intensive inquiry.[67] The discussion in this Section explores the key, interrelated technical issues: (1) whether the alleged prior art reference includes working examples of the invention or merely describes it, (2) the PHOSITA's knowledge at the time of publication, and (3) the nature of the technology.

It stands to reason that the enablement analysis should be straightforward if the prior art reference discloses working examples. Yet it is more likely that the third-party patentee never physically made the subject matter in question (*X*).[68] The Federal Circuit has held that an anticipatory reference need not include actual experimental results.[69] This is because the teachings of the reference must be considered together with the knowledge in the art.[70] The court has often explained that a reference "need not . . . explain every

67. *See* Seymore, *Heightened Enablement*, *supra* note 45, at 147–50 (describing what constitutes undue experimentation). Relevant considerations include the nature of the invention, the breadth of the claims, the level of predictability of the art, the quantity of experimentation necessary, the presence or absence of working examples, the amount of direction presented, the prior art, and the relative skill of those in the art. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (explaining that the *Wands* factors are illustrative and not mandatory). For cases applying the *Wands* factors in the anticipatory-enablement context, see Impax Labs., Inc. v. Aventis Pharm. Inc., 545 F.3d 1312, 1314–15 (Fed. Cir. 2008); Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1306–07 (Fed. Cir. 2006).

68. For instance, consider again U.S. Patent No. 5,422,351 (filed June 21, 1991). *See supra* note 38. While the patent discloses at least one novemdecillion (10^{60}, or one followed by sixty zeroes) chemical compounds, the patentee only provided working examples for thirty-nine of them. '351 Patent cols. 7–133.

69. *See* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (finding secret tests conducted before the critical date to be irrelevant); *see also In re* Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985) (sustaining an anticipation rejection for a primary reference disclosing a compound and other references disclosing sufficient information to make that compound). This accords with the lack of express requirement in the Patent Act that an applicant physically reduce an invention to practice before obtaining a patent. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60–61 (1998) (interpreting the statute).

70. *See In re* Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994) ("[A] prior art reference must be 'considered together with the knowledge of one of ordinary skill in the pertinent art.'" (quoting *In re* Samour, 571 F.2d 559, 562 (C.C.P.A. 1978))); *see also In re* LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962) (explaining that the proper test is whether the PHOSITA "could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought").

detail" because the PHOSITA can rely on this knowledge in the art to fill in the gaps omitted from the disclosure.[71]

But gap filling raises several concerns. First, PHOSITAs can more easily fill gaps in certain fields than in others. A chemist usually cannot extrapolate from the result of one chemical reaction to predict how another chemical will react with any reasonable expectation of success because of the unpredictable nature of the art.[72] On the other hand, inventions in applied technologies like paper-clip making and rock crushing are often regarded as predictable because they are rooted in well-defined, calculable factors.[73] The PHOSITA has an easier time filling gaps in this latter category.[74]

Second, courts allow the decisionmaker to use additional references to elucidate the PHOSITA's knowledge at the time of the asserted prior art reference.[75] At first glance, this recourse to extrinsic evidence seems to violate the "four corners" rule of anticipation doctrine, which requires that each and every element of the claimed invention be found in a *single* prior art document.[76] The Federal

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71. *Paulsen*, 30 F.3d at 1480 (quoting DeGeorge v. Bernier, 768 F.2d 1318, 1323 (Fed. Cir. 1985)).

72. In the unpredictable arts, a PHOSITA typically must engage in trial and error to figure out what works and what does not. *See* BURK & LEMLEY, *supra* note 66, at 115 (explaining that if the art is uncertain, "the court will be inclined to require greater disclosure to satisfy the requirements of section 112, and correspondingly to narrow the scope of claims permissible from any given disclosure"); Karen S. Canady, *The* Wright *Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 458 (1994) (presenting a biotechnology example); cases cited *supra* note 46. "In view of the rapid advances in science," however, it may be that what is "unpredictable at one point in time may become predictable at a later time." Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 n.10 (Fed. Cir. 1999). This helps explain why enablement is a shifting, unstable doctrine. *See* Holbrook, *supra* note 31, at 176 ("[E]nablement doctrine . . . is far from pristine. It is more of a standard than a rule.").

73. *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving a "predictable" factor such as a mechanical or electrical element is less than that required for the unpredictable arts); BURK & LEMLEY, *supra* note 66, at 115 (explaining that less disclosure is required "[i]f the art is predictable and the PHOSITA quite skilled").

74. Nonetheless, elucidating the PHOSITA's knowledge is a fact-specific inquiry. *See supra* note 21. The unpredictable-predictable dichotomy thus is not always dispositive in resolving the gap-filling question. *See supra* note 46.

75. *See infra* note 96 and accompanying text.

76. *See* Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("[A]nticipation requires that the four corners of a single, prior art document describe every element of the claimed invention . . . ."); *supra* notes 17–18 and accompanying text. One commentator argues that the Federal Circuit's broadening of the "four corners" definition of anticipation has led to conflicts with other patent law doctrines. *See* Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 29–39 (2005).

Circuit has in fact emphasized that using the additional reference to expand the technical content of the asserted prior art reference violates the rule[77] and knocks the inquiry out of the novelty realm.[78] But courts have generally held that the rule is not violated when the purpose of the additional reference is to educate the decisionmaker in one of the following ways: (1) to clarify, interpret, or explain the asserted prior art's teachings;[79] or (2) to show that a PHOSITA could in fact make a chemical compound (*X*) even though the asserted prior art reference merely discloses the compound's name or structure.[80]

Although drawing a line between permissible and impermissible uses of additional references might be easy for simple technologies like paper clips, recourse to extrinsic evidence to show enablement for chemical compounds always poses a high risk of violating the four-corners standard for anticipation.[81]

II. THE NOVELTY PARADOX

A. Assessing Novelty

1. *The Current Examination Framework.* In determining whether chemical compound *X* is novel, the Patent Office undertakes a three-step analysis.[82] First, the examiner must construe the relevant claim in the patent application to determine its scope.[83] In the case of

77. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991) (explaining that the role of the additional reference is not "to fill gaps" in the asserted prior art document), *abrogated on other grounds by* Abbott Labs v. Sandoz, Inc., 566 F.3d 1282 (Fed. Cir. 2009); Studiengesellschaft Kohle, M.B.H. v. Dart Indus., Inc., 726 F.2d 724, 727 (Fed. Cir. 1984) (affirming the district court's findings on anticipation because the accused infringer sought to use the additional references not to interpret or shed light on the prior art reference, but to impermissibly supplement its teachings).

78. For a discussion of lack of nonobviousness as an alternative basis for unpatentability, see *infra* note 104.

79. *See Scripps*, 927 F.2d at 1576 ("It is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference."); *see also In re* Baxter Travenol Labs., 952 F.2d 388, 390 (Fed. Cir. 1991) ("[E]xtrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference.").

80. *See infra* Part II.B.

81. *See infra* Part II.

82. Courts undertake a similar analysis. *See* Mehl/Biophile Int'l Corp. v. Milgraum, 8 F. Supp. 2d 434, 443–44 (D.N.J. 1998) (articulating the three steps), *aff'd*, 192 F.3d 1362 (Fed. Cir. 1999).

83. *See* Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1294 (Fed. Cir. 2002) ("[T]he anticipation inquiry first demands a proper claim construction."). At the prosecution stage, the examiner must give claim terms the broadest reasonable interpretation a PHOSITA

X, this tends to be straightforward because the claim's elements can be easily deduced from the compound's structure.[84] Second, to check for strict identity, the examiner must compare the construed claim with the compound recited in the prior art reference to determine if each claim element is found in it.[85] Third, the examiner must determine whether the alleged prior art reference was sufficiently enabling to teach a PHOSITA how to make *X* without undue experimentation at that time. If so, *X* is already in possession of the public.[86]

If the subject matter disclosed in the reference is identical to that which is later claimed by the subsequent inventor,[87] the analysis essentially reduces to a question of enablement. Whether a prior art reference is enabling is a question of law based on underlying factual inquiries.[88] On appeal, the question of whether a reference is enabling is reviewed de novo, and the underlying factual inquiries are reviewed deferentially.[89] Whether a reference anticipates is a question of fact.[90]

The U.S. Court of Customs and Patent Appeals (C.C.P.A.)[91] articulated a burden-shifting framework to handle anticipatory-enablement issues that arise during patent examination.[92] As a

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would give them while simultaneously conferring an interpretation consistent with the applicant's written description. *In re* Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

84. *See In re* Marshall, 578 F.2d 301, 304 (C.C.P.A. 1978) (explaining that "every material element of the claimed subject matter, the chemical compound, could be found in the primary reference, a disclosure of that compound"). For a hypothetical example, consider the following: if the inventor seeks to patent $Ni(CO)_4$, and a third-party patent recites $Ni(CO)_4$ by structure or chemical name ("nickel tetracarbonyl"), then strict identity is met because the prior art teaches each and every element of the subject matter (a nickel atom surrounded by four carbonyl groups).

85. *See, e.g.*, Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention . . . .").

86. Akzo N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1479 (Fed. Cir. 1986) (citing *In re* Brown, 329 F.2d 1006, 1011 (C.C.P.A. 1964)); *see also supra* Part I.

87. *See supra* notes 26–27 and accompanying text.

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

89. 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.

90. *In re* Hyatt, 211 F.3d 1367, 1371 (Fed. Cir. 2000) (citing Bischoff v. Wethered, 76 U.S. (9 Wall.) 812, 814–15 (1869)).

91. The C.C.P.A. was a predecessor to the Federal Circuit. *See supra* note 46.

92. The framework took shape soon after the C.C.P.A.'s adoption of the possession standard for anticipatory enablement. *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*

starting point, at the time of filing, § 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.[93] This means that the examiner has the initial burden of coming forward with evidence of anticipation.[94] The examiner can make a prima facie case whenever a reference specifically describes *X* by name or structure.[95] If the allegedly anticipatory reference (the primary reference) does not describe how to prepare the compound, the examiner can rely on one or more secondary references to prove that the PHOSITA was capable of making *X* at the time of the primary reference.[96] In any event, the examiner can reject the applicant's claim to *X* for anticipation without conducting an inquiry into whether the third-party patent enables the subject matter.[97] Put simply, the third-party patent enjoys a presumption of enablement.[98] The applicant must rebut this presumption through persuasive argument or proof, by a preponderance of the evidence,[99] that the asserted third-party patent is nonenabling and therefore insufficient

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Wilder, 429 F.2d 447, 450–52 (C.C.P.A. 1970) (outlining the burden-shifting process for the anticipatory-enablement inquiry); *In re* Jacobs, 318 F.2d 743, 745 (C.C.P.A. 1963) (stating that the appellants can prevail only if they carry the burden of proof).

93. *Wilder*, 429 F.2d at 450 (quoting 35 U.S.C. § 102 (2006)) (internal quotation marks omitted); *see also* Ex parte Thorne, No. 95-4440, 1999 WL 33204520, at *3 (B.P.A.I. Mar. 9, 1999) (reversing the examiner's rejection under §§ 102 (a) and (b) because the Board was "constrained" to do so based on the presumption of novelty); Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1249 (1994) ("If the claimed invention is patentable, the applicant is *entitled* to a patent (because [§ 102 of] the statute says so)—not eventually, but as soon as patentability can be determined.").

94. *Wilder*, 429 F.2d at 450; *accord In re* Sun, 31 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1993) ("The examiner bears the burden of presenting at least a prima facie case of anticipation."); *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); *see also In re* Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (explaining that an examiner must affirmatively prove unpatentability); *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (describing the examiner's initial burden of putting forth a prima facie case of unpatentability).

95. *Wilder*, 429 F.2d at 451 (noting that a prima facie case is effectively established "whenever a reference is shown to contain a disclosure which is specific as to every critical element of the appealed claims").

96. *See In re* Samour, 571 F.2d 559, 562–63 (C.C.P.A. 1978) (explaining that although a single prior art reference must disclose each and every element of the claimed compound, the examiner may rely on additional references to show that a PHOSITA had sufficient knowledge to make it); *supra* text accompanying notes 75–80.

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

98. *Id.*

99. *Id.* (citing *In re* Sasse, 629 F.2d 675, 681 (C.C.P.A 1980)).

to have placed *X* in possession of the public.[100] Facts suggesting inoperativeness—such as actual experimental data or affidavits from experts in the field—are often "highly probative."[101] The examiner can then submit evidence to rebut the applicant's contention of nonenablement.[102] The burden of production may continue to shift as each side presents new evidence;[103] however, the examiner carries the ultimate burden of persuasion.[104]

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100. According to the Federal Circuit,

> In response to the [Patent Office]'s asserted *prima facie* case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the [Patent Office] did not correctly apply or understand the subject matter of the reference, or if the [Patent Office] drew unwarranted conclusions therefrom. However, when the [Patent Office] shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.

In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990).

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

102. *Sasse*, 629 F.2d at 681.

103. *Id.* at 681–82.

104. *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) (Plager, J., concurring) (articulating the rule that the Patent Office carries the burden of persuasion in showing why an applicant should not receive a patent). Absent any other grounds of unpatentability, the applicant is entitled to the patent. *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). This raises an interesting question: if the applicant wins on the novelty rejection, can the examiner rely on lack of nonobviousness (§ 103) as an alternative basis for unpatentability? Like novelty, nonobviousness is assessed by comparing the claimed subject matter to the prior art:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in § 102 . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a [PHOSITA] to which said subject matter pertains . . . .

