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PATENTING THE UNEXPLAINED

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ABSTRACT

It is a bedrock principle of patent law that an inventor need not understand how or why an invention works. The patent statute simply requires that the inventor explain how to make and use the invention. But explaining how to make and use something without understanding how or why it works yields patents with uninformative disclosures. Their teaching function is limited; one who wants to understand or figure out the underlying scientific principles must turn elsewhere. This limited disclosure rule does not align with the norms of science and tends to make patent documents a less robust form of technical literature. To address this problem, this Article proposes a two-tiered disclosure paradigm. While compliance with the extant statutory disclosure requirements would still be sufficient to obtain a patent, the inventor could opt to provide a mechanistic disclosure—one that describes how and why the invention works. Providing a mechanistic disclosure would have several upsides for the inventor, improve patent (examination) quality, enrich the public storehouse of technical knowledge, and promote broader goals of the patent system.

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INTRODUCTION

It might be surprising that an inventor can invent something and obtain a patent without understanding how or why it works. Yet such knowledge is not required.[1] If the patent document's disclosure is sufficiently detailed to explain to those skilled in the technology of the invention how to make and use the invention, that is enough to satisfy patent law's so-called

1. Eames v. Andrews (The Driven-Well Cases), 122 U.S. 40, 55–56 (1887) ("It may be that the inventor did not know what the scientific principle was . . . . That does not vitiate the patent." (quoting Andrews v. Cross, 8 F. 269, 277 (C.C.N.D.N.Y. 1881))); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests."). *See also infra* Part II.A.

enablement requirement.[2] But this minimal disclosure threshold can produce patents that are *uninformative* from a technical standpoint, meaning that they provide little meaningful information to truly fulfill patent law's disclosure function.[3] Uninformative patents have far-reaching and perhaps unintended consequences that, until now, have been unexplored.

To illustrate, consider the following hypothetical. Suppose that an inventor-researcher seeking to address the prevalence of stomach ulcers discovers how to cure them by administering penicillin to affected individuals.[4] Although the inventor can describe how to provide a therapeutically effective dosage and disclose data from successful use in human subjects, the inventor does not know how or why penicillin works. Although penicillin is an antibiotic, the inventor cannot even identify which (if any) bacteria are involved.[5] While figuring out these details might be demanded for acceptance of the inventor's claim by the scientific community,[6] this minimal disclosure would be sufficient to satisfy patent law's enablement requirement.[7]

Yet while enabling, the resulting patent raises several concerns that cannot be overlooked. First, the patent document merely explains how to

2. Enablement is one of the three disclosure requirements set forth in 35 U.S.C. § 112(a):

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

35 U.S.C. § 112(a) (2012) (emphasis added). Enablement is discussed *infra* Part I.B.

3. *See* discussion *infra* Part I.A.

4. Successful treatment of stomach ulcers with penicillin was first reported in 1951. *See* Lyudmila Boyanova, *Historical Data*, *in* HELICOBACTER PYLORI 2 (Lyudmila Boyanova ed., 2011).

5. Complicating matters was the widely held belief in the scientific community that the stomach was a sterile environment due to its acidity. *Id.*

6. *See* Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1508–09 (2011) (discussing scientific gatekeeping and the requirements for communal acceptability). As for penicillin, the scientific community initially rejected the findings because it was dogma that stomach ulcers were caused by gastric acid due to stress or diet; any notion that a pathogen was involved was "regarded as whimsical," and "the use of antibiotics or metallic ions were deemed to be quackery." Mark Kidd & Irvin M. Modlin, *A Century of Helicobacter pylori: Paradigms Lost–Paradigms Regained*, 59 DIGESTION 1, 1 (1997).

7. *In re* Libby, 255 F.2d 412, 415 (C.C.P.A. 1958) ("It is not necessary that a patentee should understand the scientific principles underlying his invention, so long as he makes a sufficient disclosure to enable other persons skilled in the art to practice the invention."). The U.S. Courts of Customs and Patent Appeals (C.C.P.A.) was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Pub. L. No. 97-164, 96 Stat. 25 (1982) (codified as amended in scattered sections of 28 U.S.C.). The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") adopted C.C.P.A. decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

practice the invention[8] (or replicate what the inventor did).[9] Arguably this does not go far enough—to be sure, scholars have criticized the current enablement standard as being de minimis.[10] Interested researchers must fill this knowledge void. Because they can rely on neither their own knowledge nor knowledge in the technical field to figure out the omitted information, interested researchers must engage in their own experimentation. But experimental activity by anyone other than the patentee might require a license to avoid liability for infringement.[11]

Second, any subsequent experimentation may come at a point far into the future—perhaps at the end of the twenty-year patent term[12]—or maybe not at all. But what if the inventor could have easily figured out how and why the invention works and disclosed that information in the patent? That would provide an enormous benefit to the public, which otherwise will get nothing more than a "cookbook recipe" replicating what the inventor did.[13] This knowledge void should be a cause for concern given the tremendous societal benefits that emanate from a robust patent disclosure.[14] In the case of drugs, for example, unraveling mechanistic information can lead to more effective or less toxic versions.[15] Relatedly, it is easier to develop new drugs when researchers understand how old ones work.[16]

But figuring out how and why an invention works—what I now define as *mechanistic* enablement—can also benefit the inventor. At present,

8. The courts often use the term "practice" when referring to the how-to-make and how-to-use prongs of the enablement requirement of § 112(a). *See In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000) (per curiam) ("To satisfy the enablement requirement of § 112 . . . a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation.").

9. *Cf. In re* Isaacs, 347 F.2d 887, 892 (C.C.P.A. 1965) ("All that an applicant need do is enable a person skilled in the art to duplicate [the inventor's] efforts . . . .").

10. *See* sources cited *infra* notes 25, 142, and 270.

11. Practicing the claimed invention without the patentee's permission constitutes patent infringement. *See* 35 U.S.C. § 271(a) (2012) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."). And there is generally no experimental use defense for third parties to figure out how and why the invention works. *See infra* Part III.C.2. But it is also true that some infringers, particularly academic researchers, are rarely sued. *See infra* note 141.

12. The patent term begins on the day of issuance and expires twenty years from the filing date. 35 U.S.C. § 154(a)(2) (2012).

13. *Cf.* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 397 (4th ed. 2015) (explaining that an enabling disclosure provides a "cookbook recipe" for those skilled in the technology of the invention).

14. *See infra* Part I.A; Kevin Emerson Collins, *The Structural Implications of Inventors' Disclosure Obligations*, 69 VAND. L. REV. 1785, 1790–91 (2016) (discussing the public-knowledge theory of disclosure and its grounding in social benefit).

15. Carolyn Y. Johnson, *One Big Myth About Medicine: We Know How Drugs Work*, WASH. POST: WONKBLOG (July 23, 2015), https://www.washingtonpost.com/news/wonk/-wp/2015/07/23/one-big-myth-about-medicine-we-know-how-drugs-work.

16. *Id.*

inventors have an incentive to claim as much as possible while disclosing as little as possible.[17] Such "overclaim[ing]" creates a statutory enablement problem;[18] nonetheless, inventors argue that broad claim scope is warranted because the minimal disclosure provided can be extrapolated to other embodiments of the invention[19] that have not been made or tested.[20] This argument is often suspect and unsuccessful.[21] But it would be much more plausible if the inventor provided mechanistic enablement—thereby tying everything together.[22] *Thus, mechanistic enablement could actually bolster statutory enablement*.[23] So broader claim scope could be used as a carrot to induce inventors to provide mechanistic enablement. This inducement could also work in *voluntary nondisclosure* paradigms—scenarios where the inventor knows mechanistic details but opts for nondisclosure because of some perceived value of maintaining secrecy.[24]

This Article explores uninformative patents, which have largely escaped the attention of legal scholars and commentators. It also makes the normative case for mechanistic enablement and explains how mechanistic enablement aligns with broader policy goals of the patent system. This Article is part of a larger project that seeks to develop a more robust disclosure function for the patent system and to bridge the disconnect between patent law and the norms of science.[25]

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17. *See infra* note 142 and accompanying text.

18. Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1193 (Fed. Cir. 2002) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 336 U.S. 271, 277 (1949)); *see also In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (explaining that the enablement requirement mandates a "reasonable correlation" between what is claimed and what is disclosed in the patent).

19. An "embodiment" is a concrete, physical form of an invention described in a patent application or patent. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 33 (7th ed. 2017).

20. *See* Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984) (evaluating the accused infringer's argument "that the broad scope of the claims is not supported by the limited disclosure present").

21. *See infra* note 186 and accompanying text. This is more true nowadays since the Federal Circuit is policing enablement more aggressively. *See infra* note 92 and accompanying text.

22. *See* discussion *infra* Part III.B.1.

23. For an illustration, see *infra* Part III.B.2(a).

24. J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 960–61 (2011) (explaining that "inventors will choose secrecy when the expected return from secrecy exceeds the expected return from" disclosure); Brenner v. Manson, 383 U.S. 519, 533–34 (1966) (recognizing the inventor's incentives to favor secrecy over full disclosure).

25. *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 fields which, by requiring applicants to disclose actual experimental results, resolves a striking incongruity between patent law and science); 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); Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 1037 (2013) [hereinafter Seymore, *Presumption*] (articulating a proposal that "is designed to strike a balance between an inventor's need to file early and a broader interest in using disclosure to promote the patent system's overarching goal of scientific and

The remainder of the Article proceeds as follows. Part I explores the teaching function of patent documents. It begins by discussing the primacy of disclosure in patent law and then explains how the enablement requirement seeks to ensure that the disclosure is meaningful. Next, Part II examines the rule that permits uninformative disclosures and explores the problems that arise from it. Part III proposes a new disclosure paradigm with mechanistic enablement. It also describes how to induce inventors to provide mechanistic enablement, including its ability to bolster statutory enablement and yield broader patent scope. Finally, Part IV discusses the policy implications of the proposal, with a particular emphasis on how it would promote patent law's disclosure function and help bridge the disconnect between patent law and science.

I. PATENTS AS TEACHING DOCUMENTS

A principal function of the patent document, aside from providing notice of the invention and its claimed scope,[26] is to disclose details about the invention to the public.[27] An often-overlooked aspect of disclosure is teaching.[28] The basic idea is that, while the patentee can exclude others from practicing the invention until the patent term expires, the technical information disclosed in the written description[29] has potential *immediate* value to the public,[30] which can use the information for any purpose that does not infringe upon the claims.[31] Thus, the patent document is a form of

technological progress").

26. *See* PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1358 (Fed. Cir. 2004) ("One important purpose of the written description is to provide notice to the public as to the subject matter of the patent, while the claim provides notice as to the scope of the invention." (citing Bates v. Coe, 98 U.S. 31, 39 (1878))).

27. *See infra* note 33 and accompanying text.

28. *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 n.5 (Fed. Cir. 2004) ("[W]hile the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to *teach*, both what the invention is (written description) and how to make and use it (enablement)."") (emphasis added).

29. The written description is the part of the patent document that completely describes the invention. 35 U.S.C. § 112 (2012) ("The specification shall contain a written description . . . . it shall conclude with one or more claims . . . ."). Although I will not do so in this Article, it is worth noting that the terms "written description" and "specification" are often used interchangeably (and mistakenly) in patent law. F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 155 n.4 (5th ed. 2011).

30. As noted by one commentator:

> Because every patent application contains a complete description of someone's technology, and because patent applications are published, and now appear in on-line databases, you can trawl [through them] for information vital to your own research and development efforts. Why struggle to solve a technical problem already solved by another and published in an application?

Anthony Murphy, *Intellectual Property*, *in* INNOVATION: HARNESSING CREATIVITY FOR BUSINESS GROWTH 87, 92 (Adam Jolly ed., 2003).