35 U.S.C. § 103(a) (2006). So in contrast to novelty, which asks whether the invention is new, the nonobviousness inquiry seeks to ascertain whether the invention is "new enough" to be patented. 2 CHISUM, *supra* note 16, § 3.01. The facts in *In re Hoeksema*, 399 F.2d 269 (C.C.P.A. 1968), illustrate a typical scenario. Upon filing a patent application claiming *X*, the examiner rejected the claim under § 103 based on a reference that disclosed the structurally similar compound, *X′*. *Id.* at 270–72. Under well-settled law, structurally similar compounds are prima facie obvious. *In re* Hass, 141 F.2d 122, 125–26 (C.C.P.A. 1944) (early recognition); *In re* Dillon, 919 F.2d 688, 692–93 (Fed. Cir. 1990) (en banc) (collecting cases and reaffirming *Hass*). In rebuttal, the applicant (1) proved by affidavit that the cited reference did not teach a PHOSITA how to make *X* and (2) pointed out that the examiner did not cite any secondary references that did so. *Hoeksema*, 399 F.2d at 271–72. The Board nonetheless affirmed the examiner's rejection, contending that a method of making *X* was only one factor to be considered in the § 103 analysis. *Id.* at 273. The C.C.P.A. reversed the Board. In accordance with its post–*Von Bramer* jurisprudence, the C.C.P.A. held that "if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public." *Id.* at 274. *But see In re* Mahoney, 411 F.2d 1321, 1323–24, 1325 (C.C.P.A. 1969) (affirming a § 103 rejection because, in contrast to *Hoeksema*, the examiner proved that there were obvious,

The Federal Circuit adopted this burden-shifting framework and tweaked it for use in patent litigation.[105] In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,[106] the court held that the underlying presumption of enablement encompasses both claimed and unclaimed subject matter in the third-party patent.[107] As support for its holding, the court explained that the examiner should not bear the burden of analyzing enablement each time an allegedly anticipating third-party patent is challenged.[108]

2. *The Proof Paradox.* Although the allocation of burdens and presumptions may seem evenhanded and fair, a closer look may paint a very different picture. Consider the hypothetical below, which is based on a leading case.[109]

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available processes for making the compound at issue). In sum, an examiner cannot rely on § 103 to circumvent the requirement for enabling prior art. As Judge Rich later 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 . . . .

In re Collins, 462 F.2d 538, 542–43 (C.C.P.A. 1972) (citation and internal quotation marks omitted); *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."). But the prior art as a *whole* must be enabling, not just a single reference. Holbrook, *supra* note 31, at 171–73 (citing Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989) ("Even if a reference discloses an inoperative device, it is prior art for all that it teaches.")).

105. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), the Federal Circuit held that when an accused infringer asserts a prior art patent against the patentee (as part of an invalidity defense for a lack of novelty), the district court judge may presume that the subject matter in that patent is enabled. *Id.* at 1355. Simply put, the accused infringer need not prove enablement. But "[l]ike the applicant in ex parte prosecution, . . . the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art." *Id.* If the district court finds the patentee's evidence of nonenablement persuasive, the court "must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome." *Id.*; *see also* Impax Labs., Inc. v. Aventis Pharm. Inc., 545 F.3d 1312, 1316 (Fed. Cir. 2008) (affirming a district court's determination that a prior art patent was nonenabling and thus insufficient to anticipate the claims of the patent-in-suit).

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

107. *Id.* at 1355. The court also made clear that the presumption of enablement is rooted in policy and "does not rely on" the statutory presumption of validity afforded to an issued patent under 35 U.S.C. § 282. *Id.* at 1355 n.21.

108. *Id.*

109. *In re* Sasse, 629 F.2d 675 (C.C.P.A. 1980).

Suppose that an inventor synthesizes *X* in 2004 and determines that it exhibits anti-inflammatory activity. In light of this utility,[110] the inventor decides to file a patent application that year, claiming *X*. The examiner rejects the claim as anticipated under § 102(b) by a third-party patent that issued in 2000 (primary reference), in which *X* appears in a voluminous list of compounds.[111] Although *X* was never made, the primary reference states that it can be prepared by treating precursor *A* with *B* according to the following reaction:

$$A + B \rightarrow X$$

Although *B* is commercially available from a chemical supplier, precursor *A* is not, and the primary reference is silent about how to obtain it. To bolster a prima facie case of anticipation, the examiner cites another third-party patent that issued in 1999 (secondary reference #1) and that, although not disclosing a method for making *A*, teaches that *A* is a suitable precursor for producing compounds *other than X*. Yet the examiner reasons that if *A* appears in both the primary reference and secondary reference #1, there must be sufficient knowledge in the art for a PHOSITA to make it.

In response, the applicant submits a sworn declaration to rebut the examiner's prima facie case.[112] The declaration states that attempts to make *A* by conventional techniques known in the art have failed. Therefore, the applicant argues, if the primary reference's teachings combined with knowledge in the art are nonenabling with respect to precursor *A*, then they must also be nonenabling with respect to *X*. Thus, the applicant contends that the primary reference is insufficient for anticipation purposes.

Impliedly conceding that the applicant rebutted the prima facie case, the examiner asserts an additional reference: a pharmacology

110. Contrary to popular belief, one cannot obtain a patent on a compound simply because it is novel. It must also be useful. 35 U.S.C. § 101 (2006) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor."), *construed in* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (holding that a compound that lacks a known use and thus fails to provide a specific benefit to the public is unpatentable). Utility is determined as of the applicant's filing date. *In re* Brana, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

111. For a discussion of 35 U.S.C. § 102(b) as a basis for unpatentability, see *supra* notes 15, 24 and accompanying text.

112. *See* 37 C.F.R. § 1.132 (2009) (stating that when a claim is rejected, any evidence submitted by the applicant to overcome the rejection must be by way of oath or declaration).

textbook published in 1983 (secondary reference #2). Although the textbook does not specifically mention *A*, it explains that structurally similar compounds were successfully made during the previous decade by following a conventional technique with a catalytic amount of copper.[113] But the textbook also states that success requires careful calibration of the reaction conditions, which are quite sensitive to the nature of the starting materials. Nonetheless, the examiner contends that a PHOSITA has sufficient knowledge and skill to calibrate the reaction conditions to make *A*.

The applicant's contention of nonenablement having been rebutted, the burden of production shifts back to the applicant. When the applicant produces no evidence to challenge the textbook, the examiner makes the rejection final.[114] The Board of Patent Appeals and Interferences sustains the examiner's rejection.[115] In affirming the Board's decision, the appellate court finds that the applicant's evidence lacks a persuasive factual basis for dismissing the catalytic route described in the textbook, specifically noting that the applicant's declaration does not employ any copper catalyst in the attempted synthesis of precursor *A*.[116] In the end, the court holds that the primary reference, in view of secondary reference #2, contains an enabling disclosure that anticipates the applicant's claim to *X*.[117]

This hypothetical illustrates the evidentiary problems that an applicant may face when trying to overcome an allegedly anticipating reference. First, even if the applicant successfully rebuts the examiner's initial prima facie case, the examiner can continue to assert secondary references to prove that there is sufficient knowledge in the art to make *X*.[118]

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113. A catalyst is a substance (often a metal) that speeds up a reaction. Catalysts are not consumed during the reaction and are often recovered upon its completion. ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 90 (James Trefil ed., 2001).

114. *See* 37 C.F.R. § 1.113 (stating that on a second or subsequent examination the rejection may be made final). A rejection is not appealable until it has been made final. 35 U.S.C. § 134(a) (2006).

115. For a discussion of the Board and its procedures, see *infra* note 142.

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

117. *Id.* at 682.

118. *See* Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1379 (Fed. Cir. 2001) (explaining that the factfinder may look to "any" additional references that establish that the allegedly anticipatory reference was enabling to a PHOSITA during the relevant time period, including references that postdate the primary reference).

Second, attempting to elucidate what the PHOSITA knew at some point in the past introduces hindsight problems.[119] As Professor Gregory Mandel explains,

> [I]ndividuals are not cognitively able to prevent knowledge gained through hindsight from impacting their analysis of past events. Rather, individuals routinely overestimate the ex ante predictability of events after they have occurred. Critical for patent law, once individuals have hindsight information, they consistently exaggerate what could have been anticipated in foresight and not only tend to view what has occurred as having been inevitable, but also as having *appeared* relatively inevitable beforehand.[120]

In the enablement context, "[h]indsight bias . . . normally lead[s] factfinders to overestimate the level of skill in the art, since subsequent advances . . . suggest that the invention could not have been that difficult to do."[121]

Third, the hypothetical reveals that in order to overcome the rejection, the applicant probably needed experimental proof that the

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119. Though tempting, hindsight reasoning is impermissible in both novelty (35 U.S.C. § 102) and nonobviousness (35 U.S.C. § 103) analyses. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) (cautioning factfinders to be aware of hindsight bias and its reliance on ex post reasoning); Graham v. John Deere Co., 383 U.S. 1, 36 (1966) (discussing the need to "guard against slipping into use of hindsight" (quoting Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co., 332 F.2d 406, 412 (1964)); *In re* Ruschig, 343 F.2d 965, 974 (C.C.P.A. 1965) (warning against "hindsight anticipation[]," in which the applicant's disclosure is used as a guide to dissect and recombine references to describe specific compounds within the meaning of § 102); *In re* Sporck, 301 F.2d 686, 690–91 (C.C.P.A. 1962) (explaining the court's unwillingness to substitute speculation and hindsight appraisal of the prior art for factual evidence of nonobviousness). It is important to note that *Ruschig*-type "hindsight anticipation" is inapposite when a compound is specifically recited by name or structure. *See* Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 1000 (2006) (exploring anticipation issues that can arise when the asserted prior art reference discloses a voluminous list of compounds). Nonetheless, hindsight problems might arise when the examiner is allowed to pick and choose among documents to describe what the PHOSITA knew in the past.

120. Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration That the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1402 (2006) (citing Baruch Fischhoff, *For Those Condemned to Study the Past: Heuristics and Biases in Hindsight*, *in* JUDGMENT UNDER UNCERTAINTY 335, 341 (Daniel Kahneman et al. eds., 1982)).

121. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1199 (2002); *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 cognitive biases, such as a hindsight bias, increases." (footnote omitted)).

conventional technique did not work with an added copper catalyst.[122] An applicant may thus need to engage in actual experimentation to prove that an allegedly anticipatory reference is nonenabling. Herein lies a major paradox: A bedrock principle of patent law is that an inventor need not engage in any actual experimentation before obtaining a patent.[123] So it seems odd that an inventor, who is not required to physically reduce *X* to practice in order to prove § 112 enablement, may have to engage in experimentation to prove that a *reference* is nonenabling. Savvy third-party patentees accordingly have an incentive to purposely create novelty hurdles for subsequent inventors by strategically disclosing unclaimed, unmade compounds in their patents.[124]

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122. *See Sasse*, 629 F.2d at 681–82 ("It was incumbent upon appellants to rebut the presumed operability of the copper catalyst method described in [the organic textbook]. As did the [B]oard, we find the Sasse declaration devoid of any persuasive factual bases for dismissing the proposed catalytic synthesis. *Sasse does not employ any copper catalyst in the attempted preparation of the precursors*." (emphasis added)).

123. It is well settled in U.S. patent law that conception, and not any physical act, is the key facet of the inventive process. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60–61 (1999) ("[T]he word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea."); Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (explaining that "[c]onception is the touchstone of inventorship," which only requires "'the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention'" (quoting Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986))). Thus, an applicant who "constructively" reduces an invention to practice by merely filing a patent application presumably has complied with the disclosure requirements of § 112, including the obligation to enable a PHOSITA to make and use the invention without undue experimentation. *Hybritech Inc.*, 802 F.2d at 1376.

There may be occasions, however, when an actual reduction to practice is a de facto requirement. *See* Seymore, *Teaching Function*, *supra* note 45, at 646–52. For example, several cases suggest that an applicant must supply actual experimental data for inventions in unpredictable technologies in the early stages of development or when an applicant purports to invent something that is contrary to well-settled scientific principles. *Id.*

124. A document that specifically names thousands or millions of chemical compounds is referred to as a "shotgun" reference. *In re* Schoenewaldt, 343 F.2d 1000, 1002 (C.C.P.A. 1965). Yet a shotgun reference can potentially anticipate each recited compound if the disclosure is sufficiently enabling. *See infra* note 192.

There are at least five reasons why a patentee would disclose subject matter but not claim it. First, a third party may intentionally disclose unclaimed material to create novelty problems for subsequent inventors. Second, it could be an unintentional error. *See* Michael J. Meuer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1951–52 (2005) (explaining that an applicant's ability to claim everything the applicant has enabled depends on the talent and effort of the inventor and patent prosecutor in identifying what has been enabled). Third, because the written description places an outer limit on claim scope, Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999), one way to avoid § 112, ¶ 1, issues is

Fourth, given that the third-party patentee does not claim X, one might ask why is it reasonable to presume that the disclosed process for making it ($A + B \rightarrow X$) will work. The key point here is that the Patent Office does not conduct a § 112 enablement analysis on unclaimed subject matter disclosed in an application.[125] That subject matter is simply dedicated to the public.[126] Thus, disclosing unclaimed subject matter is an excellent "defensive disclosure" strategy to thwart subsequent patent applicants.[127] For example:

> [A third-party patentee] could . . . generate millions upon millions of plausible chemical structures and load them into multiple patent applications together with one compound that actually meets all of

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to draft a disclosure that is broader than the claims. Fourth, the applicant could strategically craft narrow claims to avoid scrutiny by the Patent Office during prosecution and then, after issuance, rely on the broad disclosure to enlarge the scope of the claims in litigation. *See* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994) (discussing this strategy). This tactic has been severely limited by the disclosure-dedication rule. *See* PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1361 (Fed. Cir. 2004) (explaining that the disclosure-dedication rule should "motivate patentees to draw the broadest claims that they consider to be patentable, and to submit the broad claims to the [Patent Office] for examination"); Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) (per curiam) (holding that disclosed but unclaimed subject matter is dedicated to the public). Fifth, an applicant may want to use continuation practice to gain advantages over competitors. *See infra* note 232.