31. Seymore, *Teaching Function*, *supra* note 25, at 624 (citing Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. [2004] UKHL 46, [2005] RPC 9 [77] (Hoffmann LJ) (UK)); *cf.* PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS 10 (1975) ("[A]nyone is free to think and to write about

technical literature.[32]

A. Disclosure and Patent Law's Teaching Function

The essence of the U.S. patent system is a quid pro quo between the patentee and the public.[33] The basic idea is that in order to promote the full disclosure of information about the invention to the public, the patentee must receive something in return.[34] What the patentee gets is the limited period of exclusivity conferred by the patent grant.[35] The public gets detailed knowledge about the invention as soon as the patent document publishes[36] and possession of the invention at the end of the patent term.[37]

The inventive act produces *two* things that are potentially useful to the public: the invention itself, which will be defined here as the subject matter claimed in the patent (i.e., machine, product, process, composition of matter),[38] and the *disclosure*, which furnishes technical details about the invention (i.e., how to make it, how to use it).[39] Though the invention is probably the first thing that comes to mind when patents are discussed, the importance of the disclosure cannot be overlooked. Indeed, the Supreme Court has said that "the ultimate goal of the patent system is to bring new designs and technologies into the public domain *through disclosure*."[40]

Why is disclosure so important? First, since the public gets many new and useful things through trade secrecy,[41] the patent system incentivizes the

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what is covered by the patent without trespassing upon the exclusive right of the patentee.").

32. *See infra* note 43 and accompanying text.

33. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

34. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974).

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

36. *See id.* at 481 (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development); Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 332 (2008) ("[T]he public is free to read the patent and use the invention once the patent expires twenty years after it is filed, and even before that time scientists can learn from the patent disclosure and use that information to improve on the invention or to design around it.").

37. Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . so that interference with it may be avoided while the patent continues, and its benefits may be fully enjoyed by the public, after the patent expires.").

38. *See* 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . .").

39. *See infra* Part I.B.; Lemley, *supra* note 36, at 333 ("[I]t seems quite clear that dissemination, not just invention, of new information is one of the goals of the patent system.").

40. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (emphasis added).

41. Famous examples are the public's enjoyment of Coca-Cola's syrup formula and use of Google's search algorithm. *See* Van Lindberg, INTELLECTUAL PROPERTY AND OPEN SOURCE: A PRACTICAL GUIDE TO PROTECTING CODE 130 (2008) ("Nobody outside of Google knows the exact

disclosure of information that the public might not otherwise get.[42] This is particularly important for "non-self-disclosing" inventions like complex molecules or industrial processes, which cannot be easily replicated or reverse engineered.[43]

Second, the disclosure conveys technical information (and becomes a part of the technical literature),[44] which "add[s] to the sum of useful knowledge"[45] immediately—not at the end of the patent term but as soon as the patent document publishes.[46] Patent theory posits that the early entry of useful information into the public storehouse of technical knowledge[47] reduces research-and-development (R&D) waste,[48] spurs creativity,[49] leads others "to climb onto the patentee's shoulders in seeking improvements or

details of its search algorithms and, despite the best efforts of the search engine optimization crowd, nobody has been able to fully figure them out."); Andrew A Schwartz, *The Corporate Preference for Trade Secret*, 74 OHIO ST. L.J. 623, 651 (2013) (discussing how Google's algorithm is a carefully maintained trade secret which gives the company a "potentially perpetual monopoly"). Unlike patents, trade secrets can last forever, as long as secrecy is maintained. *See* Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1622 (2011) ("[T]rade secrecy protection can theoretically provide even more powerful incentives than patents because trade secrecy rights are potentially infinite in duration."); Anderson, *supra* note 24, at 923–27 (exploring the patent vs. trade secret distinction).

42. The "incentive to disclose" rationale for patents is based on the notion that "the patent system is designed to bring inventions out into public view." J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1585 (2016). Without the patent system, inventors would monetize their inventions through trade secrecy, thereby depriving the public of the benefit of technical information about the invention. *Id.* Thus, the quid pro quo—the patent bargain—is required to induce the inventor to disclose (which adds this technical information to the public storehouse of knowledge). Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, *in* 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 107, 108 (Peter K. Yu ed., 2007).

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

44. Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 400 (1960). Like technical journals, for example, patent disclosures can show the state of technology, set forth what others have already achieved, and provide technical information that others can avoid repeating. Seymore, *Teaching Function*, *supra* note 25, at 623–24.

45. Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

46. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that when the information disclosed in a patent becomes publicly available it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) (explaining that a purpose of a patent system is "to add to the body of published scientific/technologic knowledge"), *vacated*, 545 U.S. 193 (2005).

47. *See* cases cited *supra* note 46; *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that the full disclosure of how to make and use the invention "adds a measure of worthwhile knowledge to the public storehouse").

48. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 n.79 (1994).

49. *Kewanee*, 416 U.S. at 481; *see also* MICHAEL A. GOLLIN, DRIVING INNOVATION 15–19 (2008) (explaining that disclosure adds to the pool of accessible knowledge that other creative individuals can use and improve upon).

wholly new inventions,"[50] and, of course, extends the frontiers of science and technology.[51]

It is for these reasons that disclosure is regarded as the "centerpiece of patent policy."[52] It produces a font of useful knowledge which, in turn, promotes technological progress.[53] But it is very easy for the public not to get what it bargained for because "[t]here always exists, on the part of some people, a selfish desire to obtain patent protection without making a full disclosure."[54] This is why the law strives to secure the public's part of the patent bargain by compelling applicants to comply with the statutory patentability requirements.[55] The requirements work individually and collectively to ensure that the public gets a meaningful disclosure.

To illustrate, consider the basic purpose of each of the patentability requirements. Novelty ensures that the invention is "*new*, that is, bestowed for the first time upon the public by the patentee"[56] and protects knowledge that the public already possesses.[57] Nonobviousness ensures that the invention is "new enough"[58] by denying patents for trivial extensions of

50. Dam, *supra* note 48, at 264; *cf.* Rich, *supra* note 44, at 400 ("The literature of the art is enriched, another way of doing something is made known and even if it be inferior to the means already known, there is no telling when it may give another inventor an idea or when someone will improve on it in such a way as to surpass all that is known.").

51. *See* Rich, *supra* note 44, at 400 ("Whenever novel subject matter, unobvious to the workers of ordinary skill in an art, is published, progress in the art is promoted.").

52. Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2011 (2005); *see also* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) (explaining that the patent system should be viewed as "a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time").

53. *See* discussion *infra* Part I.B.

54. *In re* Nelson, 280 F.2d 172, 184 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936, 946 (C.C.P.A. 1967); *cf.* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 804 (2011) "[Applicants] have reasons to provide just enough information to satisfy § 112 and no more so that the patentee could retain aspects of the invention as a trade secret, potentially providing a competitive advantage in the market even after the patent is published or expires.").

55. The patentability requirements appear in Title 35 of the United States Code. Briefly, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–103 (2012). In addition, the application must adequately describe, enable, and set forth the best mode contemplated for carrying out the invention and conclude with claims that delineate the invention with particularity. *Id.* § 112(a), (b).

56. 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 221, at 305 (Bos.: Little, Brown, & Co. 1890) (emphasis in original). Novelty ensures that an invention is new by denying a patent if the claimed subject matter is identical to what is already known. *See* 35 U.S.C. §§ 101–102; *In re* Marshall, 578 F.2d 301, 304 (C.C.P.A. 1978).

57. *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'" (alteration in original) (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., Library ed. 1904))).

58. 3 DONALD S. CHISUM, CHISUM ON PATENTS § 3.01.

what is already known[59] and for inventions that would have come about through ordinary technological progress.[60] The disclosure requirements[61] ensure that, at the time of filing, the public can use the technical details provided in the patent document to (1) improve upon or design around the invention during the patent term; and (2) practice the invention either during the patent term with a license or freely once the patent term expires.[62] The patentable subject matter requirement[63] ensures that the inventor makes a meaningful and genuine contribution to the public by excluding things like abstract ideas, laws of nature, mathematical formulas, physical phenomena, and applied knowledge.[64] Together, these requirements ensure that the Patent Office only awards patents for inventions that yield a meaningful disclosure and support the patent system's broader mission of promoting scientific progress and extending the frontiers of knowledge.[65] As discussed below, the patent system goes to great lengths to promote and safeguard the disclosure function.[66]

59. Graham v. John Deere Co., 383 U.S. 1, 14–15 (1966); *see also* John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 6–7 (2007) (exploring the wisdom of denying patents for trivial inventions).

60. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007). If an invention lacks nonobviousness, it would have inevitably come about through routine advances; thus the inducement of a patent (and the accompanying disclosure) are thought to be unnecessary. ALAN DEVLIN, FUNDAMENTAL PRINCIPLES OF LAW AND ECONOMICS 261 (2014); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA*, 19 BERKELEY TECH. L.J. 885, 886 (2004); *see also* Timothy R. Holbrook, *Patent Anticipation and Obviousness as Possession*, 65 EMORY L.J. 987, 1028 (2016) (explaining that "[o]bviousness acts . . . as a form of constructive possession, where the law treats the invention as being within the possession of the public even though the invention has not been actually made or disclosed in its entirety.").

61. *See supra* note 2.

62. *See supra* notes 36–37 and accompanying text. For an excellent exploration of the temporal dynamic of patent disclosures, see Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1480–1506 (2016).

63. *See supra* note 38.

64. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014); *see also* Parker v. Flook, 437 U.S. 584, 594 (1978) (noting that such things are unpatentable without some inventive concept in their applications); Bilski v. Kappos, 561 U.S. 593, 602 (2010) ("The concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.'" (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948))); Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1340 (2014) (arguing that Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2014), "prevents knowledge-advances of any kind from being patent eligible subject matter").

65. 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 constitutional command is the patent system's "ultimate purpose"); Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) ("[T]he primary purpose of our patent laws . . . is 'to promote the progress of science and useful arts' . . . " (citation omitted)).

66. But there are debates on whether it succeeds. *Compare* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 547–54 (2009) (cataloguing the beneficial uses for disclosure in patent law, including stimulating innovation, preventing duplication, gauging patentability, and signaling research-

B. The Enablement Requirement

An oft-touted justification for the patent system is that society will get some benefit from the invention's disclosure.[67] In theory, the disclosure adds to the public storehouse of useful knowledge, which, in turn, promotes technological progress.[68] But this paradigm only works if the disclosure is sufficiently robust from a technical standpoint to actually teach meaningful information about the invention to the public.

Enablement is the patentability requirement with the principal task of safeguarding the teaching function.[69] It compels an applicant to prepare a written description of the invention sufficient to teach a person having ordinary skill in the art (PHOSITA)[70] how to make and use it without undue experimentation.[71] The enablement requirement is the essential aspect of the quid pro quo of the patent bargain[72] because it constrains the scope of the claims[73] (which can be no broader than the enablement provided).[74] This

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and-development strength), *and* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 133–47 (2006) [hereinafter Holbrook, *Possession*] (describing the "pervasive" role of disclosure in patent law and policy, including enriching the state of the art contemporaneously with the invention and showing evidence of possession of the invention), *with* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 412 (2010) (arguing that "disclosure as an objective of patent policy should be discarded in certain circumstances" because it "serves . . . an ancillary role within the larger purpose of the patent regime"), Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1187 (2016) ("[P]atents rarely provide much in the way of useful scientific knowledge in most industries; scientists who are doing research tend to look elsewhere than patents for their learning."), *and* Note, *supra* note 52, at 2007 ("If disclosure is an important policy goal of the patent system, then the system is in desperate need of repair.").

67. *See supra* notes 28–32 and accompanying text; Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that the federal government "is willing to pay the high price" of exclusivity conferred by a patent for its disclosure, which, "it is assumed, will stimulate ideas and the eventual development of further significant advances in the art").

68. *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

69. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 4, at 3–4 (2003) [hereinafter FTC REPORT] (explaining that enablement plays a central role in "safeguard[ing] the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others . . . can learn").

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

71. *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). While "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the specification 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).

72. *See supra* note 33 and accompanying text.

73. Claim scope is the "technological territory" that the inventor claims is his or hers to control. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990).

74. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 121 (1854); *see also* Nat'l Recovery Techs., Inc.

ensures that: (1) the disclosure sufficiently enriches the public storehouse of technical knowledge; and, (2) the public will get complete possession of the invention once the patent expires.[75]

Enablement is a standard.[76] Determining whether a disclosure was enabling as of its filing date[77] is a legal conclusion that rests on underlying factual inquiries.[78] The Federal Circuit set forth several factors relevant to the enablement analysis in *In re Wands*.[79] They are: (1) the amount of direction or guidance presented in the disclosure; (2) the existence of working examples; (3) the nature of the invention; (4) the predictability or unpredictability of the art; (5) the PHOSITA's level of skill; (6) the state of the prior art (preexisting knowledge and technology already available to the public);[80] (7) the scope of the claims;[81] and, (8) the quantity of experimentation necessary to practice the claimed invention.[82] While not mandatory,[83] the *Wands* factors are ubiquitous in evaluating enablement[84]—probably because they touch on issues that are important in virtually all enablement determinations.[85] These include issues related to the technical scope and substance of the disclosure (factors one and two),[86] the nature of the technology (factors three and four),[87] the PHOSITA's knowledge and skill (factor five),[88] and the scope of the claim sought (factor seven).[89]

Given that enablement is a standard, the *Wands* factors can be

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v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (noting that enablement's purpose is to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims."). The scope of enablement is the sum of what is taught in the written description plus what a PHOSITA already knows. *Id.*

75. *See supra* note 37.

76. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); Seymore, *Heightened Enablement*, *supra* note 25, at 130.

77. MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012) ("The enablement determination proceeds as of the effective filing date of the patent.").

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

79. 858 F.2d 731, 737 (Fed. Cir. 1988).

80. *See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (defining prior art). Prior art is used to determine the novelty or nonobviousness of claimed subject matter in a patent application or patent. *Id.*

81. *See supra* notes 73–74.

82. *Wands*, 858 F.2d at 737 (factors reordered from original text).

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

84. *See* 3 CHISUM, *supra* note 58, § 7.03 (collecting cases).

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

86. The two factors are clustered together because working examples are a form of guidance. Seymore, *Teaching Function*, *supra* note 25, at 641–46.

87. *See infra* note 143 (discussing predictable and unpredictable technologies).

88. This factor has become increasingly important over the past decade as the Federal Circuit has compelled patentees to enable the full scope of the claimed invention. *See infra* note 92.

89. Enablement places an outer limit on claim scope. *See* sources cited *supra* notes 73–74.

manipulated to modulate the enablement threshold. For example, a PHOSITA might benefit from more teaching in a nascent technology because there is little extant knowledge in the field to draw from.[90] This is also true for fields where results are "uncertain, unpredictable and unexpected."[91] But even in these cases where there is a high enablement threshold, such as when "full scope" enablement is demanded,[92] enablement still has a limited teaching function. After all, requiring an inventor to describe how to make and use what is claimed does not shed light on mechanism. Thus, more rigorous enforcement of the statutory enablement requirement cannot produce more *informative* patents.

II. PERMISSIBLE IGNORANCE IN PATENT LAW

Enriching the public storehouse of knowledge is only part of the story of the disclosure function. There is hope that it will help achieve two broader ends shared by patent law and science—namely, to coordinate the future development of technology[93] and spur innovation.[94] It would seem that patent law could do a better job of achieving both if it encouraged inventors to disclose mechanistic information. This Part explores rationales for patent law's minimal disclosure paradigm and situations where it is particularly problematic.

A. Understanding the Nondisclosure Rule

The rule that an inventor need not know mechanism has an interesting history in patent law. Consider the 1911 Supreme Court case *Diamond Rubber Co. v. Consolidated Rubber Tire Co*.[95] The patent was for "improvements in rubber tire wheels . . . designed for use on ordinary

90. Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction.").

91. Schering Corp. v. Gilbert, 153 F.2d 428, 433 (2d Cir. 1946); *see also* Seymore, *Heightened Enablement*, *supra* note 25, at 137–39.

92. The Federal Circuit has reiterated that "[c]laims are not enabled when, at the effective filing date of the patent, [a PHOSITA] could not practice their *full scope* without undue experimentation." Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1384 (Fed. Cir. 2013) (emphasis added) (citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380–81 (Fed. Cir. 2012)). For commentary, see Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 284–89 (2008) [hereinafter Seymore, *Enablement Pendulum*] (describing the emergence of "full scope" enablement as a "lever to invalidate patents").

93. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977); *see also* Merges & Nelson, *supra* note 73, at 871.

94. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989); *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").

95. 220 U.S. 428 (1911).

vehicles, such as wagons, buggies, and carriages."[96] The patentee's tire became a commercial success because it had an anti-tilting feature that distinguished it from tires in the prior art.[97] But since the inventor did not explain the scientific principles underlying the anti-tipping feature in the patent's written description, the accused infringer argued that the patent was invalid.[98] The Court disagreed:

> A patentee may be baldly empirical, seeing nothing beyond his experiments and result . . . . It is certainly not necessary that [an inventor] understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative ideas involved.[99]

Thus, an invention is patentable even if "the theory of operation is not correctly explained or even understood."[100] All that matters is if the disclosure is sufficiently enabling to allow a PHOSITA to practice the invention.[101]

This nondisclosure rule explains why inventions are patentable even if they come about unexpectedly.[102] Perhaps the quintessential modern illustration of this point is the 1999 case *In re Cortright*.[103] The inventor discovered that Bag Balm, an ointment first made in 1899 for treating irritated cow udders,[104] could successfully treat baldness in humans.[105] While the disclosure speculated as to which Bag Balm ingredient caused the hair growth, no proof was given for the observed physiological phenomenon.[106] Viewing the inventor's observations as inherently suspect,[107] the Patent Office rejected the method-of-treatment claim for

96. *Id.* at 430.

97. *Id.* at 430–33. *See supra* note 80 and accompanying text. An invention that is identical to or a trivial extension of what is known in the prior art is unpatentable. *See supra* notes 57–60 and accompanying text.

98. *Diamond Rubber*, 220 U.S. at 434.

99. *Id.* at 435–36.

100. Newman v. Quigg, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989).

101. *In re* Chilowsky, 229 F.2d 457, 463 (C.C.P.A. 1956).

102. *See* STUART FIRESTEIN, FAILURE: WHY SCIENCE IS SO SUCCESSFUL 44–45 (2015) (explaining serendipitous discoveries that come from failure; that is, "[s]omething doesn't work the way you thought it should and exploring the reasons for that leads to the initially unexpected and now surprising result."). *See generally* Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185 (2009) (exploring accidental discoveries in patent law and how they mesh with the law of invention).

103. 165 F.3d 1353 (Fed. Cir. 1999).

104. *Our Heritage*, BAG BALM, https://www.bagbalm.com/our-heritage [https://perma.cc/S6UJ-REG9] (last visited Oct. 19, 2018).

105. *Cortright*, 165 F.3d at 1355.

106. *Id.* at 1359.

107. The Patent Office and the courts had long regarded baldness treatments as an "inherently unbelievable undertaking." *Id.* at 1357; *see also In re* Oberweger, 115 F.2d 826, 829 (C.C.P.A. 1940) (affirming the Patent Office's rejection for a baldness treatment despite the inclusion of scientific evidence because such preparations were "generally understood to be a fraud upon the public"); *In re*

nonenablement.[108] Writing for the court, Judge Mayer explained that the rejection was improper because "an inventor [need not] correctly set forth, or even know, how or why the invention works."[109] It was also improper for the Patent Office to suggest that the inventor had to offer proof for the claimed result.[110] The patent issued the following year[111] with a single claim[112] and a written description that taught how much Bag Balm to apply and when to expect results.[113] But particularly relevant for present purposes, the patent provided no information about how or why Bag Balm works.[114]

B. Early Disclosure as a Justification

Early disclosure is viewed as a basic goal of the patent system.[115] In fact, "the patent law[s] place[] strong pressure on filing the patent application *early* in the development of the technology, often before . . . all of the boundaries [are] fully explored."[116] This incentive is even stronger under the first-inventor-to-file regime of the America Invents Act of 2011 (AIA).[117] For example, the *Manual of Patent Examining Procedure* (MPEP)[118] instructs examiners that a drug can be patented without *in vivo*

Ferens, 417 F.2d 1072, 1074 (C.C.P.A. 1969) (reaching the same conclusion because baldness treatments belonged to "a field of endeavor where 'little of a successful nature ha[d] been developed' despite constant effort . . . .") (quoting *In re* Oberweger, 115 F.2d 826, 827 (C.C.P.A. 1940)); Seymore, *Patently Impossible*, *supra* note 6, at 1514–17 (criticizing these views). But the *Cortright* court explained that views have now changed and the Patent Office had granted approximately one-hundred patents for treating baldness. *Cortright*, 165 F.3d at 1357.

108. *Cortright*, 165 F.3d at 1359.

109. *Id.* (quoting Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989)).

110. *Id.*

111. *See* Treatment of Scalp Baldness with 8-Hydroxyquinoline Sulfate, U.S. Patent No. 6,033,676 (filed Mar. 11, 1992) (issued Mar. 7, 2000).

112. It recites "[t]he method of treating scalp baldness with an antimicrobial to restore hair growth, which comprises rubbing into the scalp the ointment wherein the active ingredient 8-hydroxy.quinoline sulfate 0.3% is carried in a petrolatum and lanolin base." *Id.* col. 2 ll. 61–66.

113. *See, e.g.*, *id.* col. 2 ll. 7–47 (providing working examples with three human subjects).

114. The patent merely speculates about what is going on. *See id.* col. 2 ll. 1–4 ("*It is believed* that the rubbed-in ointment offsets the effects of lower levels of male hormones in the papilla and/or provides an antimicrobial effect on infection.") (emphasis added).

115. W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983) ("Early public disclosure is a linchpin of the patent system."), *cert. denied*, 469 U.S. 851 (1984); Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558 (Fed. Cir. 1994) (rejecting an interpretation of § 112 that would "subvert the patent system's goal of . . . encouraging early disclosure"), *cert. denied*, 513 U.S. 1151 (1995).

116. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (en banc) (Newman, J., concurring) (emphasis added), *rev'd on other grounds*, 520 U.S. 17 (1997); *see also* Kitch, *supra* note 93, at 267–71 (explaining the rules in patent law that force and permit early filing).

117. The AIA converted the U.S. patent system from a first-to-invent regime to a first-inventor-to-file regime. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285–87 (2011) (codified as amended at 35 U.S.C. § 102(a)(2012)) (amending 35 U.S.C. § 102(a) (2006) and repealing 35 U.S.C. § 102(g) (2006)). Under the AIA, the first inventor to file an application is entitled to a patent, with some exceptions, regardless of who created the invention first. § 102(a).