125. *See* U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.08 (8th ed., rev. 8, 2010) [hereinafter MPEP] ("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.").

126. Miller v. Bridgeport Brass Co., 104 U.S. 350, 352 (1881) ("[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed."); *Johnson & Johnston*, 285 F.3d at 1054 ("[W]hen a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public."). This practice may trigger the disclosure-dedication rule, which bars a finding of patent infringement when an accused infringer practices disclosed but unclaimed subject matter. *See supra* note 124.

127. STEPHEN A. HANSEN & JUSTIN W. VANFLEET, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY 24 (2003), *available at* http://shr.aaas.org/tek/handbook/handbook.pdf. Defensive disclosure is "information or documentation intentionally made available to the public as prior art in order to render any subsequent claims of invention or discovery ineligible for a patent." *Id.* Several commentators have explored the strategy of defensive publication. *See, e.g.*, Douglas Lichtman, Scott Baker & Kate Kraus, *Strategic Disclosure in the Patent System*, 53 VAND. L. REV. 2175, 2175–76 (2000) (discussing a competitor's strategic incentive to create prior art); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 927 (2000) (same); sources cited *infra* notes 128–29.

> the patentability [requirements] in each patent application. The applicant could then 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 . . . .[128]

As one commentator explains, "This is a 'spoiler' tactic—you disclose your technology without pursuing patent protection for yourself just to be sure that no one else can have a patent for it either."[129]

B. The Quintessential Novelty Problem

1. *What Is It?* Several patent doctrines, including anticipatory enablement, emerged during the first century of the U.S. patent system, when inventions were still primarily mechanical devices.[130] The invention landscape changed around the time of World War II, when key breakthroughs in antibiotic, vitamin, and hormone research spawned the "therapeutic revolution"[131] and led to the discovery of many first-generation "wonder drugs."[132] During this period,

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128. CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION GUIDE TO PATENT LAW 170 n.4 (2010); *see also* Scott Baker & Claudio Mezzetti, *Disclosure as a Strategy in the Patent Race*, 48 J.L. & ECON. 173, 175 (2005) ("[These] disclosures are designed to preempt patents in instances where the disclosing firm does not itself plan to pursue patent protection but fears that its rivals might."); Bill Barrett, *Defensive Use of Publications in an Intellectual Property Strategy*, 20 NATURE BIOTECH. 191, 191–93 (2002) (providing strategies for drafting patent disclosures in unpredictable fields); *infra* note 161.

129. Anthony Murphy, *Intellectual Property*, *in* INNOVATION: HARNESSING CREATIVITY FOR BUSINESS GROWTH 92 (Adam Jolly ed., 2003).

130. *See* John Hoxie, *A Patent Attorney's View*, 47 J. PAT. & TRADEMARK OFF. SOC'Y 630, 636 (1965) (exploring the evolution of inventions from being mostly electrical-mechanical to chemical in nature); William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 263–64 (1990) (same); *supra* note 54. Quite curiously, the first patent granted in the United States was for an improved method for making potash (potassium carbonate), America's first industrial chemical. *See* U.S. Patent No. X1 (issued July 31, 1790).

131. NAT'L ACAD. OF ENG'G, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 7–11 (1983); Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 365–66 (1991) (describing the pharmaceutical industrial revolution).

132. *See, e.g.*, Process for Obtaining Vitamins, U.S. Patent No. 2,049,988 (issued Aug. 4, 1936) (Vitamin B_1; assigned to Research Corporation); Alloxazines and Isoalloxazines and Processes for Their Production, U.S. Patent No. 2,261,608 (issued Nov. 4, 1941) (Vitamin B_2; assigned to Merck); Process of Treating Pregnene Compounds, U.S. Patent No. 2,462,133 (issued Feb. 22, 1949) (synthesis of cortisone; assigned to Merck). Interestingly, the familiar wonder drugs sulfanilamide (the first sulfa drug) and penicillin were unpatentable (for a lack of novelty) by the time their therapeutic properties came to light because the substances were already in the public domain. *See* Ronald Bentley, *Different Roads to Discovery; Prontosil (Hence Sulfa Drugs) and Penicillin (Hence β-Lactams)*, 36 J. INDUS. MICROBIOLOGY & BIOTECH. 775, 775–86 (2009).

pharmaceutical companies quickly switched from a manufacturing to a research-based model and secured patents that allowed them to dominate sectors of specific therapeutic markets.[133] This, in turn, quickly forced the Patent Office and the courts to wrestle with fields key to drug research, like organic chemistry.[134] But the courts did so, at least initially, by rigidly applying mechanical-electrical patent doctrine to these unpredictable fields.[135] This shoehorning led to

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133. *See* NAT'L ACAD. OF ENG'G, *supra* note 131, at 7–11; Peter Drahos & John Braithwaite, *Intellectual Property, Corporate Strategy, Globalization: TRIPS in Context*, 20 WIS. INT'L L.J. 451, 463–64 (2002) (explaining that during this era drug companies found patent protection vital because they knew that "[p]enicillin, which had not been patented, had gone from costing $3,955 per pound in 1945 to $282 per pound in 1950"); Peter Temin, *Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry*, 10 BELL J. ECON. 429, 436 (1979) (describing the transformation of the pharmaceutical industry from a production to a research model).

134. *See* Noonan, *supra* note 130, at 263–69. The "antibiotic revolution" presents an interesting story. Given penicillin's success and the potential for antibiotics to generate unprecedented profits, pharmaceutical companies sought other antibiotics by screening potential antibiotic-producing microorganisms from nature. GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: PAST, PRESENT AND FUTURE 141–42 (2d ed. 2009). But "it was uncertain if the patent system and the courts could deliver [the blanket patent protection] they wanted" because the compounds were essentially "gifts of nature" and thus evinced very little inventive creativity. *Id.* at 142. Professor William Kingston describes how the pharmaceutical industry took quick action:

> The previous [Patent Act] dated from 1870, and did not suit the new methods of research needed for antibiotics . . . . On behalf of their pharmaceutical industry clients, New York Patent Bar Association members drafted a Bill and were able to get it introduced in Congress, and this, supplemented by other Bills and pressures, brought about the changes they wanted.

William Kingston, *Removing Some Harm from the World Trade Organization*, 32 OXFORD DEV. STUD. 309, 310 (2004). The basic change was the incorporation of language in the nonobviousness provision of the 1952 Patent Act, *see* Act of July 19, 1952, Pub. L. No. 82-593, § 1, 66 Stat. 792, 792, 798 (codified as amended at 35 U.S.C.) ("Patentability shall not be negatived by the manner in which the invention was made."), tailored to keep the innovation threshold rather low. DUTFIELD, *supra*, at 142.

135. *See* Hoxie, *supra* note 130, at 636 (explaining how the judiciary tried to fit chemical inventions into the mold of mechanical-electrical inventions and contending that the judiciary's interpretation of the patent statute did not change even as chemical inventions became more frequent). The courts quickly developed a bias against patent applications involving biological systems and pharmaceutical compounds. *See* Noonan, *supra* note 130, at 263–69. As an example, consider streptomycin, another first-generation wonder drug that is (like penicillin) a mold-produced antibiotic. Historically, purified natural products were not always patentable. *See* Am. Wood-Paper Co. v. Fiber Disintegrating Co., 90 U.S. (23 Wall.) 566, 593–94 (1874) (holding that purified cellulose was unpatentable although the process for obtaining it might be). Yet, in 1948, the Patent Office granted Merck a patent for streptomycin because the chemical modifications allowing it to be purified created a new composition of matter. *See* Complex Salts of Streptomycin and Process for Preparing Same, U.S. Patent No. 2,446,102 cols. 2.4–.8 (issued July 27, 1948) ("[F]or the first time streptomycin is available in a form which not only has valuable therapeutic properties but also can be produced, distributed, and administered in a practicable

nonsensical outcomes and a disconnect between the judicial bench and the laboratory bench.[136] And although a body of "unpredictable art" jurisprudence slowly developed to bridge the disconnect, several issues remain unsettled.[137]

Perhaps the most important unresolved issue is whether and under what circumstances the appearance of a chemical name or structure in the prior art anticipates a subsequent inventor's claim for the compound. Consider the hypothetical posed earlier: An inventor who files a patent application claiming compound *X* is faced with a third party's prior patent that recites the structure of *X* (or includes it within a very small genus of compounds)[138] but says little else about

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way."); *cf.* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (upholding a patent for a purified adrenaline salt because removing it from gland tissue produced a new composition of matter), *aff'd in part and rev'd in part on other grounds*, 196 F. 496 (2d Cir. 1912). The streptomycin patent was an important legal development because "it clarified to the industry that the new antibiotics were patentable despite being 'products of nature.'" GRAHAM DUTFIELD & UMA SUTHERSANEN, GLOBAL INTELLECTUAL PROPERTY LAW 300 (2008).

136. The law of patents as applied to the experimental sciences has been described as "a child (or orphan) of mechanical patent law." Paul H. Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 51 J. PAT. & TRADEMARK OFF. SOC'Y 768, 783 (1969).

137. *See, e.g.*, Jackie Hutter, Note, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 719–21 (1995) (arguing that the Federal Circuit should adopt a standard of invention tailored to meet the needs of unpredictable activities like drug discovery).

138. It is well settled that the disclosure of a small genus may be sufficient to anticipate a species, even if the species is not specifically recited. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1380 (Fed. Cir. 2001). The test is if a PHOSITA can "at once envisage" each member of the limited class of compounds. *In re* Petering, 301 F.2d 676, 681 (C.C.P.A. 1962). For example, suppose *X* is a salt with the formula $Na_4Fe(CN)_5F$. The examiner finds a third-party patent that discloses "a salt with the formula $Na_4Fe(CN)_5$(halide)." Given that a PHOSITA (or anyone who has taken a general chemistry course) knows that there are only five halides (F, Cl, Br, I, At), the disclosure almost certainly meets the *Petering* test. In other words, the third-party patent "has described to [the PHOSITA] each of the various premutations [*sic*] . . . involved as fully as if [the patentee] had drawn each structural formula or had written each [by] name." *Id.* at 682. Thus, if the disclosure is enabling, the third-party patent might be sufficient to anticipate a subsequent claim to *X*, even though *X* is not specifically recited. But just because the genus is small (as in the case of the halides) does not mean that enablement of one member of the group is always sufficient to enable the others. For an example explaining that, because the other halides require different reaction protocols, the general method used to prepare aryl chlorides and aryl bromides from diazonium salts and copper does not work for them, see MICHAEL B. SMITH & JERRY MARCH, MARCH'S ADVANCED ORGANIC CHEMISTRY 984 (6th ed. 2007).

The case of *In re Soll*, 97 F.2d 623 (C.C.P.A. 1938), also illustrates this point. The applicant attempted to claim the product and process of reacting a butadiene moiety with a hydrogen halide. *Id.* at 623. The written description disclosed the reaction of natural rubber (which contains a butadiene moiety) with hydrogen fluoride. *Id.* at 624. After noting that the application dealt with an obscure and complex reaction, the examiner rejected several broad

it.[139] Because the structure recited in the prior art and the one claimed in the patent application are identical, the key question in the novelty analysis is not one of strict identity but one of enablement: whether the teachings of the prior patent, together with the PHOSITA's knowledge at that time, were sufficient to place *X* in possession of the public.[140] Although the Patent Office and the courts began grappling with this issue during the earliest days of the chemical era,[141] it is one that inventors aggressively fight today.[142] And so it is, at least within the realm of the unpredictable arts, the quintessential novelty problem.

2. *Exacerbation.* The judiciary's early response to the quintessential novelty problem revealed its unfamiliarity and discomfort with complex technologies. And somewhat clumsy reasoning in an early decision only exacerbated the problem. In the 1942 case *In re Von Bramer*,[143] the Patent Office rejected a claim to *X* because it appeared in a voluminous list of compounds recited in a third-party patent. On appeal, Von Bramer argued that an anticipatory reference must disclose "a sufficient number of [*X*'s] physical and chemical attributes" or, alternatively, a process that

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claims for nonenablement because "no implied or direct statements can be found in the application, as originally filed, that the other hydrogen halides will react similarly to give the same product." *Id.* The applicant contended that the disclosure of one member of a well-known small group was sufficient to enable claims covering the entire group. *Id.* The court affirmed the Board's rejection, explaining that "[c]ertain members of a well-defined group of chemicals may be equivalents for one purpose and not equivalents for another. *Experimentation is required* to ascertain the particular action of a member of the group upon the particular material to be treated." *Id.* at 625 (emphasis added). Applying *Soll* to the hypothetical presented above, even if the third-party patent were to disclose a method for making, for example, $Na_4Fe(CN)_5I$, it would not necessarily enable a method for making $Na_4Fe(CN)_5F$.

139. *See supra* notes 26–27 and accompanying text.

140. *See supra* Part I.

141. *See infra* Part II.B.2.

142. *See, e.g.*, *In re* '639 Patent Litig., 154 F. Supp. 2d 157, 172–87 (D. Mass. 2001) (determining that the claims of a patent that recited a compound were invalid due to anticipation by a prior art reference), *aff'd*, SmithKline Beecham Corp. v. Copley Pharm., Inc., 45 F. App'x 915 (Fed. Cir. 2002); Ex parte Nicolaou, No. 2007-1076, 2007 WL 3408644, at *4 (B.P.A.I. Nov. 13, 2007) (reversing an examiner's rejection of claims to compounds because the prior art's disclosure was nonenabling). In its appellate role, the Board of Patent Appeals and Interferences reviews adverse decisions of examiners. 35 U.S.C. § 6(b) (2006). An applicant whose claims have been twice rejected by the examiner may appeal to the Board. *Id.* § 134(a). The Board can affirm a rejection or reverse and remand to the examining corps. 37 C.F.R. § 1.197 (2009) (promulgating Patent Office regulations pertaining to the Board). An applicant dissatisfied with a Board decision can appeal to the Federal Circuit. 35 U.S.C. § 141 (2006).

143. *In re* Von Bramer, 127 F.2d 149 (C.C.P.A. 1942).

unquestionably produces it.[144] The C.C.P.A. disagreed and held that a reference depicting the name or structure of *X* was sufficient to anticipate a subsequent claim to it even if the reference did not disclose an operative process for making the compound.[145] Although it cited a nineteenth-century Supreme Court patent case to support its holding,[146] the *Von Bramer* court notably failed to mention enablement or to explicitly discuss what was known in the art at the time of the third-party patent.[147] And regardless of what the court meant to say,[148] the holding and dicta quickly morphed into the "*Von Bramer* doctrine," which held that "the mere name [of a compound,] without more[,] anticipates."[149]

Even if the C.C.P.A. felt that *Von Bramer* had been misread, subsequent opinions addressing the quintessential novelty problem did not immediately bear this out. To the contrary, the court cited the doctrine as doctrine and even expanded its breadth.[150] For instance, in

144. *Id.* at 152. Thirty-six years later, Judge Baldwin made a similar argument: "A compound is described by a reference, in my view, if the reference recites the structure and recites or reliably and accurately predicts at least one significant property of the compound. . . . I would treat the actual existence of the compound as legally equivalent to such a significant property." *In re* Samour, 571 F.2d 559, 564 (C.C.P.A. 1978) (Baldwin, J., concurring).

145. *Von Bramer*, 127 F.2d at 151.

146. *See* Cohn v. U.S. Corset Co., 93 U.S. 366, 377 (1876) ("It is quite immaterial, even if it be a fact, that the [third-party patent's disclosure] is insufficient to teach a manufacturer how to make the patented corset. It is enough if it sufficiently describes the corset itself."). For further discussion of this case, see *supra* note 54. In contrast to corset making, organic chemistry is an unpredictable art. *See supra* note 46. Nonetheless, it appears that the *Von Bramer* court may have taken dictum in *Cohn* out of context. *See Von Bramer*, 127 F.2d at 152 (citing *Cohn* for the proposition that "[i]t is not necessary that a reference patent for a device or chemical compound disclose an operative process for producing the article or product").

147. Twenty years later, the C.C.P.A. explained that a consideration of knowledge in the art was "implicit" in the *Von Bramer* opinion. *See In re* LeGrice, 301 F.2d 929, 942 (C.C.P.A. 1962) (stating that there is an assumption that a PHOSITA will use his knowledge in combination with the printed materials).

148. The opinion included an excerpt from the examiner's correspondence, which stated that the compound-at-issue "ha[s] generally predictable properties such as found for any similar N-alkyl amino phenol, and is generally capable of synthesis by the recognized classical organic reactions." *Von Bramer*, 127 F.2d at 152. Two decades later, Judge Jackson (the author of the *Von Bramer* opinion) stated that this so-called predictability was a relevant consideration. Phillips Petrol. Co. v. Ladd, 219 F. Supp. 366, 369 (D.D.C. 1963); *accord In re* Brown, 329 F.2d 1006, 1010 (C.C.P.A. 1964) (suggesting that predictability should be considered in evaluation of claims). But trying to classify organic synthesis as predictable, even for compounds within the same class, can be problematic. *See supra* note 46.

149. Donald G. Daus, *Chemical Names as Anticipation and Support*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 377, 381 (1988).

150. *See In re* Stoll, 161 F.2d 241, 243 (C.C.P.A. 1947) ("A compound previously described by name in a printed publication such as an issued patent is a disclosure which is sufficient to

a 1956 case in which an applicant submitted proof that the third party's method for making *X* did not work, the C.C.P.A. held that "[i]t is well settled . . . that a reference which clearly names a compound or identifies it by structural formula constitutes a full anticipation of a claim to that compound, even though the reference contains only an inoperative method for producing the compound, or no method at all."[151]

Although commentators immediately argued that *Von Bramer* had been read out of context,[152] the Patent Office took the absolute position that the mere recitation of *X* by name or structure in a reference, even if done by accident or typographical error, served as a complete anticipation.[153] And if the reference lacked an operative method for making *X*, whether a PHOSITA could rely on knowledge in the art to make it was seemingly immaterial.[154]

Twenty years elapsed before the C.C.P.A. attempted to put the *Von Bramer* doctrine to rest.[155] The decision to abandon the doctrine

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support the rejection of a claim for that compound."); *In re* Crosley, 159 F.2d 735, 736 (C.C.P.A. 1947) ("Furthermore, this court is committed to the doctrine that where a product is clearly disclosed in a publication, the operativeness of any of the processes by which it is claimed the product could be produced is immaterial, and that the disclosure of the composition is sufficient to anticipate a claim therefor."); *see also* Daus, *supra* note 149, at 381–83 (tracing the development of the doctrine); Maurice W. Levy, Von Bramer*: A Plea for Reorientation*, 33 J. PAT. OFF. SOC'Y 401, 401–27 (1951) (same).

151. *In re* Baranauckas, 228 F.2d 413, 415 (C.C.P.A. 1956).

152. *See* Daus, *supra* note 149, at 382–83 (arguing that *Von Bramer* was "carried to extremes"); Levy, *supra* note 150, at 401 (arguing that the *Von Bramer* doctrine evolved from reading dicta out of context).

153. *See* WEGNER, *supra* note 38, § 129, at 173–74 (explaining that misprints naming a particular structure were sufficient to anticipate); Levy, *supra* note 150, at 401–03 (collecting cases and suggesting that examiners felt constrained to make this type of rejection even if it was substantively unsound).

154. Levy, *supra* note 150, at 402. For example, see Ex Parte Nagy, 106 U.S.P.Q. 424, 425 (P.T.O. Bd. App. 1955) (holding that a compound recited in the prior art was sufficient to anticipate even though the prior art method of preparation failed).

155. *In re* Brown, 329 F.2d 1006, 1010 (C.C.P.A. 1964) ("To the extent that anyone may draw an inference from the Von Bramer case that the *mere* printed conception . . . of a 'compound' is sufficient to show that [it] is old [for § 102 or § 103 purposes], we totally disagree."); *In re* LeGrice, 301 F.2d 929, 942 (C.C.P.A. 1962) (stating that the court disagrees with any case, including *Von Bramer*, that conflicts with *Cohn*). Why did the C.C.P.A. change its mind? It may have done so due to several substantial enhancements to the court's technical competence. First, the addition of Judges Giles Rich and Arthur Smith (author of *LeGrice*) in the 1950s brought technical astuteness and patent expertise to the court. *See* GILES S. RICH, A BRIEF HISTORY OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS 131–33, 143–44 (1980) (discussing the appointments of Judges Rich and Smith to the C.C.P.A. and describing each of these judges' professional backgrounds). Second, in 1955, Judge Eugene Worley (later Chief Judge) argued that each judge on the C.C.P.A. should have a technical

was due in no small part to the wisdom of Judge Giles S. Rich, co-drafter of the 1952 Patent Act. He wrote in *In re Papesch*[156] that a formula does not describe a compound:

> From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, the chemical nomenclature, [and] the systems of classification . . . are mere symbols by which compounds can be identified, classified, and compared. *But a formula is not a compound*[,] and while it may serve in a claim to *identify* what is being patented, as the metes and bounds of a deed identify a plot of land, the *thing* that is patented is not the formula but the compound identified by it.[157]

Guided by this reasoning, the C.C.P.A. held in *In re Wiggins*[158] that merely naming a compound in a reference, without more, is inadequate to describe it because the mere recitation "constitute[s] nothing more than speculation about [its] potential or theoretical existence."[159] Judge Almond explained what would happen if the court were to hold otherwise:

> [L]ists of thousands of theoretically possible compounds could be generated and published which, assuming it would be within the level of skill in the art to make them, would bar a patent to the actual discoverer of a named compound no matter how beneficial to mankind it might be. In view of the fact that the purpose sought to be effectuated by the patent law is the encouragement of innovation, such a result would be repugnant to the statute.[160]

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advisor to assist in patent cases. *Id.* at 118–19. He envisioned a group of advisors "thoroughly skilled in the advanced fields of electronics, chemistry, and related sciences" to assist with the "increasing volume and technicalities" of the court's patent docket. *Id.* at 119. Although Judge Worley initially faced resistance from his colleagues, the court hired its first technical advisor, the (former) Solicitor of the Patent Office, that same year. *Id.* at 118–19. Eventually the C.C.P.A. judges began a tradition of hiring technically trained law clerks, giving the court "a considerable pool of technological assistance" that was kept fresh because newer clerks had "the latest training in their respective fields." *Id.* at 121.

156. *In re* Papesch, 315 F.2d 381 (C.C.P.A. 1963).

157. *Id.* at 391 (first emphasis added); *cf.* Regents of the Univ. of N.M. v. Knight, 321 F.3d 1111, 1122 (Fed. Cir. 2003) ("Indeed, a chemical structure is simply a means of describing a compound; it is not the invention itself.").

158. *In re* Wiggins, 488 F.2d 538 (C.C.P.A. 1973).

159. *Id.* at 543; *cf.* Picard v. United Aircraft Corp., 128 F.2d 632, 635 (2d Cir. 1942) ("[A]nother's experiment, imperfect and never perfected, will not serve either as an anticipation or as part of the prior art, for it has not served to enrich it.").

160. *Wiggins*, 488 F.2d at 543.

But despite efforts to put *Von Bramer* to rest, the case had already left its mark on patent law. It opened the door for third parties to pad the patent literature with voluminous lists of unmade compounds to hinder bona fide claims to those compounds down the road.[161] And *Von Bramer* planted a seed in patent jurisprudence that blossomed into the notion that a PHOSITA can figure out how to make a compound just from knowing something about its structure.[162]

3. *Unresolved Issues.* The courts now use the enablement-possession test to handle the quintessential novelty problem.[163] Although this test is substantively better than the harsh *Von Bramer* doctrine, there are still unresolved issues. Dividing the post–*Von Bramer* cases into two categories helps to unpack the lingering issues and to shed light on the problems they cause for subsequent inventors.

The first category addresses situations in which the allegedly anticipatory reference discloses an unsuccessful attempt to make *X*. In *In re Sheppard*[164] and *In re Wiggins*, the C.C.P.A. held that such a reference is insufficient to anticipate, particularly if there is no evidence of record that a PHOSITA could make *X* at the time of the reference.[165] More recently, the Federal Circuit relied on *Sheppard* and *Wiggins* to craft a per se rule that a reference describing an experimental failure is nonenabling.[166]

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161. Interestingly, the court hinted at this problem during the *Von Bramer* era:

> At the same time, however, though our decision is compelled by the existing law, we feel constrained to point out that there are limits to the [*Von Bramer*] doctrine . . . . What the precise boundary lines are, we are unable now to discern. Certainly they do not extend so far as to permit publication of theoretical lists of hundreds or thousands of possible compounds to deny patent protection on such compounds to those who actually discovered them later. The exact boundaries will have to be delineated on a case by case basis.

In re Baranauckas, 228 F.2d 413, 416 (C.C.P.A. 1956). For a discussion of defensive publication, see *supra* notes 127–29 and accompanying text.

162. *See supra* Part II.A.

163. *See supra* Part I.B.

164. *In re* Sheppard, 339 F.2d 238 (C.C.P.A. 1964).

165. *Wiggins*, 488 F.2d at 542–44 (explaining that although the reference described *X* by name, its failed synthesis, plus the lack of evidence that a PHOSITA could make it at that time, made the reference nonenabling); *Sheppard*, 339 F.2d at 241 (explaining that *X*'s decomposition during synthesis created uncertainty about the reference's teaching and thus made the disclosure nonenabling). Neither opinion cites *United States v. Adams*, 383 U.S. 39 (1996), in which the U.S. Supreme Court stated that "[a]n inoperable invention or one which fails to achieve its intended result does not negative novelty." *Id.* at 50 (citing Smith v. Snow, 294 U.S. 1, 17 (1935)).

166. *See infra* note 177.

The second category includes those situations in which *X* appears in an allegedly anticipatory reference (the primary reference) with no intrinsic synthetic details. In other words, the primary reference either does not disclose an attempt to make *X* or states that *X* can be made from general methods known in the art. Interestingly, *In re Samour*[167] and subsequent cases make clear that the examiner may rely on one or more secondary references to prove that the PHOSITA was capable of making *X* at the time of the primary reference.[168] Although this may raise concerns about the single-reference rule required for anticipation,[169] reliance on secondary references does not transform the inquiry into one concerning nonobviousness,[170] the lack of which can be established by combining the teachings of multiple prior art references.[171] In sum, a primary reference that merely recites *X*'s structure satisfies strict identity, whereas the secondary reference, by showing that there is sufficient knowledge in the art to make *X*, shows possession.[172] So, in a sense, "[a] reference that was not enabling upon its publication *can become*

167. *In re* Samour, 571 F.2d 559 (C.C.P.A. 1978).

168. *See* Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991) (discussing the "modest flexibility" in the single-reference rule that allows a secondary reference to accommodate situations in which the PHOSITA's knowledge cannot be gleaned from the primary reference); *In re* Donahue, 766 F.2d 531, 534 (Fed. Cir. 1985) (applying *Samour* to affirm a Patent Office multiple-reference rejection for a lack of novelty); Studiengesellschaft Kohle, M.B.H. v. Dart Indus., Inc., 726 F.2d 724, 726–27 (Fed. Cir. 1984) (recognizing the "caveat" to the single-reference rule); *Samour*, 571 F.2d at 562–63 (explaining that while a single prior art reference must disclose each and every element of the claimed compound, the examiner may rely on additional references to show that a PHOSITA had sufficient knowledge to make it). The secondary reference can even postdate the primary reference. *See Samour*, 571 F.2d at 563 (explaining that the relevant inquiry is whether the compound was already in possession of the public more than one year prior to the applicant's filing date under § 102(b) and not whether evidence showing such possession came before or after the date of the primary reference).