118. The MPEP provides guidance to patent examiners and is entitled to judicial notice as the

testing;[119] the applicant need only show a "reasonable correlation" between the drug and its asserted therapeutic activity.[120] Of course, this approach encourages patent applicants to "adopt several troublesome strategies,"[121] including claiming more broadly than the experimental data warrants.[122] But inventors file early to attract investors,[123] minimize risk,[124] and to safeguard patent rights in the United States and abroad.[125] This gives rise to a tradeoff between the perceived need to race to the Patent Office with an underdeveloped invention[126] and performing more pre-filing work to produce a more robust disclosure.[127]

Patent Office's official interpretation of statutes and regulations. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995). The MPEP "is also made available to patent applicants and their lawyers as well as to the general public . . . . [and] is used frequently by patent lawyers and agents in advising applicants and in preparing their various papers for filing in the Patent Office." *In re* Kaghan, 387 F.2d 398, 401 (C.C.P.A. 1967).

119. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (9th ed., rev. 08.2017) [hereinafter MPEP].

120. *Id.*

121. Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 884 (2017).

122. *Id.*

123. *See* JOHN SAMSON, INVENTIONS AND THEIR COMMERCIAL DEVELOPMENT 51 (1896) ("To have the use of capital is nearly always indispensable for the development of an invention, and, unless the inventor is of that fortunate class who have the means to work their own patents, he must appeal for support to one or more people with money."); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 143–44 (2000) (discussing the role of venture capital); Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 759 (1999) ("The prospect of certainty in the patentee's property interest has several benefits, one of which is to create a sense of security which permits the patentee to secure risk capital from investors, which in turn facilitates the commercialization of the claimed invention.").

124. *See, e.g.*, Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 393 (2010) ("If building a prototype is costly . . . the risks of not securing a patent [before actual reduction to practice] may be too large to justify doing so.").

125. *See* 35 U.S.C. § 102(a) (2012) (encouraging diligence by penalizing inventors for the delayed filing of patent applications); Convention on the Grant of European Patents art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272 (invoking an absolute novelty requirement that regards any pre-filing disclosure, including activity by the inventor, as patent defeating).

126. In a formal sense, "[a] patent race is a race among competing firms to be the first to discover and patent some new idea having commercial potential." WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 300 (2003). But races sometimes "encourage premature and sketchy technological disclosures in hastily-filed patent applications." Wendy Schacht & John R. Thomas, *Patent Reform: Innovation Issues*, *in* PATENT TECHNOLOGY 1, 11 (Juanita M. Branes ed., 2007).

127. Early filing has drawbacks. *See* Seymore, *Teaching Function*, *supra* note 25, at 659–61 (arguing that ex ante incentives that encourage early filing can thwart innovation); Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 88–119 (2009) [hereinafter Cotropia, *Early Filing*] (discussing the costs of early filing); Lemley, *supra* note 66, at 1186–87 (arguing that the benefits of early filing are often illusory, particularly for patent applications filed by those who have not physically made the invention).

C. The Transparent-Opaque Invention Dichotomy

It is fair to say that whether an inventor discloses mechanistic details in the patent only matters if a PHOSITA cannot easily elucidate the information. Put differently, if a PHOSITA can look at an invention and elucidate its mechanism, there is no need for the inventor to disclose that information in the patent document.[128] Indeed, minimal disclosure is unobjectionable for what I define as *transparent* inventions—those which, once seen, can be readily made, used, and understood.[129]

To illustrate, consider a (patented) paper clip.[130] The invention is so simple that a drawing or commercial product is sufficient to adequately disclose how or why it works.[131] A PHOSITA who wants to understand the physical forces involved in the friction between the wire and the paper that cause binding could turn to readily available knowledge in the field (like a physics textbook) to obtain this information.[132] So asking the inventor to disclose mechanistic details in the patent document would be redundant and unnecessary.[133] In sum, the invention's simplicity makes it *transparent* with respect to its mechanism.[134]

Yet the story is quite different for more complex inventions like chemicals, pharmaceuticals, or industrial processes. Here a drawing or

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128. Similarly, if a PHOSITA can look at an invention and figure out how to make and use it, there is no need to provide a detailed disclosure. Lawther v. Hamilton, 124 U.S. 1, 9 (1888) ("These several steps being well known in the art when the patent was applied for, required no particular explanation."). This is because "patents are written by and for skilled artisans." Vivid Techs., Inc. v. Am. Sci. and Eng'g, Inc., 200 F.3d 795, 804 (Fed. Cir. 1999); *cf.* S3 Inc. v. NVIDIA Corp., 259 F.3d 1364, 1371 (Fed. Cir. 2001) ("The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention.").

129. Transparent inventions are akin to—but not the same as—so-called "self-disclosing" inventions. *See* Strandburg, *supra* note 43, at 105–06 (coining the term). They are defined as inventions that are easy to replicate because reproduction is enabled by "mere commercialization." *Id.* at 105. In other words, the "invention itself reveals its operation," including how to make and use it. Anderson, *supra* note 42, at 1583. But a self-disclosing invention need not be transparent—that is, the invention itself might reveal how to make and use it but *not* how and why it works.

130. *See, e.g.*, Paper Clip, U.S. Patent No. 581,901 (filed Apr. 13, 1896).

131. Christopher A. Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. REV. 1543, 1559 (2016); *cf.* Lemley, *supra* note 36, at 338–39 (noting that an invention like a paper clip or a wheel is easy to discern by evaluating the product).

132. *See, e.g.*, JOHN MATOLYAK & AJAWAD HAIJA, ESSENTIAL PHYSICS 173–76 (2014). For further discussion of this hypothetical, see *infra* notes 226–228 and accompanying text.

133. The same is true for statutory enablement. *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art."), *cert. denied*, 480 U.S. 947 (1987); Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1347 (Fed. Cir. 2000) (explaining that a patent "is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention"), *cert. denied*, 532 U.S. 1019 (2001); *see also* Loom Co. v. Higgins, 105 U.S. 580, 586 (1881) (explaining that an inventor is not required to disclose what is already familiar to the PHOSITA).

134. This presupposes that the underlying science is easily understood. For the paper clip, Hooke's law is the underlying scientific principle. *See infra* text accompanying note 227.

physical product neither reveals how to make or use the invention *nor* its mechanism—meaning that this information cannot be discerned by inspection.[135] And elucidating this information through reverse engineering is difficult, if not impossible (at least without considerable effort or expense).[136] I call this type of invention *opaque* with respect to its mechanism.

To illustrate, consider again a patented method for treating baldness with Bag Balm.[137] Bag Balm is comprised of four ingredients—petroleum jelly, lanolin, paraffin wax, and 8-hydroxyquinoline.[138] The patent teaches that 8-hydroxyquinoline is the active ingredient, since it is well known in the art that petroleum jelly and lanolin do not regrow hair.[139] But the patent discloses *nothing* about how or why 8-hydroxyquinoline works. Again, such disclosure is not required to comply with the statutory enablement requirement.[140] This means that a PHOSITA who wants to figure out how or why 8-hydroxyquinoline works must engage in some experimentation—an activity that might require a license from the patentee.[141] The bottom line is that the omitted technical information will take some effort to obtain. Under the present disclosure paradigm, the inventor has no incentive to figure out the invention's mechanism before filing or, for that matter, to disclose *any* information other than that minimally required by the patent statute.[142]

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135. This is also true for non-self-disclosing inventions. *See* Lemley, *supra* note 36, at 338–39. It is worth noting that, particularly in the chemical and biotech fields, sometimes an inventor can explain how to make and use a product yet cannot identify the product by name or structure. Nevertheless, the inventor can claim the unidentified product with a so-called "product-by-process" claim, which permits recitation of the process by which it is made if there is no other way to define the invention. 3 CHISUM, *supra* note 58, § 8.05; *In re* Bridgeford, 357 F.2d 679, 682 (C.C.P.A. 1966).

136. Anderson, *supra* note 24, at 958 n.222; *see also* Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575, 1582–91 (2002).

137. *See supra* Part II.A.

138. *See* source cited *supra* note 104.

139. *See* '676 Patent, col. 2 ll. 50–55.

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

141. *See supra* note 11. In the hypothetical, an interested researcher could begin with experiments on animals to avoid infringement; however, any subsequent human experimentation would probably require a license. Cochrane v. Deener, 94 U.S. 780, 787 (1876) ("[E]ach inventor is precluded from using inventions made and patented prior to his own, except by license from the owners thereof."). But it is worth noting that many patent owners opt not to enforce their patents against academic researchers because of the high costs of detecting infringement, high litigation costs, and the low value of a potential lawsuit. *See* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1062 (2008); *cf.* F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 705 (2001). Patentees may engage in this "rational forbearance" of unlicensed use because "scientific norms still generate social pressure to share materials, particularly with nonprofit entities." Peter Lee, Note, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 677 (2004).

142. As a general matter, "under the existing regime, patentees have every incentive to disclose as little as possible." Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV.

While the courts might require more teaching to sufficiently enable a PHOSITA how to make and use an opaque invention than a transparent one (particularly if the invention emerges from an unpredictable field[143] or nascent technology),[144] there is no corresponding obligation to elucidate or disclose mechanism.[145] Those interested in mechanism must fend for themselves and try to figure it out. Placing this burden on the public rather than the inventor is the principal consequence of the nondisclosure rule.

But the rule's persistence is an anomaly. Patent law is one of the most dynamic areas of the law because it evolves as technology evolves.[146] This dynamism allows the patent system "to adapt flexibly to both old and new technologies, encompassing 'anything under the sun that is made by man.'"[147] Maintaining the nondisclosure rule, however, evinces a one-size-fits-all approach to transparent and opaque inventions, as they are treated

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207, 209 (2011) (citing R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2150–51 (2009) (discussing factors that lead applicants to limit their disclosures)); H. JACKSON KNIGHT, PATENT STRATEGY FOR RESEARCHERS AND RESEARCH MANAGERS 88–89 (2d ed. 2001) (explaining how much information an inventor should disclose). Of course, the inventor could forego patent protection altogether and opt to keep the technical information secret. *See* Strandburg, *supra* note 43, at 105–06; *see also* Lemley, *supra* note 36, at 339 ("Companies . . . who develop inventions that are not transparent to the world, such as chemical processes and some formulas—might well decide to keep an invention secret in the absence of legal protection.").

143. As previously discussed, enablement depends on the nature of the technology. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988), discussed *supra* Part I.B. An enduring approach is to classify a technological field as either "unpredictable" or "predictable." Seymore, *Heightened Enablement*, *supra* note 25, at 136–39; Seymore, *Enablement Pendulum*, *supra* note 92, at 282–84. The courts refer to fields like chemistry and biotechnology as "unpredictable" because PHOSITAs in these fields often cannot predict whether a reaction protocol that works for one embodiment will work for others. Cedarapids, Inc. *ex rel.* El-Jay Div. 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"). By contrast, applied technologies like electrical and mechanical engineering are often regarded as "predictable" because they are rooted in well-defined, predictable factors. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991). Of course, 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 a rigid dichotomy).

144. *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction.").

145. *See supra* Part II.A.

146. A famous example is the removal of judicially-imposed limitations on patent-eligible subject matter. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (holding that live, genetically engineered microorganisms are patentable after pronouncing that "Congress intended statutory [patent-eligible] subject matter to 'include anything under the sun that is made by man.'" (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952))); Rebecca S. Eisenberg, *The Story of* Diamond v. Chakrabarty*: Technological Change and the Subject Matter Boundaries of the Patent System*, *in* INTELLECTUAL PROPERTY STORIES 327, 327–57 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss eds., 2006). This responsiveness is not surprising because "any law[s] purporting to provide a regulatory foundation for innovation must be able to account for both the broad range of technologies and the rapid pace of [technological] change." R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341, 1344 (2003).

147. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003) (quoting *Chakrabarty*, 447 U.S. at 309).

similarly. The important question is whether there should be one rule that applies to all inventions or whether patent law's disclosure function can be improved by tailoring it to the specific attributes of different inventions.[148]

III. TOWARD MECHANISTIC ENABLEMENT

All agree that disclosure of mechanism in the patent document would be ideal—particularly for opaque inventions.[149] However, tinkering with disclosure doctrines raises concerns about inventor behavior, the effect on other patentability doctrines (like novelty),[150] and lingering tensions in patent law.[151] For example, *requiring* an inventor to disclose mechanism *as a condition for patentability* could postpone filing or possibly push inventors out of the patent system altogether.[152] This would give the public a delayed disclosure, or perhaps none at all.[153] But the *de minimis* statutory enablement requirement often provides the public with a less-than-robust disclosure.[154] To solve this problem, this Part offers a new disclosure paradigm.

148. *Cf.* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 203 (2004) (criticizing the one-size-fits-all regime and asking "whether we should have one set of patent rules that govern all inventions, or whether the system can be [improved] by tailoring patent rules to the specific attributes of different technologies").

149. *See* discussion *supra* Part II.C.

150. Novelty requires that an invention be new. *See supra* note 56. Determining novelty requires a comparison of the claimed invention with the prior art. *See supra* note 80 and accompanying text. One requirement for novelty-defeating prior art is that the asserted reference could have enabled a PHOSITA to make the invention without undue experimentation. *In re* Morsa, 803 F.3d 1374, 1377 (Fed. Cir. 2015); Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008). One might ask if the proposed paradigm would also require that a novelty-defeating prior art reference provide mechanistic enablement. The answer is no because, as discussed in the main text, a mechanistic disclosure would not be a condition for patentability. *See infra* Part III.A.

151. Patent law operates as an "interdependent mix of incentives and restraints that bestow benefits and impose costs on society" and "strives to strike a balance between the promotion of technological invention and the dissemination of and access to its fruits." DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 1 (3d ed. 2004).

152. *Cf.* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1567–68 (Fed. Cir. 1990) (arguing that limiting the scope of the claims to the specific embodiments disclosed to satisfy the enablement requirement of § 112 is a poor way to stimulate invention and discourages early disclosure). *See also* Seymore, *Teaching Function*, *supra* note 25, at 658 (discussing the effects of heightened disclosure requirements on inventor behavior).

153. Recall that the public gets detailed knowledge about the invention as soon as the patent document publishes. *See supra* note 36 and accompanying text. Patent documents include issued patents and published patent applications. Since 1999, most patent applications publish eighteen months after the earliest effective filing date. 35 U.S.C. § 122(b)(1)(A) (2012). Once a patent application publishes, the information it discloses is considered publicly known. *See id.* § 102.

154. For illustrations, see *supra* text accompanying notes 4–7; Part II.A.

A. New Disclosure Paradigm

Perhaps the biggest roadblock to robust disclosures is the one-size-fits-all nature of the patent system.[155] For example, an inventor who satisfies the how-to-make and how-to-use prongs of the enablement requirement of § 112(a) is *entitled* to a patent.[156] Whether to go beyond the statutory requirements and disclose additional information—such as mechanism—is a bit more complicated. On one hand, additional disclosure has several upsides for the inventor. For example, it can aid in compliance with the written description requirement of § 112(a).[157] Additional disclosure can also create patent-defeating prior art against others.[158] For example, such disclosure might render future claims obvious to try.[159] On the other hand, if the inventor plans to seek one or more subsequent improvement patents,[160] that is a reason to disclose as little as possible in the initial patent to avoid creating prior art against oneself.[161] Thus, the decision to provide additional

155. *See supra* note 148 and accompanying text.

156. The introductory clause of § 102 of Title 35 of the Patent Act states that "[a] person shall be entitled to a patent unless . . . ." 35 U.S.C. § 102(a) (2012). This creates a presumption of patentability. Seymore, *Presumption*, *supra* note 25, at 997–1014; *see also* FTC REPORT, *supra* note 69, at 9 ("[T]he courts have interpreted the patent statute to require the [Patent Office] to grant a patent application unless the [Patent Office] can establish that the claimed invention does not meet one or more of the patentability criteria. Once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the [Patent Office] can prove otherwise.").

157. "Written description" has two meanings in patent law. First, it refers to the descriptive part of the patent document. *See supra* note 29. Second, it refers to the patentability requirement that the patent document "objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc). The written description requirement is related to, but separate from, enablement. *Id.* at 1351.

158. *See, e.g.*, Douglas Lichtman et al., *Strategic Disclosure in the Patent System*, 53 VAND. L. REV. 2175, 2175–76 (2000) (discussing a research organization's strategic incentive to create prior art); Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926, 927 (2000) (same); Bill Barrett, *Defensive Use of Publications in an Intellectual Property Strategy*, 20 NATURE BIOTECH. 191, 191–93 (2002) (providing specific drafting strategies for creating prior art).

159.

> An 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.

In re Eli Lilly & Co., 902 F.2d 943, 945 (Fed. Cir. 1990); *see also* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) ("[T]hat a combination was obvious to try might show that it was obvious under § 103.").

160. An improvement patent is a patent that (as the name implies) improves on an invention disclosed and claimed in an earlier patent. JANICE M. MUELLER, PATENT LAW 18–19 (5th ed. 2016). Such patents are explicitly authorized by statute. *See* 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, *or any new and useful improvement thereof*, may obtain a patent therefor, subject to the conditions and requirements of this title.") (emphasis added).

161. *See* 35 U.S.C. § 102(a) & (b)(1) (rendering an invention unpatentable if it was disclosed more than one year before the filing of the patent application). For a discussion of more upsides to disclosing as little as possible, see *supra* note 142 and accompanying text.

disclosure involves tradeoffs.

Mindful of these tradeoffs, I propose a new disclosure paradigm to induce the elucidation and ultimate disclosure of mechanism in patent documents. The *statutory* enablement requirement would remain unchanged—disclosure of how to make and use the invention would be sufficient to obtain a patent.[162] Optionally disclosing how or why the invention works would constitute what I define as *mechanistic* enablement. The term *mechanism* comes from the realm of the experimental sciences, where it refers to a detailed picture of how a result is obtained.[163]

Of course, inventors might be reluctant to provide mechanistic enablement. Aside from the reasons noted above, inventors may balk at the additional experimentation required—or, if the information is known, may want to keep it secret.[164] To overcome these hurdles, the next two sections describe ways to get mechanistic enablement.

B. Inducing Disclosure with Broadened Claim Scope

Claims are central to every aspect of patent law.[165] They define the "technological territory" that the inventor claims is his or hers to control[166] and "provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention."[167] So patentees will seek the broadest claim scope possible.[168] But claim scope is closely tied to the amount of information that the applicant discloses in the patent application. The principal constraint on claim scope is enablement—the claim scope sought must be commensurate with the amount of enablement provided.[169] This aligns with the quid pro quo theory of patents previously discussed: the inventor must give more

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162. For a discussion of statutory enablement, see *supra* Part I.B.

163. *See, e.g.*, JOHN W. MOORE & RALPH G. PEARSON, KINETICS AND MECHANISM 2–3 (3d ed. 1981) (defining mechanism as a description of the processes involved (including atoms, molecules, individual steps) to produce an overall reaction); JAMES A. COWAN, INORGANIC BIOCHEMISTRY 24 (2d ed. 1997) ("A reaction mechanism is a detailed picture of the way reactant species are turned into products . . . .") (emphasis omitted).

164. *See supra* notes 24 and 142.

165. Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 101 (2005); *see also* Giles S. Rich, *The Extent of the Protection and Interpretation of Claims—American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990) (stating that in patent law, "the name of the game is the claim"). At the application stage the inventor "dicker[s] with the [Patent Office] to obtain an expansive exclusory right; and in litigation the parties try to convince the court to construe the claims in their favor." Seymore, *Heightened Enablement*, *supra* note 25, at 128–29.

166. Merges & Nelson, *supra* note 73, at 844.

167. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

168. Merges & Nelson, *supra* note 73, at 840; ANTHONY L. MIELE, PATENT STRATEGY 98 (2001) (arguing that applicants have an incentive "to obtain very broad claims for which a colorable argument can be made for patentability").

169. *See supra* notes 72–75 and accompanying text.

(information about the invention) to get more (claim scope).[170] Below I describe how mechanistic enablement can make it easier for applicants to obtain broader claims.

1. Enabling Generic Claims

The broadest scope of patent protection is obtained with generic claims.[171] These are claims which use functional language or generic formulas to cover embodiments of the invention that share a common attribute.[172] For example, consider a claim to a plastic-coated steel screw.[173] Given that there are thousands of different plastics,[174] the claim encompasses a genus of thousands of embodiments.[175] And since patent law does not require an inventor to actually make each embodiment claimed,[176] generic claiming can afford broad claim scope with relatively little experimentation.[177]

Although generic claims appear in all areas of technology,[178] they are ubiquitous in the chemical and pharmaceutical arts.[179] In these fields a typical generic claim has a core generic chemical structure with an array of variables appended to it—which can each represent countless chemical moieties.[180] When the number of variables on the core chemical structure is

170. *See* discussion *supra* Part I.

171. Seymore, *Heightened Enablement*, *supra* note 25, at 145–46.

172. *See* MPEP, *supra* note 119, § 806.04(d) (defining a generic claim).

173. *Cf.* Coated Metal Fastener, U.S. Patent No. 4,964,774 (filed Sept. 29, 1989).

174. Mohammed Alauddin et al., *Plastics and Their Machining: A Review*, 54 J. MATERIALS PROCESSING TECH. 40, 40 (1995).

175. These include steel screws coated with nylon, polystyrene, polyvinyl chloride, etc. '774 Patent.

176. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60 (1998) (explaining that "the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea"); Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." (quoting *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956))).

177. For criticisms, see Seymore, *Heightened Enablement*, *supra* note 25, at 145–54; Seymore, *Teaching Function*, *supra* note 25, at 628–32.

178. *See, e.g.*, LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345–46 (Fed. Cir. 2005) (determining that a generic claim covering methods of digital image compression technology which taught a single method did not enable the entire claimed genus).

179. *See* Lucille J. Brown, *The Markush Challenge*, 31 J. CHEMICAL INFO. COMPUTER SCI. 2–3 (1991) (discussing the widespread use of generic structures in chemical patents and the broad protection they convey); Ned A. Israelson & Rose M. Thiessen, *Chemical and Pharmaceutical Patents*, *in* DRAFTING PATENTS FOR LITIGATION AND LICENSING 603, 603 (Bradley C. Wright ed., 2d ed. 2008) (advising drafters of chemical patent applications to provide adequate support for claims that often covers billions of species).

180. *See In re* Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (explaining that the practice of describing a class of chemical compounds in terms of structural formulas, where the substituents are recited in the claim language, has been sanctioned by the courts). This style of claiming—ubiquitous in the chemical and pharmaceutical arts—is called Markush practice. A Markush claim is an alternative claim format that allows an applicant to define a genus or subgenus by enumeration of species. *See In*

large, and the number of possible chemical moieties is also large, the number of species encompassed by the generic claim can be millions,[181] billions,[182] or more.[183]

The breadth of generic claims brings enablement's commensurability requirement to the fore.[184] Recall that the basic premise of generic claiming is that the enablement of a few species can be extrapolated across the entire claimed genus.[185] But this premise is often dubious. In unpredictable fields, extrapolation often cannot be done with a reasonable expectation of success.[186] And when a generic claim covers millions of embodiments, enablement across the entire genus becomes particularly suspect.[187] It is the lack of commensurability—the inability to enable the entire genus—that makes generic claims vulnerable to rejection (or narrowing) at the application stage or invalidation in litigation.[188]

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re Harnisch, 631 F.2d 716, 719–20 (C.C.P.A. 1980) (explaining the history and current law of Markush practice).

181. *See, e.g.*, U.S. Patent No. 4,801,613 (filed June 17, 1987). Claim 1 recites "[a] modified bradykinin type peptide having the formula A–Arg–B–C–D–W–X–Y–Z–Arg," wherein A, B, C, D, W, X, Y, Z are each generic substructures reciting smaller peptides or amino acids. Thus, the primary generic structure contains eight smaller generic substructures. *See id.* col. 19 l. 21–37. Altogether, this claim covers 10,235,904 formulations of a peptide.

182. *See, e.g.*, U.S. Patent No. 4,838,925 (filed Sept. 25, 1987) (including a broad generic claim which covers billions of compounds).

183. For an extreme example, see U.S. Patent No. 5,422,351 (filed June 21, 1991) (including a structural formula in claim 1 which encompasses at least one novemdecillion (which is ten followed by sixty zeroes) chemical compounds).

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

185. *See In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993); *cf.* AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the [PHOSITA's] knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.").

186. *Wright*, 999 F.3d at 1564 (analyzing enablement by determining if a PHOSITA 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 covered by the genus claim); *see also In re* Prutton, 200 F.2d 706, 712 (C.C.P.A. 1952) (holding that claims to a class of chemical compounds, which were broad enough to require speculation, lacked enablement even though specific working examples were provided).

187. As explained by one commentator:

> Generic structures are allowed under the premise that a compound as a whole will exhibit specific activity regardless of what is substituted on the basic molecule. Clearly, where variable structure represents greater than three or four or ten million compounds, it is unreasonable to expect that so many compounds will exhibit activity similar to the activity shown by substances for which practical data is supplied.

Brown, *supra* note 179, at 3. But enablement is not all about numbers. Sometimes an inventor can be hard pressed to enable a very small genus. A famous example is *In re Soll*, 97 F.2d 623 (C.C.P.A. 1938), where the court affirmed the Patent Office's determination that a single working example of one member of a well-defined group of four chemical compounds was insufficient to enable the four-member genus. *Id.* at 625. Neither knowledge in the art nor any teachings in the patent document suggested that the other three members of the genus would react similarly to yield the claimed result. *Id.* at 624.

188. Commensurability is receiving more attention now that the Federal Circuit is insisting on full

Mechanistic enablement could totally change the commensurability calculus. I contend that an extrapolation argument is more plausible if the inventor can articulate the underlying *mechanism* that ties everything in the claimed genus together.

2. Illustrations

Traditional considerations for determining whether an inventor is entitled to a generic claim include "the type[s] of reactions, the state of the art, the representative nature of the examples, and the breadth of the claim[]."[189] In the illustrations that follow, I show how providing mechanistic enablement can make it easier for applicants to obtain broad generic claims.

a. Opaque Generic Claims

A generic claim covering an opaque invention is expansive in scope but covers subject matter where the mechanism cannot be readily discerned.[190] Good examples are inventions emerging from unpredictable fields like chemistry and pharmacology.[191] As previously discussed, these claims are particularly susceptible to enablement problems.[192] I contend that mechanistic enablement can bolster statutory enablement and render these claims patentable.

To illustrate, I build upon the stomach ulcer hypothetical presented in the Introduction.[193] Suppose the inventor discovered how to treat the disease by administering penicillin to affected individuals.[194] While the inventor can describe how to provide a therapeutically effective dosage and disclose data from successful use in human subjects, the inventor does not know how or why penicillin works.

The inventor files a patent application which discloses the aforementioned information and contains the following claim matrix:

1. A method of treating peptic ulcer disease comprising administering

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scope enablement. *See supra* note 92.

189. *In re* Rainer, 377 F.2d 1006, 1012 (C.C.P.A. 1967).

190. *See supra* notes 135–136 and accompanying text.

191. *See supra* note 143.

192. *See* discussion *supra* Part III.B.1.

193. *See supra* Introduction (second paragraph).

194. *See* Xavier Calvet, Helicobacter pylori *Infection: Treatment Options*, 73 (Supp. 1) DIGESTION 119, 119 (2006) (discussing an older treatment involving penicillin). Now the typical initial course of therapy includes combinations of 2-3 antibiotics with a proton pump inhibitor. *Id.* at 120; William D. Chey et al., *ACG Clinical Guideline: Treatment of* Helicobacter pylori *Infection*, 112 AM. J. GASTROENTEROLOGY 212, 219–25 (2017).

a therapeutically effective amount of a beta-lactam antibiotic.

2. A method of treating peptic ulcer disease comprising administering a therapeutically effective amount of a penam antibiotic.

3. A method of treating peptic ulcer disease comprising administering a therapeutically effective amount of penicillin.

This is a typical claim drafting strategy for a generic invention.[195] Claim 1 is the broadest and covers the genus of antibiotics containing a beta-lactam ring in their structures.[196] It covers thousands of compounds.[197] Claim 2 is narrower and covers a subgenus—here "penam" refers to the subclass of beta-lactam antibiotics that share a common bicyclic chemical structure but differ in the appended functional groups.[198] Claim 3, the narrowest claim, covers the single embodiment (penicillin) for which work was actually performed.[199] In this claim matrix the narrowest claim is almost certainly enabled, whereas the broadest claim is most susceptible to enablement attack.[200]

To begin, consider what happens if mechanistic details are not disclosed. The question is whether a PHOSITA is sufficiently enabled to practice the full scope of the claimed invention without undue experimentation.[201] A *Wands* analysis[202] reveals that the answer is probably yes for claim 3 but no for claims 1 and 2. The principal issues are the technical scope and substance of the disclosure (factors one and two), the nature of the technology (factors three and four), the PHOSITA's knowledge and skill (factor five), and the scope of the claim sought (factor seven).[203] That the underlying science is complex and unpredictable means that the patent document must provide the PHOSITA with considerable guidance because

195. *See* MPEP, *supra* note 119, § 608.01(m) (instructing applicants to draft claims so that the first claim presented is the broadest in scope); Jason Rantanen, *The Malleability of Patent Rights*, 2015 MICH. ST. L. REV. 895, 944 (2015) ("Patents rarely contain just a single broad or narrow claim, but rather consist of a series of broad and narrow claims . . . .").

196. *See* Derek J. Hook, *Production of Antibiotics by Fermentation*, *in* BASIC BIOTECHNOLOGY 433, 435 (Colin Ratledge & Bjorn Kristiansen eds., 3d ed. 2006).

197. *See* Karen Bush & Patricia A. Bradford, *β-Lactams and β-Lactamase Inhibitors: An Overview*, COLD SPRING HARBOR PERSP. MED., Aug. 1, 2016, at 1 (2016).

198. *See* Hook, *supra* note 196, at 436.

199. The narrowest claim typically covers a specific embodiment, perhaps a product that the patentee is selling to the public. JANICE M. MUELLER, MUELLER ON PATENT LAW: PATENTABILITY AND VALIDITY 2-36 (2012); JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION 6-77 to -78 (2005).

200. *Cf.* Rantanen, *supra* note 195, at 944 (explaining that claims typically "funnel down from the broad and more likely invalid, to the narrow . . . but more likely valid").

201. *See supra* note 71 and accompanying text.

202. *See* discussion *supra* notes 79–82 and accompanying text.

203. *See* discussion *supra* notes 86–89 and accompanying text.

of a lack of extant knowledge in the field.[204] Here the inventor provides actual experimental information about one embodiment—penicillin itself—which is sufficient to enable the species claim (claim 3). But there is no reason to believe that a PHOSITA could take the teaching from that single embodiment and extrapolate it across the entire penam subgenus (claim 2) or beta-lactam genus (claim 1) with a reasonable expectation of success. Thus, claims 1 and 2 are nonenabled.

But the story is quite different if the inventor provides mechanistic enablement. Suppose that after the initial breakthrough, the inventor engages in additional experimentation and identifies *Helicobacter pylori* as the bacteria involved.[205] It becomes clear that penicillin interferes with bacterial cell-wall synthesis and other cellular functions, causing the cell to degrade.[206] The inventor discloses this mechanistic information in the patent document.

This mechanistic information does two things. First, it provides the public with a very detailed disclosure—one that truly fulfills the bargained-for exchange justifying the patent grant.[207] Second, it allows the inventor to persuasively make the case for broad claim scope. For example, consider claim 2. Applying the aforementioned multifactor test,[208] it may be that the types of reactions involved, the state of the art of penam chemistry, the representative nature of the example(s) disclosed, and the number of penam antibiotics claimed—when viewed in light of the mechanistic enablement provided—justify a claim covering the entire subgenus. This is because mechanistic enablement fills a knowledge gap and allows a PHOSITA to extrapolate the teachings of work actually performed across the entire subgenus with a reasonable expectation of success.[209] As for claim 1 (the genus claim), the inventor could plausibly get *some* of its scope—bearing in mind that it covers thousands of compounds![210] The bottom line is that mechanistic enablement can bolster statutory enablement—allowing the inventor to obtain considerably broader claim scope than would have been possible without it.

204. *See supra* notes 90–91 and accompanying text.

205. *See* M. Varbanova et al., Helicobacter pylori *and Other Gastric Bacteria*, 29 DIGESTIVE DISEASES 562, 562 (2011) ("The dogma of the stomach being a sterile organ has been turned down by the discovery of *Helicobacter pylori*."). Scientific consensus of *Helicobacter pylori* as a cause of stomach ulcers came in 1994. *See id.* at 563–64.

206. Hongbaek Cho et al., *Beta-Lactam Antibiotics Induce a Lethal Malfunctioning of the Bacterial Cell Wall Synthesis Machinery*, 159 CELL 1300, 1300–11 (2014).

207. *See* discussion *supra* Part I.A.

208. *See supra* note 189 and accompanying text.

209. *See In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993).

210. *See* Bush & Bradford, *supra* note 197, at 1.

b. Transparent Generic Claims

A generic claim covering a transparent invention is expansive in scope but covers subject matter in which the mechanism can be readily discerned.[211] So this type of invention teaches its own mechanism.[212] To illustrate, consider the following hypothetical example based on the paper clip previously discussed.[213] Suppose that in 2013 an inventor identifies a problem with the standard paper clip[214]: only one end of the clip can be used to clip sheets of paper together.[215] A user must first determine the attachable end of the clip and align the paper accordingly. This adds time and effort and makes paper handling cumbersome.[216] To solve this problem, the inventor develops a double-ended paper clip; that is, "an improved paper clip which is provided with an extra loop of wire so that the clip *can be used from either end* to attach papers together."[217] The inventor files a patent application with drawings, a written description disclosing how to make and use the clip, and a single claim:

> 1. A new and improved paper clip having first and second ends, said first end including first and second internested loops positionable on opposed sides of said paper, said second end including third and fourth internested loops positionable on opposed sides of said paper, whereby said first or second end of said paper clip facilitates a conventional use thereof . . . .[218]

Since the claim language does not limit the invention to a particular size or composition of clip,[219] it broadly covers clips of various sizes and compositions.[220]

Demonstrating statutory enablement would be easy for this type of invention. The key *Wands* factors are the nature of the invention, the

211. *See supra* text accompanying note 134.

212. *See supra* note 131 and accompanying text.

213. *See* discussion *supra* Part II.C (second paragraph). The facts are loosely based on Time Saving Paper Clips, U.S. Patent No. 5,170,535 col. 1 ll. 17–28 (filed Feb. 4, 1992) (issued Dec. 15, 1992).

214. The classic "Gem" paper clip was never patented, but the machine for making the clip was patented. *See* Machine for Making Wire Paper Clips, U.S. Patent No. 636,272 (filed Apr. 27, 1899) (issued Nov. 7, 1899). The patent also discloses a picture of the clip. *Id.* at Fig. 2.

215. '535 Patent col. 1 ll. 17–19.