169. *See supra* note 76 and accompanying text.

170. Lack of novelty (35 U.S.C. § 102) and lack of nonobviousness (35 U.S.C. § 103) are substantively distinct grounds for denying patentability. Most would agree that nonobviousness only comes into play after the novelty inquiry is complete. *See In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979) (explaining that an applicant must "hav[e] separate keys to open *in succession* the three doors of sections 101, 102, and 103") (emphasis added)), *aff'd in relevant part sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

171. For novelty, all of the claim elements are found within the primary reference. *Samour*, 571 F.2d at 563. By contrast, obviousness is often shown when the claim elements are found across multiple references. *See* Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1363–64 (Fed. Cir. 2008) (explaining the distinction). Nonetheless, the prior art used for a nonobviousness rejection must also be enabling. *See* discussion *supra* note 104.

172. *In re* Marshall, 578 F.2d 301, 304 (C.C.P.A. 1978) (discussing *Samour* and how its holding still comports with the single-reference rule).

enabling and therefore an anticipation at a later time when additional [references] become[] available."[173]

A good illustration of this second scenario is *In re Donahue*.[174] There, the allegedly anticipatory reference was a 1970 journal article that recited the structure of *X* but did not explain how to make it. The examiner rejected Donahue's claim to *X*, contending that secondary sources, including a third-party patent that issued in 1975, showed that a PHOSITA could have relied on knowledge in the art to make *X* in 1970.[175] In affirming the rejection, the Federal Circuit explained that the use of secondary references to show the level of skill in the art is not inconsistent with the general rule that each element of a claim must be found in a single prior art document.[176]

Having explained the two types of cases, it is now possible to explore several problems with the current regime. First, given that the disclosure of an unsuccessful attempt to synthesize *X* makes a reference insufficient to anticipate,[177] third parties have a strong incentive to conceal experimental failures so as to maximize the document's novelty-defeating potential. This is because a reference's silence with respect to an attempt to make *X* "does not indicate one way or the other" whether it is enabling.[178]

The problem here is that disclosing experimental failure is good for both scientific progress and the innovation-related goals of the patent system.[179] At minimum, the disclosure saves time and money

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173. Chisum, *supra* note 31, at 63 (emphasis added).

174. *In re* Donahue, 766 F.2d 531 (Fed. Cir. 1985).

175. *Id.* at 532.

176. *Id.* at 534.

177. In attempting to distinguish *Donahue* from the *Sheppard-Wiggins* scenario, the Federal Circuit stated,

> In those cases, the references were deemed insufficient, because they stated that attempts to prepare the claimed compounds were unsuccessful. Such failures by those skilled in the art (having possession of the information disclosed by the publication) are strong evidence that the disclosure of the publication was nonenabling.

Id. at 533; *see also* Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1558 (Fed. Cir. 1985) (noting that a failed experiment reported in a third-party patent makes it irrelevant as a prior art reference).

178. *See Donahue*, 766 F.2d at 533 ("By contrast, the fact that the author of a publication did not attempt to make his disclosed invention does not indicate one way or the other whether the publication would have been enabling.").

179. *See, e.g.*, GERARD H. GAYNOR, INNOVATION BY DESIGN 140 (2002) (observing that experimental failure is part of the innovative process and that lessons can be learned from it); ALVIN TOFFLER, POWERSHIFT 213 (1990) ("Innovation . . . requires experimental failure to achieve success.").

by preventing the repetition of dead-end experiments.[180] There is indeed hope that reading the details of the failed experiment will induce innovative thinking to solve that specific problem or others.[181] In sum, disclosing experimental failures is something that the patent system should encourage.

Second, it is not immediately clear why experimental failure should be dispositive on the enablement issue because the cases make clear that the PHOSITA's knowledge is also important. Consider *In re Jacobs*,[182] in which the applicant argued that a third-party patent should be insufficient to anticipate because the disclosed process for making *X* did not work.[183] Affirming the rejection, the C.C.P.A. explained that "[i]n order for appellants to prevail, and in view of the [third-party patent's] disclosure, we think that appellants have the burden of proving that [the disclosed] process was not operative to produce [*X*] *and could not be made operative by use of ordinary skill of the art*."[184] Thus, the PHOSITA may have sufficient knowledge to

180. FREDERICK GRINNELL, EVERYDAY PRACTICE OF SCIENCE 9 (2009). As one commentator notes,

> Physical scientists often publish their failed experiments. Though not as satisfying as successful ones, certain failures give information that is truly useful. If nothing else, a well-documented failure says, "You don't have to bother with this technique. It doesn't work, at least not . . . the way I tried it." . . . [Thus p]hysical scientists, in publishing their failures, help their brethren . . . .

BRUCE JACKSON, FIELDWORK 14 (1987).

181. *See* ALAN AXELROD, EDISON ON INNOVATION 40–42 (2008) (describing Thomas Edison's view that failed experiments always provide useful information and thus are not really failures at all); DOROTHY LEONARD-BARTON, WELLSPRINGS OF KNOWLEDGE 119–20 (1998) (exploring the role of failed experiments in knowledge building); STEFAN H. THOMKE, EXPERIMENTATION MATTERS: UNLOCKING THE POTENTIAL OF NEW TECHNOLOGIES FOR INNOVATION 23 (2003) ("Innovators learn from failure . . . . [K]nowledge of either failure or success itself can be stockpiled, providing a resource that, if not applicable to one set of experiments, can be used for subsequent inquiries."). Failed experiments can lead to accidental discoveries, thereby converting failure into success. *See* LEONARD-BARTON, *supra*, at 120 (recounting the story of penicillin); Seymore, *Serendipity*, *supra* note 45, at 192–211 (exploring the role of accidental discoveries in patent law).

182. *In re* Jacobs, 318 F.2d 743 (C.C.P.A. 1963).

183. *See id.* at 745 ("[A]ppellants' argument in effect is that the disclosure in the Miller patent is inoperable to produce [*X*] and hence in error."). The applicant's argument that the disclosed method did not work raises an interesting technical question. As one commentator explains, "It is all too easy for a skilled person to say that he tried, but failed, to prepare a prior art compound, but is that because his task was impossible or because he performed the task incompetently, or at least not so competently as other skilled workers might do?" White, *supra* note 31, at 318.

184. *Jacobs*, 318 F.2d at 745 (emphasis added).

make *X* even if the process disclosed in the third-party patent fails.[185] So it is somewhat curious that the Federal Circuit has drawn such a sharp distinction between the *Sheppard-Wiggins* and *Samour-Donahue* scenarios.

Third, contrary to the strong language used in *Wiggins*, it appears that a third-party patent's mere recitation of *X* by name or structure *is*, as a practical matter, sufficient to anticipate a subsequent inventor's claim to the compound. Why is this so? To begin, the mere appearance of *X* in the third-party patent meets novelty's strict-identity requirement in that it discloses each and every element of the subject matter to be claimed (*X*).[186] Even if the primary reference provides no experimental details, all the examiner has to do is assemble secondary references that suggest that the PHOSITA was capable of making *X* at the time of the primary reference. This, in fact, is the *Samour-Donahue* scenario.[187] The problem here is that even if there is no dispute that the subsequent inventor was the first to actually make *X*, the compound lacks novelty and is therefore unpatentable as a new composition of matter because it probably could have been made in the prior art.[188] This disturbing result suggests that the *Von Bramer* doctrine, in fact, never died.

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185. The Patent Office has tried, albeit unsuccessfully, to make this argument. *See In re* Coker, 463 F.2d 1344, 1346–48 (C.C.P.A. 1972) (rejecting the Board's argument that a PHOSITA in the field of organic chemistry is well aware of numerous methods for making compounds like *X* even though the third-party patentee was unsuccessful in doing so).

186. For a hypothetical example, see *supra* note 84.

187. *See supra* notes 167–76 and accompanying text.

188. The subsequent inventor can possibly obtain a "new use" patent for *X* even if it is known in the prior art. *See* 35 U.S.C. § 100(b) (2006) (defining a patentable "process" to "include[] a new use of a known . . . composition of matter, or material"); Merck & Co., Inc. v. Teva Pharm. USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003) (explaining that a new use for a known compound can be patented with a "method" claim). There are, however, two principal reasons why a "compound" or "composition of matter claim" covering *X* itself tends to be more valuable than those directed to a specific "method of making" or "method of using" *X*. First, compound claims afford the broadest protection. As Professor Harold Wegner explains,

> Compound claims have always been the premium form of patent protection in the chemical industry . . . . A claim to the compound, per se, dominates every method of making that compound and every single use of that compound, every single mixture of different components that includes that compound, and every end use composition inclusive of the compound.

WEGNER, *supra* note 38, § 260, at 301; *see also In re* Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963) (discussing the "well-recognized advantages" of composition-of-matter claims); MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 82–85 (2d ed. 2008) (describing the "hierarchy" of patent claims and noting that composition patents are the best for pharmaceuticals).

III. REFRAMING THE NOVELTY INQUIRY

The quintessential novelty problem endures because vestiges of the *Von Bramer* doctrine remain. Though a document that merely recites *X* by name or structure cannot by itself defeat patentability,[189] that modicum of disclosure is still sufficient to satisfy the first prong of the anticipation inquiry.[190] And because the examiner can easily satisfy the second prong by using *any* additional references to show that a PHOSITA could rely on knowledge in the art to make *X*,[191] establishing a prima facie case of anticipation is relatively easy. In

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Second and relatedly, method patents are difficult to enforce because the patentee "acquires only the right to preclude others from using the chemical in the exact manner he has disclosed." Eggert, *supra* note 136, at 781. Thus, the new-use patent might be too narrow to cover other uses for *X* that come to the fore during its lifespan. *See* Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 720 (2005) ("The discovery of a new use for an old drug might support a patent on a method of treatment, but such a patent offers little effective protection against generic competition once the drug itself is off-patent and may lawfully be sold for an older, unpatented use."); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 351 (2007) [hereinafter Eisenberg, *The Role of the FDA*] ("Patents on particular methods of treatment involving the use of a drug are generally considered less valuable[] because they cannot be used to stop competitors from selling the same product for other uses."); Roin, *supra* note 35, at 548 n.243 (describing ways to avoid infringing a new-use patent).

Third, a patentee seeking a new-use claim may face a formidable nonobviousness hurdle. *See* Allegheny Drop Forge Co. v. Portec, Inc., 541 F.2d 383, 386 (3d Cir. 1976) ("A new use for an old process or product is patentable if the new use or application is itself not 'obvious' to [a PHOSITA]."); Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1100 (2007) (explaining that in the drug context, a new-use patent "may be difficult to obtain because the 'new' use may have been obvious, even if it was not obvious that the new use would be effective").

But despite these drawbacks, a method patent can provide fairly strong protection in certain situations. *See, e.g.*, Lorie Ann Morgan & Jeffrey Tidwell, *Patents: United States Perspective*, *in* 4 ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY 2616, 2617 (James Swarbick ed., 3d ed. 2007) (arguing that method-of-use claims can afford important protection for pharmaceuticals because FDA approval is linked to specific therapeutic uses); Kevin Outterson, *Death from the Public Domain?*, 87 TEX. L. REV. SEE ALSO 45, 50 (2009), http://www.texaslrev.com/sites/default/files/seealso/vol87/pdf/87TexasLRevSeeAlso45.pdf (observing that if *X* is already patented or in the public domain, pharmaceutical companies will seek claims for new uses or formulations). Perhaps not surprisingly, savvy patentees who pursue composition-of-matter claims to *X* often also include at least one method-of-use claim so that if an opponent (in litigation) uncovers prior art sufficient to invalidate the former, the patentee will retain a strong patent position. WEGNER, *supra* note 38, § 261, at 302.

Yet regardless of the potential availability of a method-of-use patent, a subsequent inventor should not have to settle for one if the asserted prior art has not truly enabled *X*; the subsequent inventor should still be able to claim the compound itself.

189. *See supra* notes 155–60 and accompanying text.

190. *See supra* notes 84, 186 and accompanying text.

191. *See supra* notes 167–76 and accompanying text.

sum, *X*'s mere appearance in a document often places it on the fast track to anticipation. Considering the presumptions and proof problems described above, a subsequent inventor's attempt to patent *X* can be difficult if not impossible. To solve this problem, this Part offers a new analytical framework for gauging *X*'s novelty.

A. A New Paradigm

1. *Mechanics.* Determining which references should be available to the examiner lies at the core of the quintessential novelty problem. The first question is whether a third-party patent merely reciting *X* should even serve as anticipatory prior art. The second question is whether there should be a limit on the potential universe of secondary references that can be used to prove that the PHOSITA could make *X* at the time of the primary reference.

First, a third-party patent would not enjoy a presumption of enablement under the new paradigm. Determining whether the document can serve as prior art for anticipation purposes would depend on the amount of relevant, substantive technical information it discloses. For instance, if *X* appears among a voluminous list of compounds with no technical information about *X*'s synthesis, then the document would be insufficient to serve as anticipatory prior art because the mere recitation of chemical name or structure adds nothing to the storehouse of knowledge.[192] Thus, in contrast to the current regime, the third-party patent's mere recitation of a name or structure would not, without more, raise a presumption that the reference is enabled. Logically, if a third-party patent disclosing an unsuccessful attempt to make *X* is insufficient to anticipate, it is hard to understand why one merely reciting a structure warrants different (or better) treatment.[193]

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192. Technically speaking, it is possible for a shotgun reference (one reciting a voluminous list of compounds) to sufficiently enable each recited compound. *See In re* Sivaramakrishnan, 673 F.2d 1383, 1384–85 (C.C.P.A. 1982) (holding that in contrast to *Wiggins* and the applicant's contention that the disclosure was speculative, a PHOSITA could follow the reference's teachings and rely on knowledge in the art to make the specific compound at issue, even though the teaching was generic); Ex Parte A, 17 U.S.P.Q.2d 1716, 1718–19 (B.P.A.I. 1990) (explaining that if a reference specifically teaches a listed compound, the reference anticipates regardless of the size of the list).

193. *See* CURTIS, *supra* note 49, § 292 (explaining that speculations about an experiment lacking in practical direction "are entirely analogous in their character to abortive and unsuccessful experiments in practice").

On the other hand, if the document discloses a theoretical method for making *X*, in the first instance the disclosure would be presumed nonenabling because unpredictability in the art would raise an inference that undue experimentation would be required to make the compound.[194] The presumption could be rebutted, but unlike under the current framework, the examiner would have the initial burden of proving enablement by a preponderance of the evidence.

Rebuttal would require the examiner to show that the prior art provided *some* specific technique that enabled a PHOSITA to make *X*.[195] Here, the examiner could point to information disclosed in the third-party patent itself and, as discussed below, a limited universe of secondary references. If the examiner rebuts the presumption, the burden would shift to the applicant to rebut the examiner's contention of enablement, just as in the current framework. And although the burden of production could shift back and forth, in the new paradigm the ultimate burden of persuasion would still rest with the examiner.[196] Thus, if the examiner could not carry the burden, the allegedly anticipating reference would be insufficient to anticipate.[197]

Second, the new analytical framework would limit the universe of secondary references that could be used to prove that a PHOSITA could make *X* at the time of the primary reference. Importantly, only documents with publication dates earlier than or contemporaneous with the third-party patent could be used for this purpose. The

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194. *See supra* Part I.B.2.

195. The principle that anticipatory prior art must provide specific details finds its roots in English patent cases:

> Whatever, therefore, is essential to the invention must [appear in] the prior publication. If specific details are necessary for the practical working . . . of the alleged invention, they must be found substantially in the prior publication. Apparent generality, or a proposition not true to its full extent, will not prejudice a subsequent statement which is limited and accurate . . . .

Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 555 n.24 (1870) (citing Hill v. Evans, (1862) 45 Eng. Rep. 1195, 1200 (Q.B.)). In a leading British case addressing anticipatory enablement, Lord Hoffmann described the requisite level of disclosure for a third-party patent:

> To anticipate the [subsequent inventor's] claim the prior publication must contain clear and unmistakable directions to do what the [subsequent inventor] claims to have invented. A signpost, however clear, upon the road to the . . . invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the [subsequent inventor].

Gen. Tire & Rubber Co. v. Firestone Tyre & Rubber Co., [1972] R.P.C. 457, 486 (U.K.) (citations omitted).

196. *See supra* note 104 and accompanying text.

197. And if there are no additional grounds for unpatentability, the Patent Office must grant the patent. *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

examiner could no longer point to recent documents to prove what a PHOSITA knew long ago. And like the primary reference and other forms of prior art, the secondary reference must have been "sufficiently accessible" to the PHOSITA during the relevant time period.[198] Limiting the universe of secondary references in this way would reduce problems with hindsight stemming from speculation about the PHOSITA's then-existing abilities.[199]

2. *Application.* To illustrate the new analytical framework, consider the following hypothetical patent prosecution, which shows that novelty problems can arise even when *X* does not appear in a voluminous list of compounds.

Suppose that in 2006 an inventor at a drug company synthesizes *X*, a steroid that exhibits promising pain-relieving activity. Later that year, the inventor files a patent application claiming *X*. The examiner rejects the claim under § 102(b) as anticipated by a third-party patent that issued in 1969 (primary reference) disclosing the following:

> We have discovered that treatment of cortisone under the conditions herein described yields steroid *W* in good yield. Various changes and modifications might be made by those skilled in the art without departing from the spirit of the invention. The solvent and specific reaction temperature employed will be primarily dependent on the particular reactants used therein. It is envisioned that modifications of the technique described herein will produce steroids *X*, *Y*, and *Z* in excellent yield.[200]

198. *See* Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1568 (Fed. Cir. 1988) ("The statutory phrase 'printed publication' has been interpreted to mean that [during the relevant time period] the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a prior art reference was 'published.'"); *cf. In re* Wyer, 655 F.2d 221, 226 (C.C.P.A. 1981) (explaining that a document is publicly accessible if it "has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation").

199. *See supra* notes 119–21 and accompanying text.

200. This type of broad disclosure is ubiquitous in patent documents. *See* Seymore, *Teaching Function*, *supra* note 45, at 633–41 (exploring the use of "patentese" to "cast [an] invention in broad terms"). In this hypothetical, some language is excerpted from Certain Halogenated 2-(2-Thiazolyl)aminofuran-5-ones, U.S. Patent No. 3,444,178 (filed June 16, 1967).

Although *X* was never made, the examiner contends that the disclosure is sufficiently detailed to overcome a presumption of nonenablement.

In response, the applicant argues that the presumption has not been rebutted because steroid synthesis is so unpredictable that a PHOSITA cannot extrapolate the result from one experiment (the synthesis of *W*) to another (the synthesis of *X*) with any reasonable expectation of success.[201] This is true, for example, because minor changes in structure can result in large changes in reactivity.[202] Impliedly conceding the argument, the examiner then attempts to show knowledge in the art by asserting a review article entitled "Fifty Years of Steroid Chemistry" published in 2005 (secondary reference). Although the review article does not report or cite a synthesis for *X*, it notes that steroids of the class encompassing *W*, *X*, *Y*, and *Z* were first made in the 1960s.

The applicant responds with both a substantive and a procedural argument. First, the applicant contends that the review article, like the primary reference, is nonenabling because it lacks specific information about how to make *X*. Second, the applicant contends that the review article is an improper secondary reference because it postdates the allegedly anticipating reference by thirty-six years. Upon reconsideration, the examiner acquiesces and withdraws the § 102(b) rejection.

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201. One way to test enablement is to determine if a skilled scientist would have believed that the inventor's success with the described embodiment(s) "could be extrapolated with a reasonable expectation of success" to other embodiments encompassed by the broad claims. *In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993). Another jurist framed the analysis in similar terms:

> [W]ith respect to generic claims to chemical and biological inventions, the scope of the claims is limited to what [the PHOSITA] could reasonably predict from the inventor's disclosure. This precept recognizes that one skilled in these chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances. Thus, in so-called "chemical" patent law practice, the claims of a patent are limited by the scope of what the disclosure reasonably teaches to [the PHOSITA].

Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839 (M.D. Fla. 1976), *aff'd*, 584 F.2d 714 (5th Cir. 1978). Important considerations include "the type[s] of reactions, the state of the art, the representative nature of the examples, and the breadth of the claims." *In re* Rainer, 377 F.2d 1006, 1012 (C.C.P.A. 1967).

202. *See* AstraZeneca Pharm. LP v. Teva Pharm. USA, Inc., 583 F.3d 766, 775 (Fed. Cir. 2009) (recognizing that "the properties of these structurally similar compounds [can] vary significantly with minor structural changes"); *In re* Soll, 97 F.2d 623, 625 (C.C.P.A. 1938) (explaining that a patentee that discloses one member of a class of compounds may not be entitled to claim the entire class because certain members may react differently).

This new framework fulfills the fundamental purpose of the novelty requirement because it allows the applicant to claim an invention that the PHOSITA was incapable of making.[203]

B. Benefits of the Proposed Framework

1. *The Framework Will Solve the Quintessential Novelty Problem.* Perhaps the most troubling aspect of the quintessential novelty problem is that the mere recitation of *X* by name or structure in a third-party patent can ultimately thwart a subsequent inventor's claim to the compound, even though the subsequent inventor has added to society's knowledge by creating it. The proposed framework would finally put this vestige of *Von Bramer* to rest, because such a third-party patent could no longer serve as an anticipatory prior art reference. But if the structural recitation is accompanied with minimal experimental details, the burden would shift to the examiner to prove that a PHOSITA could have made *X* using then-existing knowledge without undue experimentation. And because the examiner would have a limited universe of secondary references available, the scales of patentability would now tip in favor of the inventor who actually makes *X*.

2. *The Framework Will More Accurately Determine the Level of Skill in the Art.* Aside from protecting the patent rights of subsequent inventors, the new framework focuses more attention on the PHOSITA.[204] The heart of the enablement facet of the anticipation inquiry often turns on what the PHOSITA knows and whether the PHOSITA can fill in gaps in the reference.[205] Because "the level of skill in the [relevant] art is [the] prism or lens through which [the factfinder] views the prior art and the claimed invention," the importance of this hypothetical construct cannot be overstated.[206]

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203. *See supra* notes 20–22 and accompanying text.

204. For a discussion identifying the relevant factors for constructing the PHOSITA, see *supra* note 21. For additional commentary on the PHOSITA's identity, see generally John O. Tresansky, *PHOSITA—The Ubiquitous and Enigmatic Person in Patent Law*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 37 (1991); Joseph P. Meara, Note, *Just Who Is the Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage*, 77 WASH. L. REV. 267 (2002).

205. *See supra* notes 70–74 and accompanying text.

206. Okajima v. Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Yet it is very easy to mischaracterize the PHOSITA, either because of confusion about the artisan's identity[207] or because of insufficient factfinding.[208] Overestimating the PHOSITA's knowledge and level of skill is particularly problematic in the enablement inquiry. This is because in both patent examination and litigation contexts, the "enablement determination is made *retrospectively*, *i.e.*, by looking back to the filing date of the patent application and determining whether undue experimentation *would have been* required to make and use the claimed invention at that time."[209]

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207. The confusion arises for several reasons. First, several commentators argue that the PHOSITA does not remain constant from section to section of the patent statute but rather changes based on the purpose being served at that time. Burk & Lemley, *supra* note 121, at 1189–90 (citing Tresansky, *supra* note 204, at 52–53). Thus, "[t]he PHOSITA for purposes of obviousness may not necessarily be the PHOSITA for purposes of enablement, written description, definiteness, or equivalence." *Id.* at 1189. This means, of course, that the different PHOSITAs can exhibit different characteristics between sections. *Id.* at 1190 (explaining that while the authorities view the PHOSITA in the nonobviousness context as a problem solver, they historically viewed the PHOSITA for enablement purposes as one who "show[ed] no such innovative tendency, but [was] simply a user of the technology"). Second, "the knowledge of the PHOSITA in a particular field . . . frequently change[s] over time." Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 102 (2005); *see also infra* note 212. Third and relatedly, evidence shows that the PHOSITA varies by industry. BURK & LEMLEY, *supra* note 66, at 115 (comparing the biotechnology PHOSITA to the software PHOSITA). Fourth, unlike the PHOSITA who has a common or ordinary level of skill, patent law presumes that inventors and patentees have extraordinary skill. Burk & Lemley, *supra* note 121, at 1189 ("Unlike the inventor, who almost by definition is presumed to be one of extraordinary skill, the PHOSITA standard contemplates some median or common level of skill." (footnote omitted)); *see also* N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1580 (Fed. Cir. 1993) (Rader, J., dissenting) ("Because inventors generally have extraordinary skill, their scientific writings outside the patent are rarely even a source of knowledge about ordinary skill in the art."); Dan L. Burk, *Feminism and Dualism in Intellectual Property*, 15 AM. U. J. GENDER SOC. POL'Y & L. 183, 189–90 (2007) ("Far from being one of ordinary skill, the inventor is by definition one of extraordinary skill, so that once the mental work has been completed, all that remains to be done has been characterized as the 'work of the mere artisan'—not the work of an inventor.").

208. For instance, Judge Rich described the PHOSITA as a "plodder" who "thinks along the line of conventional wisdom in the art" and does not "undertake[] to innovate, whether by patient, and often expensive, systematic research[,] or by extraordinary insights." Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985). Until quite recently, Judge Rich's view of the PHOSITA as an unimaginative and uncreative person persisted in patent law even as inventions have become more technologically complex. *See* Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 888, 891 (2004) (explaining how the Federal Circuit "all but ignored" the PHOSITA because the court presumed "that PHOSITA [was] an uncreative plodder, incapable of making inventions of his own"). The Federal Circuit recently abandoned the plodder presumption, however, and now strives to accurately elucidate the PHOSITA's identity. *See infra* notes 215–19 and accompanying text.

209. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999).

Retrospection raises two concerns. The first concern, as discussed in Part II.A.2, is the potential for hindsight bias.[210] The notion that *X* could not have been that difficult for a PHOSITA to make becomes more problematic as the filing date becomes more distant.[211] The second concern is that the PHOSITA's knowledge and abilities can change over time, most notably between the time of filing and the time of the enablement analysis.[212] The corollary is that "whether a disclosure is enabling can shift over time; as the knowledge of the PHOSITA shifts, an identical disclosure may shift from not being enabled to being enabled."[213] This has led Professor Timothy Holbrook to conclude that "[e]nablement, while conceptually simple, is legally and factually complex."[214]

In *KSR International Co. v. Teleflex Inc.*,[215] the Supreme Court reemphasized the importance of accurately determining the PHOSITA's identity and knowledge.[216] In resolving whether the nonobviousness PHOSITA could combine the teachings of the prior art to arrive at the claimed invention, the Court rejected the Federal Circuit's narrow and inflexible approach to the question.[217] Now the

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210. *See supra* notes 119–21 and accompanying text.

211. *See* sources cited *supra* note 121.

212. Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 41–43 (2009) (explaining that the level of skill in the art may have evolved since the filing date, which is important because enablement is assessed at the time of application).