216. *Id.* at col. 1 ll. 23–25.

217. *Id.* col. 1. ll. 43–45 (emphasis added).

218. *Cf. id.* col. 4 ll. 60–66.

219. Many patents explicitly include broadening language in the written description to support broad claim scope. *See, e.g.*, *id.* col. 4 ll. 52–56 ("[I]t is not desired to limit the invention to the exact construction and operation shown and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.").

220. Thus, the claim covers metal clips, plastic clips, small clips, large clips, etc.

PHOSITA's level of skill, the predictability of the field, and the teaching provided.[221] First, it stands to reason that the PHOSITA's required level of skill for this type of rudimentary mechanical invention would be minimal.[222] Second, the field is predictable—meaning that the underlying technology is governed by well-defined, predictable scientific principles.[223] Thus, a PHOSITA can rely on knowledge in the field and the teaching provided in the patent document to make a broad range of paper clips, including those not explicitly described or exemplified.[224] Third, because of the nature of the invention, the PHOSITA's knowledge, and the field's predictability, the inventor need only provide a minimal amount of teaching to enable the broad claim scope sought.[225]

Because the invention is transparent to its inner workings—springiness and elasticity of the clip bind the paper—it provides its own mechanistic enablement.[226] A PHOSITA who wants to understand the physics involved could turn to readily available knowledge in the field to obtain this information:

> What . . . makes the paperclip do its job is springiness; or rather the force exerted on the papers that results from the paperclip's spring action. [The material of which the paperclip is made] has a characteristic springiness or elasticity. Its elastic behavior is described by Hooke's law . . . $F = -kX$, where F denotes force, X

221. For a discussion of the *Wands* factors, see *supra* Part I.B.

222. *Cf. Ex parte* Schnak, 2012 WL 3767506, at *2 (B.P.A.I. Aug. 23, 2012) ("[D]esigning and constructing vents in a polymer shell or cover would likely require little if any experimentation- [sic] the nature of the invention and relative level of skill in the art appear to require no more than technician-level assistance.").

223. *See supra* note 143 and cases cited therein.

224. The scope of enablement is the sum of what is taught in the patent document and the PHOSITA's preexisting knowledge. Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999); *see also In re* Wiggins, 488 F.2d 538, 543 (C.C.P.A. 1973) ("Every patent application . . . relies to some extent upon knowledge of persons skilled in the art to complement that disclosed in order that it be 'enabling' within the meaning of § 112.").

225. AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the [PHOSITA's] knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art."). *But see* ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940–41 (Fed. Cir. 2010) ("[T]he rule that a specification need not disclose what is well known in the art is merely a rule of supplementation, not a substitute for a basic enabling disclosure . . . . To satisfy the plain language of § 112, P 1, [an applicant] . . . cannot simply rely on the knowledge of [the PHOSITA] to serve as a substitute for the missing information in the specification." (internal citations and quotation marks omitted)).

226. "As to the explanation of how this paperclip works, Figure 5 [in the patent] says most of it . . . ." JEROEN DE RIDDER, RECONSTRUCTING DESIGN, EXPLAINING ARTIFACTS: PHILOSOPHICAL DESIGN AND EXPLANATION OF TECHNICAL ARTIFACTS 164 (Anthonie Meijers & Peter Kroes eds., 4 SIMON STEVIN SERIES IN THE PHILOSOPHY OF TECHNOLOGY 2007) (citing Paper Clip, U.S. Patent No. 1,985,866 (filed Nov. 23, 1933) (issued Dec. 25, 1934)).

> extension, and *k* an object's elasticity constant. Up to a material's elastic limit, the more we stretch something, the more resistance it offers to further stretching. Beyond this limit permanent deformation occurs. This is the key to paperclip behavior: flexing the loops out of their normal plane position causes them to exert a force in the opposite direction, and thus they hold the sheets of paper together.[227]

Thus, there is no need for the inventor to provide mechanistic details. And since a PHOSITA can readily extrapolate beyond the disclosed embodiment(s) to make clips of various sizes and compositions (and apply the aforementioned knowledge in the field to figure out what materials would work and which ones would not),[228] the inventor should be afforded broad claim scope (in this case, a genus of paper clips of various materials and sizes).

C. Reinvigorating an Absolute Experimental Use Privilege

A patent gives its owner "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[229] Engaging in any of these activities without authority during the patent term constitutes patent infringement.[230] However, the courts have long recognized a limitation to the right to exclude known as the experimental use exception.[231] This common-law privilege exempts an accused infringer's making or using of the invention from potential infringement liability if the activities are performed solely for experimental or non-commercial purposes.[232]

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227. *Id.*

228. *See supra* note 225.

229. 35 U.S.C. § 154(a)(1) (2012).

230. 35 U.S.C. § 271(a) (2012); *see also* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984) ("Section 271(a) prohibits, on its face, any and all uses of a patented invention."), *superseded by statute*, 35 U.S.C. § 271(e) (1994), *as recognized in* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997).

231. 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03. The defense can be traced back to an 1813 opinion by Justice Story, where he wrote that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). The law evolved until it became "well-settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

232. 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03. As explained by the noted patent scholar William Robinson in his famous treatise:

> [When the invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are

At its core, the experimental use exception is all about generating scientific knowledge.[233] Importantly for this Article, it promotes investigation to better understand the invention—including mechanism.[234] If the patent lacks this information, the exception permits experimentation to obtain it *during the patent term*.[235] Thus, the exception promotes the patent system's goal of rapid knowledge dissemination.[236]

Yet, despite the exception's solid grounding in patent policy, the Federal Circuit has become hostile to the experimental use exception.[237] The key case is *Madey v. Duke University*,[238] which explored the applicability of the exception to academic research.[239] The court held that even if the accused infringer's purpose is not commercial in nature, "so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."[240]

But a narrow experimental use exception does not align with patent law's disclosure function[241] and hinders elucidating mechanistic enablement.[242]

> sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.

3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 56 (Bos.: Little, Brown, & Co. 1890).

233. The experimental use exemption means that "a patentee will not be allowed to prevent experimentation using a patented product or process for bona fide research activities designed to further scientific knowledge." Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1073 (1988).

234. Notice of Hearings and Request for Comments on Issues Relating to Patent Protection for Therapeutic and Diagnostic Methods, 61 Fed. Reg. 10320, 10322 (Mar. 13, 1996).

235. *See supra* notes 231–232 and accompanying text.

236. Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 921 (2004).

237. *See, e.g.*, Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring) ("[I]n my judgment, the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement.").

238. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

239. *Id.* at 1362.

240. *Id*. It is worth noting that philosophical inquiry is an outdated term synonymous with the modern scientific experiment. Mueller, *supra* note 236, at 929.

241. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1022 (1989) (arguing that certain experimental uses should not give rise to infringement liability because "[i]f the public had absolutely no right to use the disclosure without the patent holder's consent until after the patent expired, it would make little sense to require that the disclosure be made freely available to the public at the outset of the patent term."); Fromer, *supra* note 66, at 558 n.93 (arguing that without the exception, the patent's disclosure is "practically unusable" until the end of the patent term).

242. Consider the views of Judge Newman, who has openly criticized the Federal Circuit's evisceration of the experimental use exception:

> The patent statute requires full disclosure of the invention, including details of enabling experiments and technical drawings . . . . Such details would be idle and purposeless if this

Kathy Strandburg explains that "when there is no exception for experimentation aimed at a *more complete understanding of the patented invention*, there is an incentive for patentees to provide a bare minimum of disclosure to satisfy a patent examiner . . . ."[243] And "for scientists and engineers, *understanding* is often, if not virtually always, a hands-on experience"[244] that requires a detailed physical exploration of how the "[p]ublished results . . . were obtained and to explore their limitations and features not presented in the published description [in the patent document]."[245] Timothy Holbrook concisely sums up the problem:

> The absence of an effective experimental use defense severely limits the ability of the patent disclosure to "teach" anything. *One can read the patent but cannot make or use the invention for purposes of exploring its function or the manner in which it works.* Unless the courts or Congress create a more robust experimental use defense, the ability of the patent disclosure to teach anything of worth to the public is curtailed.[246]

These views align with the overwhelming weight of academic opinion.[247]

My view is that the courts or Congress should create an *absolute* experimental use defense for third parties who make or use a patented invention to elucidate mechanistic details. There would be no patent infringement liability—even if the underlying research project ultimately becomes part of a commercialization effort—*as long as the technical*

> information cannot be used for 17–20 years. Indeed, there would be little value in the requirement of the patent law that patented information must be removed from secrecy in consideration of the patent right to exclude, if the information is then placed on ice and protected from further study and research investigation. To the contrary, the patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology.

Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part).

243. Strandburg, *supra* note 43, at 102 (emphasis added).

244. *Id.* at 103 (emphasis added).

245. *Id.*

246. Holbrook, *Possession*, *supra* note 66, at 140 (emphasis added).

247. *See, e.g.*, Mueller, *supra* note 236, at 975–77 (arguing that *Madey* hinders improving on earlier inventions and, consequently, hinders technological progress); Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 512–13 (2006) (explaining that a narrow experimental use exception retards innovation, competition, and consumer welfare and interferes with other policy goals of the patent system); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 457 (2004) (advocating in the wake of *Madey* and related cases a "new experimental use defense to maintain a robust, creative environment for modern science and biotechnology"). *But see* Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB. POL'Y 599, 626–32 (2009) (arguing that experimental use strips the patentee of the right to exclude).

knowledge has been or is on a trajectory toward public disclosure.[248] The burden of proving the defense in patent litigation would rest on the defendant.[249]

I bolster my proposal by drawing a parallel to the statutory use defense of 35 U.S.C. § 271(e)(1). While the Patent Act does not recognize a general statutory exemption for experimental use, Congress added a safe-harbor provision as part of the Hatch-Waxman Act of 1984 to permit the use of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ."[250] In *Merck KGaA v. Integra Lifesciences I, Ltd.*[251] the Supreme Court broadly interpreted this exemption to include upstream research (including that conducted by pioneer drug manufacturers) involving the preclinical use of patented inventions.[252] This includes the use of patented compounds for experiments on drugs that fail and are not ultimately the subject of a submission to the Food and Drug Administration (FDA).[253] So while the statutory safe harbor does not (directly) concern mechanistic information, it does reveal that the Court and Congress are willing to create an absolute experimental use exception for a clear purpose—to generate information reasonably related to regulatory approval.

My ultimate purpose for reinvigorating the experimental use exception is to incentivize knowledge dissemination.[254] I hope that the mere existence of the defense will encourage inventors to elucidate mechanism and disclose that information in the patent document. In this circumstance the defense would be unavailable. But if the inventor does not disclose mechanism in the patent, another researcher would be privileged to ascertain and ultimately disclose that information. *Either way, the public would get a detailed disclosure*.

248. For example, a university researcher might publish the details in a peer-reviewed publication. *See infra* note 296 and accompanying text. The defense would be available even if the article has not published by the time an infringement suit is docketed (but the manuscript is in preparation or under review).

249. Madey v. Duke Univ., 307 F.3d 1351, 1361 (Fed. Cir. 2002).

250. *See* Drug Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1) (2012)).

251. 545 U.S. 193 (2005).

252. *Id.* at 202–06.

253. *Id.* at 205–08.

254. *See supra* note 233.