213. Holbrook, *supra* note 31, at 129–30.

214. *Id.* at 129.

215. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

216. *See id.* at 420–21 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton."); *see also* Daralyn J. Durie & Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 WM. & MARY L. REV. 989, 1000 (2008) ("[After *KSR*,] courts will have to pay more attention than they have in the last quarter-century to who the PHOSITA is and what he or she thinks."); Joseph Scott Miller, *Remixing Obviousness*, 16 TEX. INTELL. PROP. L.J. 237, 250 (2008) (recognizing that *KSR* banished the Federal Circuit's "dullard" PHOSITA).

217. Before *KSR*, the Federal Circuit and the C.C.P.A. resolved the question with the "teaching, suggestion, or motivation" (TSM) test, which deemed a patent claim obvious if some motivation or suggestion to combine the prior art teachings could be found in the prior art, the nature of the problem, or the knowledge of a PHOSITA. *See, e.g.*, *In re* Rouffet, 149 F.3d 1350, 1355–56 (Fed. Cir. 1998) (explaining the TSM test); *In re* Bergel, 292 F.2d 955, 956–57 (C.C.P.A. 1961) ("The mere fact that it is *possible* to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination."). The *KSR* Court held that the Federal Circuit's rigid application of the TSM test is inconsistent with the "expansive and flexible" approach to nonobviousness set forth in prior precedent. *KSR*, 550 U.S. at 415 (citing Graham v. John Deere Co., 383 U.S. 1, 12, 17, 18 (1966); Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1850)).

Federal Circuit appears to devote more attention to the PHOSITA in both its nonobviousness[218] and § 112 enablement cases.[219] As a matter of logical consistency, it is now time to also devote more attention to the anticipatory-enablement PHOSITA. By requiring the examiner to prove with specificity what the PHOSITA knew during the relevant time period and limiting the universe of secondary references, the proposed framework does just that.[220]

3. *The Framework Will Reduce the Chaff in the Patent Literature.* Patents are a form of technical literature.[221] Considering that § 112

218. *See, e.g.*, Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301–02 (Fed. Cir. 2007) ("Ordinarily, [a PHOSITA] expects a concentrated or purified ingredient to retain the same properties it exhibited in a mixture, and for those properties to be amplified when the ingredient is concentrated or purified . . . . If it is known how to perform such isolation, doing so 'is likely the product not of innovation but of ordinary skill and common sense.'" (quoting *KSR*, 550 U.S. at 402–03)); Leapfrog Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007) (explaining that the obviousness analysis "is not the result of a rigid formula disassociated from the consideration of the facts of a case," but requires a consideration of "the common sense of those skilled in the art").

219. In the predictable arts, for many years the courts adopted the view that a single embodiment was often sufficient to enable a broad claim. *See, e.g.*, Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement); *In re* Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944) (explaining that an inventor "is generally allowed [broad] claims, when the art permits, *which cover more than the specific embodiment shown*"). In other words, a PHOSITA in the predictable arts could always fill in gaps omitted from the disclosure. Seymore, *supra* note 46, at 282–83. A few years before *KSR*, the Federal Circuit vitiated the "single embodiment" enablement doctrine and moved toward a more stringent "full scope" enablement standard. *See* Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (determining that a disclosure that enabled an injector with a pressure jacket was insufficient to support a claim that covered injectors with and without pressure jackets); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that when the claims covered a Type 1 or a Type 2 aluminum coating, yet the patent only described a Type 2 coating, the claims were nonenabled because a PHOSITA could not fill in the gaps without undue experimentation); Seymore, *supra* note 46, at 284–89 (describing the emergence of "full scope" enablement as a "lever to invalidate patents"). Several commentators suggest that the new standard is tied to a resurgence of the Federal Circuit's written-description doctrine, which has essentially blurred the line between it and enablement. *See, e.g.*, Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62–63 (2000) (contending that "neither the Federal Circuit nor the C.C.P.A. has ever articulated a persuasive rationale for distinguishing the written description requirement from the enablement requirement"); *cf.* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (observing that the two disclosure requirements are "closely related" and "usually rise and fall together").

220. *See supra* Part III.A.

221. For instance, like technical journals, patents show the state of technology, set forth what others have already achieved, and provide technical information about procedures that

compels patentees to provide an enabling disclosure, a PHOSITA should theoretically be able to rely on the patent document and existing knowledge in the art to practice the claimed subject matter without undue experimentation.[222] This teaching function becomes particularly important when one considers that most information disclosed in a patent is never published in another medium.[223]

Yet although patents are in many ways quite similar to other technical information sources,[224] they are not often viewed as an important channel for information flow.[225] One reason is that patents "seldom teach enough so that someone can actually go out and actually do the invention without some additional work."[226] Relatedly, patent documents are often indecipherable, even to those with

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others then need not repeat. THOMAS T. GORDON & ARTHUR S. COOKFAIR, PATENT FUNDAMENTALS FOR SCIENTISTS AND ENGINEERS 51 (2d ed. 2000).

222. *In re* LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962).

223. *See* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 554 (2009) ("Much of the information contained in—or that ought to be in—patents is not published elsewhere."); Esteban Burrone & Guriqbal Singh Jaiya, Intellectual Property (IP) Rights and Innovation in Small and Medium-Sized Enterprises 3 (n.d.) (unpublished manuscript), *available at* http://www.wipo.int/sme/en/documents/pdf/iprs_innovation.pdf ("It has been estimated that patent documents contain 70% of the world's accumulated technical knowledge and that most of the information contained in patent documents is either never published elsewhere or is first disclosed through the publication of the patent application.").

224. *See supra* note 221. It is also true that "in many ways, a scientific publication and the patent document share similar goals—namely to disclose something novel, to teach fellow artisans how to replicate the invention or discovery, and to spur further innovation in the field." Seymore, *Teaching Function*, *supra* note 45, at 663 (footnotes omitted).

225. *See* Wesley M. Cohen, Akira Goto, Akiya Nagata, Richard R. Nelson & John P. Walsh, *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RES. POL'Y 1349, 1362–64 (2002) (presenting empirical research showing that among information sources for diffusing research and development in the United States, patents rank third behind publications and informal information exchange). Several commentators have speculated as to why this is so. Seymore, *Teaching Function*, *supra* note 45, at 665 n.227.

226. Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2025 (2005) (quoting *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: Hearing Before the Fed. Trade Comm'n* 53 (Mar. 20, 2002) (statement of Daniel McCurdy), *available at* http://www.ftc.gov/opp/intellect/020320trans.pdf). This is true, at least in part, because an inventor need not create a working embodiment or engage in any experimentation before obtaining the patent. *See supra* note 123. Rather, an inventor can describe an invention with fictitious, constructed examples. And if these examples lack sufficient detail, there is a presumption that a PHOSITA can rely on knowledge in the field to fill in the missing information. *See supra* notes 70–74 and accompanying text. In sum, a disclosure that cannot teach a PHOSITA how to practice the invention has little substantive value. *See* Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 22 n.16 (2008) ("[R]esearch suggests that scientists don't in fact gain much of their knowledge from patents, turning instead to other sources.").

specialized knowledge.[227] Rather than fulfilling the statutory mandate to provide a written description using "full, clear, concise, and exact terms,"[228] many applicants draft a document laden with jargon and formalistic, imprecise language.[229] The applicant can thereby cast the invention in broad terms, essentially stretching the disclosure.[230] Although applicants may engage in this activity to preserve claim scope,[231] to set the stage for continuation practice,[232] and to avoid

227. *See, e.g.*, Daniel C. Munson, *The Patent-Trade Secret Decision: An Industrial Perspective*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 689, 713–14 (1996) (observing that chemical patents "tend to be shrouded in chemical nomenclature," which makes them hard to comprehend); Note, *supra* note 226, at 2022 (explaining that patents "are notoriously hard to interpret").

228. 35 U.S.C. § 112, ¶ 1 (2006).

229. *See* Note, *supra* note 226, at 2025 ("Although patent applicants are supposed to provide a 'full, clear, [and] concise' written description of their invention so that their peers in the industry can easily read and understand it, very few patents today meet that standard. Instead, the goals of clarity and brevity take a back seat to drafting strategies meant to ensure that patents are interpreted broadly by the courts."). Notwithstanding the disclosure requirements of § 112, many patentees adopt the view that the written description does not define the invention but rather provides examples or embodiments of the invention. Rather than use language that explicitly describes what the invention is, for instance, a savvy drafter would say something like, "In an embodiment, one aspect of the invention relates to . . . ." *See* George F. Wheeler, *Creative Claim Drafting: Claim Drafting Strategies, Specification Preparation, and Prosecution Tactics*, 3 J. MARSHALL REV. INTELL. PROP. L. 34, 43 (2003) (advising patent claim drafters to couch specific inventions in the broadest manner possible).

230. Seymore, *Teaching Function*, *supra* note 45, at 634–35 (noting how the disclosure can be stretched by "employ[ing] boilerplate patentese to help cast the invention in broad terms").

231. The U.S. patent system uses a peripheral claiming regime in which claim language sets forth the metes and bounds of the invention, like a deed to real property. *See* 35 U.S.C. § 112, ¶ 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."). Perhaps not surprisingly, patentees exploit the inherent indeterminacy of language to maximize claim scope by deliberately building ambiguity into the patent document. Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465, 542 & n.187 (2004); *see also* R. Carl Moy, *Subjecting Rembrandt to the Rule of Law: Rule-Based Solutions for Determining the Patentability of Business Methods*, 28 WM. MITCHELL L. REV. 1047, 1082 (2002) ("[P]eripheral claiming imposes no inherent limit on the level of abstraction that the patentee is able to use in the claim.").

232. A continuation application is a second application for the same invention disclosed in a parent (original) application that is filed before the parent application either issues as a patent or becomes abandoned. 35 U.S.C. § 120. It has the identical written description as the parent and enjoys the benefit of the parent's earlier filing date. *Id.* Applicants file continuation applications for many reasons. For example, an applicant may decide to prosecute a parent application with narrow claims (which will issue relatively quickly) and then prosecute broader claims in the continuation application. *See* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 161–62 (4th ed. 2006) (describing continuation applications, as well as the strategies and benefits associated with them). An applicant can use this strategy "to gain advantages over competitors by waiting to see what product the competitor will make, and then drafting patent claims specifically designed to

linguistic pitfalls[233] and problems with new matter,[234] they also occasionally do so to "muddy the waters in a defensive or nuisance maneuver" to thwart subsequent, deserving inventors.[235]

Under the new paradigm, padding patent documents with unclaimed subject matter will no longer give a third-party patentee a strategic advantage.[236] This raises hope that patentees will draft leaner, more technically robust documents. Thus, the new paradigm could help transform patents into repositories of valuable technical knowledge competitive with other information sources.[237]

4. *The Framework Will Promote Innovation and Other Goals of Patent Policy.* Promoting innovation is often viewed as the primary goal of the patent system.[238] Innovation is a complex process that

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cover that product." Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004); *see also* EDWARD F. O'CONNOR, INTELLECTUAL PROPERTY LAW AND LITIGATION 116–17 (2d ed. 2003) (arguing that continuation practice gives patentees considerable flexibility to craft claims directed to specific products).

233. Seymore, *Teaching Function*, *supra* note 45, at 635–36 (describing language traps that may lead to an undesired claim construction).

234. Upon filing, an applicant cannot amend the disclosure to introduce new matter into the application. 35 U.S.C. § 132(a) ("No amendment shall introduce new matter into the disclosure of the invention."); 37 C.F.R. § 1.121(f) (2009) ("No amendment may introduce new matter into the disclosure of an application."); *see also* MPEP, *supra* note 125, § 706.03(*o*) (directing examiners to be on alert for new matter). The new-matter prohibition of 35 U.S.C. § 132 and its corollary, the written-description requirement of 35 U.S.C. § 112, ¶ 1, "both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001).

235. Wainwright, *supra* note 34, at 221–22. When a patentee discloses more than he or she enables for § 112 purposes, that subject matter can nonetheless be asserted as prior art against subsequent inventors, at which time it will enjoy a presumption of enablement. *See supra* notes 125–27 and accompanying text.

236. *See supra* Part III.A.

237. *See* Seymore, *Teaching Function*, *supra* note 45, at 656–57 (arguing that transforming the patent into a readable teaching document and making an actual reduction to practice the standard of disclosure would produce patent documents that could achieve this result).

238. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) ("[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (noting that one goal of patent law is "[to] promote[] disclosure of inventions to stimulate further innovation"). 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* Eldred v. Ashcroft, 537 U.S. 186, 223 (2003) (Stevens, J., dissenting) (noting that the "ultimate purpose" of the patent grant is to "promot[e] the 'Progress of Science and useful Arts' by guaranteeing that those innovations will enter the

brings inventions into widespread, practical use by "feed[ing] on the known and convert[ing] it into the new."[239] In his recent book, *Driving Innovation*, Michael Gollin contends that innovation is a three-stage cyclical process in which individuals first engage in creative labor using existing knowledge. The product of that labor is then distributed among and adopted by society, ultimately adding to the pool of accessible knowledge for other creative individuals to use and improve on.[240] Patent laws affect each stage by providing incentives to invent, disclose, and design around patented technology;[241] by defining boundaries; and by modulating dissemination and the entry of knowledge into the accessible domain.[242]

Under the current regime, *X* may never even enter the innovation cycle. When a third-party patent discloses but does not claim *X*, the patent likely does not enable *X*.[243] Thus, the disclosure provides the PHOSITA and the public with no substantive technical information about the compound. When the Patent Office denies a patent to a subsequent inventor who can actually make *X*,[244] it not only deprives that inventor of a potential opportunity to reap an economic benefit from the compound but also deprives the patent system of an opportunity to obtain a technically robust disclosure that actually enables *X*.[245] And because the subsequent inventor will

public domain as soon as the period of exclusivity expires") (quoting U.S. CONST. art. I, § 8, cl. 8).

239. MICHAEL A. GOLLIN, DRIVING INNOVATION 11 (2008).

240. *Id.* at 15–19.

241. F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 61 (2003) ("The patent system in this country has generally been seen as offering inventors an incentive to do something they might not otherwise do—for example, invent, disclose, commercialize, or design around." (citing DONALD S. CHISUM, CRAIG ALLEN NARD, HERBERT F. SCHWARTZ, PAULINE NEWMAN & F. SCOTT KIEFF, PRINCIPLES OF PATENT LAW 58–90 (2d ed. 2001) (exploring diverse incentive theories of the patent system))); *see also* State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.").

242. GOLLIN, *supra* note 239, at 11, 18–19.

243. *See supra* text accompanying notes 26–30.

244. A subsequent inventor can possibly obtain a new-use patent, however. For an exploration and criticism of new-use patents in this scenario, see discussion *supra* note 188.

245. Rejecting a claim to *X* will essentially foreclose the opportunity to fully exploit the compound. *Cf.* Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOB. STUD. L. REV. 701, 735 (2004) (arguing that inventions that are never exploited, and thus that never reach the market, are economically irrelevant). In addition, if the subsequent inventor abandons the patent application, the public will not gain access to the presumably enabling

probably not disclose *X* in another medium,[246] the public may never get possession of the compound.[247]

Allowing a subsequent inventor to claim *X*, on the other hand, will have the opposite effect. First, the subsequent inventor can exploit the compound, thereby providing a reward for the inventive effort and encouraging further creative activity.[248] Second, the new framework will add to the store of knowledge for others to use. Assuming that the subsequent inventor files an application that complies with the requirements of § 112, the public will finally obtain an enabling (and, hopefully, technically robust) disclosure once the application publishes or the patent issues.[249] By opening the door to *X*'s patentability, the new framework will promote innovation and other goals of the patent system.

C. Criticisms

Although the new framework has several potential benefits, it has implications for the patent system that extend beyond the question of novelty. This Section explores some potential criticisms.

1. *Extended Pendency.* One potential concern with the new paradigm is that it will increase the pendency of applications in the

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technical information disclosed in it. That the subsequent inventor will disclose the information in another medium is also unlikely. *See supra* note 223 and accompanying text.

Turning back to the availability of a new-use patent, most would agree that it would provide less economic or technical benefit than a (broader) patent covering the compound itself. *See, e.g.*, Eisenberg, *The Role of the FDA*, *supra* note 188, at 351 (explaining that method-of-use patents are generally less valuable than the patent covering the compound itself); *see also* Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. ECON. 34, 52 (1995) (arguing that narrow patent protection inhibits the disclosure and dissemination of information useful to others).

246. *See supra* note 223 and accompanying text.

247. *See* GOLLIN, *supra* note 239, at 18 ("[The cycle] stops when creative people lack access to information, . . . when innovations are lost, and when law and circumstances make innovations inaccessible."); *supra* Part I.B.

248. 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); *see also* Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc) ("The reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits."). But "[e]ven if no incentive is required to produce an innovation, providing a reward after the creative act encourages [the inventor] and others to do more creative work in the future." GOLLIN, *supra* note 239, at 38.

249. *See* Seymore, *Teaching Function*, *supra* note 45, at 627 (arguing that the teaching function should be an important goal of the patent system).

Patent Office. It is certainly true that requiring the examiner to prove that a prior art reference is enabling will impact production goals.[250] This is a valid concern because the Patent Office's current compensation system emphasizes throughput,[251] which means that it rewards examiners for certain activities but not for others.[252] For instance, the first Office Action[253] and a final allowance or rejection of an application each count toward the examiner's quota. But searching the prior art, corresponding back and forth with the applicant, and issuing subsequent Office Actions—including the final one—do not.[254] An examiner thus has little incentive to bicker with an applicant over anticipatory enablement.[255] Rather, the examiner is better served by forcing a concession upon the applicant and then allowing a patent to issue.[256]

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250. "Production goals are the number of specific actions and decisions that patent examiners must make about patent applications they review during a 2-week period." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-1102, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 2 (2007), *available at* http://www.gao.gov/new.items/d071102.pdf. Implicit in these goals is an estimate of the time it takes to review a patent application.

251. The amount of time the Patent Office allots for an examiner to dispose of a case depends on factors like seniority and the technology involved. *See id.* at 7. Time estimates vary. *Compare* John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314 (estimating a sixteen- to seventeen-hour average time allotment), *with* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 n.19 (2001) (aggregating time estimates, which range from eight to thirty-two hours, depending on the technology).

252. *See generally* MPEP, *supra* note 125, § 1705 (describing the procedures for crediting an examiner's activities on the Examiner's Case Action Worksheet and the Biweekly Examiner Time and Activity Report).

253. An Office Action is an official communication from the Patent Office stating the examiner's position on patentability and the basis for any claim rejections. *See* 37 C.F.R. § 1.104(b) (2009) (describing the nature and content of the Office Action).

254. *See* MPEP, *supra* note 125, § 1705 (setting out which examiner actions receive a count).

255. Under the status quo, a savvy examiner who wants to maximize monetary and performance rewards should reject the application once, issue one Office Action, and then allow the application. *See* Nikolas J. Uhlir, Note, *Throwing a Wrench in the System: Size-Dependent Properties, Inherency, and Nanotech Patent Applications*, 16 FED. CIR. B.J. 327, 340 n.88 (2007) (explaining the compensation system and the incentives it gives to examiners).

256. *See* ANTHONY L. MIELE, PATENT STRATEGY 97–98 (2001) (discussing the examiner's concerns and incentives). Although allowances and final rejections both count toward an examiner's production goals, several commentators argue that the incentive system favors allowance. *See* Lemley, *supra* note 251, at 1496 n.3 ("[E]xaminers must write up reasons for rejection, but not reasons for allowance, giving them more incentives to allow rather than reject an application."). Thus, the skewed incentives of the current regime "make it easier and more desirable for examiners to grant patents rather than reject them." Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943,

There are at least three responses to this point. First, the Patent Office recently decided to review its production goals.[257] This long-awaited "completely fresh look"[258] at the examination process will hopefully lead the Patent Office to fix its compensation system.

Second, although negotiation is an integral facet of patent prosecution,[259] the Patent Office's incentive and reward structure should not, as a normative matter, compromise an applicant's ability to obtain a patent for a claim to which he or she is rightly entitled.[260] If the examiner rejects a claim to *X*, it should be because the compound is truly unpatentable, not because the examiner persuaded the applicant to acquiesce for the sake of expediency. At least in the novelty context, requiring the examiner to prove that an allegedly anticipatory reference is enabling will help fix this problem.

Third and relatedly, eliminating the presumption of enablement will force examiners to scrutinize prior art more carefully.[261] Many commentators and proponents of patent reform have indeed argued that a large number of patents would not issue if the examiner had access to, and adequate time to consider, the relevant prior art.[262] So

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945 (2004). Savvy applicants are aware of the skewed incentives. *See* Lemley & Moore, *supra* note 232, at 75 (contending that "an examiner faced with a determined applicant has every incentive to give in and allow the patent").

257. The current time estimates and quotas were established in 1976. Despite criticism over the past decade, Patent Office officials have not updated them to reflect increasing technical complexity, and those officials are insensitive to the number of pages or claims in an application. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 250, at 1–9 (discussing the problems examiners have with outdated, unrealistic production goals that do not accurately reflect the time needed to review applications). Finally, in response to the GAO Report, the Patent Office is seeking to reevaluate its production-management system. *Patent Examiner Production Goals Study*, U.S. PATENT & TRADEMARK OFF. (May 15, 2009), http://www.uspto.gov/web/offices/ac/comp/proc/pgs/pgshom.htm; *see also* Stephen Barr, *Backlog, Quotas Overwhelm Patent Examiners*, WASH. POST, Oct. 8, 2007, at D1 (discussing the GAO Report and comments from the Director of the U.S. Patent and Trademark Office); sources cited *supra* note 4.

258. Press Release, U.S. Patent & Trademark Office, *supra* note 4.

259. *See* MIELE, *supra* note 256, at 96–97 (describing the patent-prosecution process).

260. *See supra* notes 93–94 and accompanying text.

261. As one commentator explains, under the current system examiners have a monetary disincentive to engage in an extensive prior art search because "doing so means that they have more work to do with less pay than they would receive had they not searched for the art and simply issued the patent." David Hricik, *Aerial Boundaries: The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage*, 44 S. TEX. L. REV. 205, 228 (2002).

262. *See* Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181–82 (2008) (exploring criticisms); Lemley, *supra* note 251, at 1500 ("[M]uch of the most relevant prior art isn't easy to find—it consists of [third-party activities] that don't show up in any searchable database and will not be found by examiners in a hurry."); Michael

to the extent that the new framework would lead to an increased attentiveness to prior art, it would improve the quality of application review and ultimately the quality of issued patents.[263]

2. *Information Dissemination.* Another concern is that the new paradigm will create a disincentive for third-party patentees to disclose any more than is necessary to satisfy the disclosure requirements of § 112.[264] Most information disclosed in patents is never published elsewhere.[265] If an inventor withholds knowledge, it will likely be lost.[266] Furthermore, Judge Pauline Newman believes that any paradigm that might lead a patentee to limit the content of the disclosure frustrates innovation and technological advancement.[267]

But the nature and quality of the information under consideration is important. The new framework does not seek to curtail the disclosure of substantive technical information. To the contrary, written descriptions should include *more* information because it makes the patent document a more robust source of technical information.[268] And to the extent that this additional information describes work actually performed, it allows the patent document to more closely resemble the experimental section of a

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Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 196 (2007) ("A high-quality prior art search is difficult because of resource and time limitations."). One reform goal, stated in the Introduction to the Patent Reform Act of 2007 as proposed in the Senate, was "to improve patent quality and the patent application process." S. REP. No. 110-259, pt. 1, at 5 (2008).

263. Improving patent examination and patent quality are now priorities in the Patent Office. *See supra* note 4.

264. This is also a potential criticism of the disclosure-dedication rule. *See supra* notes 124, 126 and accompanying text; *see also* Seymore, *Teaching Function*, *supra* note 45, at 668–69 (responding to the criticism).

265. *See supra* note 223 and accompanying text.

266. *See* Seymore, *Teaching Function*, *supra* note 45, at 666 (discussing situations in which "the patent system is the sole medium of disclosure" and arguing that a heightened disclosure framework is needed when substantive technical information may otherwise be lost in unreadable patent documents).

267. *See* Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1064–72 (Fed. Cir. 2002) (en banc) (Newman, J., dissenting) (per curiam) (explaining that the disclosure-dedication rule imposes legal obstacles to the disclosure of scientific information and that those obstacles will deter innovation).

268. Seymore, *Teaching Function*, *supra* note 45, at 652–57 (describing how, by requiring working examples, written descriptions in patents could eventually provide as much useful technical knowledge as experimental sections in scientific journals).

technical journal.[269] When this happens, the patent document can achieve the goals it shares with scientific publications—"namely to disclose something novel, to teach fellow artisans how to replicate the invention or discovery, and to spur further innovation in the field."[270] Therefore, it

> may contribute significantly to bridging the divide between patent law and the experimental sciences. Including working examples, combined with some discussion of what is already known, serves a teaching role because they both provide context and allow the PHOSITA to more precisely (and more quickly) replicate the invention or discovery.[271]

In this scenario, more disclosure makes patents better vehicles for disseminating technical information.[272]

On the other hand, adding chaff to a patent document does not promote the document's disclosure function.[273] The new paradigm seeks to curtail inclusion of this material not merely because it makes patent documents thicker, but because its presence has several downsides. First, particularly in unpredictable fields, this disclosed-but-unclaimed subject matter is often unhelpful to the PHOSITA or follow-on researchers because it lacks technical substance.[274] And second, it can create roadblocks for other inventors who can actually enable the disclosed-but-unclaimed subject matter.[275] Removing the incentive to include chaff will lead patentees to draft technically robust documents that can disseminate information better than those produced under the current regime.[276]

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269. *Id.* at 656 & n.182 (explaining how the written description could resemble scientific publications' sections on experimental data, which "disclose[] working examples and other experimental details"); *see also supra* note 221.

270. Seymore, *Teaching Function*, *supra* note 45, at 663 (footnotes omitted).

271. *Id.* at 664.

272. It currently appears that patents are not a dominant channel of information flow. *See* Lemley, *supra* note 226, at 22 n.16 ("[R]esearch suggests that scientists don't in fact gain much of their knowledge from patents, turning instead to other sources."); sources cited *supra* note 225. This is unfortunate because most of the information disclosed in patents is not disclosed in another medium. *See supra* note 223 and accompanying text.

273. *See supra* note 34 and accompanying text; *see also supra* Part II.B.3.

274. Unclaimed subject matter is not subject to the disclosure requirements of § 112. *See supra* note 125 and accompanying text.

275. *See* Wainwright, *supra* note 34, at 221–22 (explaining how "nuisance prior art" can discourage applicants to the point of abandoning their patent applications); *supra* note 235 and accompanying text.

276. *See supra* Part III.B.3.

CONCLUSION

The novelty requirement seeks to ensure that a patent will not issue if the public already possesses the invention. Although current novelty doctrine is sufficient to gauge possession for inventions in applied technologies, it fails for those in unpredictable fields like chemistry. It thus at times produces paradoxical outcomes at odds with basic principles of patent law. By shifting presumptions and burdens of proof, the proposed patent examination framework will resolve these problems and improve the quality of both issued patents and the patent literature. And because patent applications in nascent technologies continue to rise, the proposed framework will spark more interest in exploring how patent law and policy should evolve to accommodate these technologies.