D. Complications

1. Difficult-to-Understand Inventions

Some inventions are difficult to understand. I address this issue in more detail in Part IV;[255] for now, I acknowledge that sometimes attempts to elucidate mechanism may lead to dead ends, mystery, and frustration.[256] To be sure, the scientific community recognizes that some things cannot be understood.[257] This may explain why the nondisclosure rule proliferates: If disclosing an invention's mechanism were a condition of patentability, then difficult-to-understand inventions might never be disclosed or patented.[258] Such a requirement would, of course, interfere with the patent system's goals of discouraging secrecy,[259] preventing duplicative research,[260] and promoting early disclosure.[261]

But recall that mechanistic enablement would *not* be a condition for patentability.[262] If elucidation of the invention's mechanism proves (or seems) futile, for generic claims the status quo would apply—the inventor would need to articulate a non-mechanistic rationale to justify broad scope.[263] As for the experimental use defense, third parties who made a bona fide attempt to elucidate an elusive mechanism could still assert it.[264]

2. Risky Disclosures

The mechanistic enablement paradigm presupposes that generating more knowledge about the invention—and the eventual disclosure of that

255. *See infra* Part IV.C.

256. To illustrate, consider acetaminophen, the popular pain reliever first used clinically in 1894. Despite its popularity, researchers have been "guessing" at the drug's mechanism for decades with no proposal accumulating sufficient evidence to gain a scientific consensus. Carmen Drahl, *How Does Acetaminophen Work: Researchers Still Aren't Sure*, CHEMICAL & ENG'G NEWS, July 21, 2014, at 31, [https://perma.cc/C4T6-2LNP].

257. STUART FIRESTEIN, IGNORANCE: HOW IT DRIVES SCIENCE 35 (2012); *see also* Sarah Boxer, *Science Confronts The Unknowable: Less Is Known Than People Think*, N.Y. TIMES, Jan. 24, 1998, at B7. Perhaps the most famous example is the Heisenberg Uncertainty Principle, which states that one can never know both the position and momentum of a subatomic particle simultaneously. *Id.*; FIRESTEIN, *supra*, at 35–37.

258. *See supra* text accompanying notes 151–152.

259. For a comprehensive discussion, see Anderson, *supra* note 24, at 922–35.

260. *See* Fromer, *supra* note 66, at 548–50 (explaining that the patent system's ability to discourage duplicative research is one reason why the system can achieve its goal of stimulating innovation); Parchomovsky, *supra* note 158, at 946 (noting that "duplicative research expenditures" are socially "wasteful in the aggregate"); *cf.* Kitch, *supra* note 93, at 276 (explaining that inadequate disclosure by the first inventor leads to wasteful investigation by subsequent researchers).

261. *See* discussion *supra* Part II.B.

262. *See supra* Part III.A.

263. *See* discussion *supra* Part III.B.1.

264. *See supra* Part III.C.

knowledge—is a win-win-win for the patentee, society, and the patent system. For the patentee, mechanistic enablement would justify broad claim scope[265] by bolstering statutory enablement[266] and the closely-related written description requirement.[267] For society, mechanistic enablement would provide more detailed disclosures (which, in turn, would prevent duplicative research efforts and foster more creative activity during the patent term).[268] Finally, mechanistic enablement would allow the patent system to better fulfill its goals of promoting technological progress.[269]

But there are several reasons why an inventor may resist disclosing mechanism—even if known. First, as previously discussed, an inventor may want to retain a competitive edge.[270] Second, an inventor might fear uncovering potentially harmful information. For example, elucidating how or why a drug works could reveal that it is unsafe.[271] Such information could devalue the patent or jeopardize FDA approval.[272] Third, there is a fear that characterizing an invention or added discussion about it could *limit* claim scope.[273]

While I acknowledge these risks, I reiterate that the proposed paradigm would not *compel* disclosure of mechanistic information.[274] The inventor would have to weigh the benefits and risks of (non)disclosure, bearing in mind the experimental use defense.[275]

265. *See* discussion *supra* Part III.B.

266. For an illustration, see *supra* Part III.B.2(a).

267. *See supra* note 157 and accompanying text.

268. *See supra* notes 49 and 260 and accompanying text.

269. *See infra* note 340 and accompanying text.

270. *See supra* notes 24 and 142; Steven C. Salop & David T. Scheffman, *Raising Rivals' Costs*, 73 AM. ECON. REV. (SPECIAL ISSUE) 267, 267 (1983) (discussing the strategy from an economic perspective).

271. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 370 (2007).

272. Sherkow, *supra* note 121, at 901.

273. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1315–16 (Fed. Cir. 2005) (en banc) (reaffirming the importance of the written description in claim construction); Benjamin Hattenbach et al., *Patent Prosecution Pitfalls: Perspectives from the Trenches of Litigation*, 92 J. PAT. & TRADEMARK OFF. SOC'Y 340, 341 (2010) (explaining that the decisionmaker "will scrutinize the patent, often dissecting nearly every word," as the patent's written description "will be used as a roadmap for understanding the invention, and will be carefully examined for statements that could be asserted as the basis for restrictive (or expansive) claim constructions"); Seymore, *Teaching Function*, *supra* note 25, at 635–36 (describing several linguistic pitfalls that the patentee must avoid in order to avoid a narrow claim construction).

274. But there might be other laws, regulations, or doctrines that compel disclosure. *See infra* note 281 and accompanying text.

275. *See* discussion *supra* Part III.C.

3. Incorrect Mechanisms

Like any human endeavor, experimental science is susceptible to errors, omissions, inaccuracies, and failures.[276] And just as scientific articles can disclose incorrect mechanisms, so too can patent documents. This can happen for unintentional reasons like poor experimental design, sloppy research technique, or a flawed hypothesis. Post-publication errors in scientific articles are handled through corrective measures like erratum and retraction.[277] Such errors in granted patents are handled through the reissue process.[278]

Interestingly, most misrepresentations in the scientific literature come from intentional misconduct.[279] To prevent such behavior in patent law, mechanistic disclosures—like all disclosures—would be subject to the Patent Office's duty of candor and good faith.[280] Intentional misconduct (such as deliberately disclosing a fanciful mechanism in order to obtain broad claim scope)[281] would bar patent issuance[282] or, if the patent has already issued, render it unenforceable.[283]

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276. CHRISTY L. LUDLOW & RAYMOND D. KENT, BUILDING A RESEARCH CAREER 64 (2010).

277. DAVID H. FOSTER, A CONCISE GUIDE TO COMMUNICATION IN SCIENCE & ENGINEERING 287 (2017).

278. Under certain circumstances, the patentee can withdraw an issued patent and submit it for further examination through a reissue process if the patent is deemed defective. 35 U.S.C. § 251 (2012). One basis for reissue is that the patentee "claim[ed] more or less than he had a right to claim in the patent." *Id.* Another basis for reissue is that "the disclosure contains inaccuracies." MPEP, *supra* note 119, § 1402.

279. Ferric C. Fang et al., *Misconduct Accounts for the Majority of Retracted Scientific Publications*, 109 PROC. NAT'L ACAD. SCI. 17028 (2012); R. Grant Steen, *Retractions in the Scientific Literature: Do Authors Deliberately Commit Research Fraud?*, 37 J. MED. ETHICS 113 (2011).

280. The Patent Office imposes a duty of candor and good faith on every individual substantively involved in the patenting process—including the inventor, the attorney that prepares the patent application, and the assignee. 37 C.F.R. § 1.56(a) & (c) (2016). The duty exists with respect to each claim in a patent application, until a patent issues or the application is abandoned. *Id.* § 1.56(a); MPEP, *supra* note 119, § 2001. The rationale for the duty is that the Patent Office "must rely on [applicants'] integrity and deal with them in a spirit of trust and confidence." Kingsland v. Dorsey, 338 U.S. 318, 319 (1949). This "requires the highest degree of candor and good faith." *Id.*; *accord* Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

281. Inequitable conduct can arise if intentional misconduct (such as a deliberate misrepresentation or omission of material information from the Patent Office) leads the patentee to obtain an unwarranted patent claim. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) (citation omitted). Post-filing experimentation that reveals that a disclosed mechanism is incorrect would require action by the applicant to avoid submission of misleading technical information and a potential charge of inequitable conduct. Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1158–73 (2018).

282."[N]o patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct." 37 C.F.R. § 1.56(a); *see also* Norton v. Curtiss, 433 F.2d 779, 792–93 (C.C.P.A. 1970) (explaining that a patent cannot issue if there is inequitable conduct).

283. Inequitable conduct is an equitable defense to patent infringement. MUELLER, *supra* note 160, at 774–75. The Federal Circuit has held that a lack of candor and good faith at the application stage with respect to statutory enablement constitutes inequitable conduct. Bristol-Myers Squibb Co. v.

IV. POLICY CONSIDERATIONS

All would agree that disclosure of mechanism in the patent document would be ideal—particularly for opaque inventions.[284] Again, the ultimate beneficiary of such disclosure is the public.[285] Other researchers could immediately build upon the mechanistic details without having to waste time and resources figuring them out themselves.[286] Thus, this proposal aligns with the stated policy goals of the patent system and could bridge the disconnect between patent law and scientific norms.

A. Patents as Technical Literature

The ultimate goal of the patent system is to promote technological progress.[287] The disclosure function achieves this goal through knowledge dissemination.[288] Disclosure adds to the public storehouse of technical knowledge that others can use.[289] This "promote[s] the flow of information about inventions from patentees to potential future innovators, thereby stimulating increased and speedier follow-up innovation."[290] Theory posits that others can improve upon the invention, design around it, or conceive entirely new inventions—all during the patent term.[291]

But this theory rests on the assumption that interested researchers *actually read patents*. While some researchers certainly do,[292] it is often asserted that most do not.[293] Scholars postulate several reasons why this is the case. First, patents are hard to read; they are often written in hard-to-understand language, limiting their teaching function.[294] Second, many

Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1233 (Fed. Cir. 2003).

284. *See supra* Part II.B.

285. *See supra* note 36 and accompanying text; Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (explaining that "the ultimate goal of the patent system is to bring new . . . technologies into the public domain through disclosure" which aligns "with the very purpose of the patent laws" of providing "building blocks of further innovation").

286. *See supra* text accompanying notes 8–11.

287. *See supra* note 65 and accompanying text.

288. *See* discussion *supra* Part I.A.

289. *See* sources cited *supra* note 49. For a discussion of the storehouse, see *supra* text accompanying notes 67–75.

290. Fromer, *supra* note 66, at 599.

291. *Id.* at 548–49.

292. Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 808 n.9, 809 (1988) ("There is a significant amount of evidence showing that inventors in many fields rely on published patents for technical information . . . ."); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 548 (2012) (drawing a similar conclusion based on an empirical study).

293. *See, e.g.*, 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.").

294. Seymore, *Teaching Function*, *supra* note 25, at 633–41 (discussing the problem of

researchers deem patent disclosures unreliable—due to both the absence of a requirement for proof of concept[295] and the lack of peer review.[296] Third and relatedly, many scientists are not trained to read patents; they have learned that research funding, reputation, and tenure decisions turn on publications in peer-reviewed technical journals.[297] Fourth, patent disclosures can become stale given the lag time between filing the application and its ultimate publication.[298] Fifth, some researchers may deliberately avoid reading patents out of fear that doing so could open the door to liability for willful infringement.[299] Sixth, some researchers ignore patents because they view them as antithetical to traditional scientific norms of open sharing and discourse.[300] Finally, the disclosed information is often lacking in substance when compared to other forms of technical literature.[301]

"patentese," which is often indecipherable).

295. An inventor can obtain a patent with no actual (physical) proof of concept; meaning that an applicant need not verify that everything claimed actually works. Hyatt v. Boone, 146 F.3d 1348, 1352 (Fed. Cir. 1998); *In re* Angstadt, 537 F.2d 498, 502–03 (C.C.P.A. 1976); *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956). It is well settled in U.S. patent law that the mental act of conception of the idea, and not any physical act, is the important facet of the inventive process. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60–61 (1998). Thus, an applicant who "constructively" reduces an invention to practice by filing a patent application which describes work that has not been actually performed presumably complies with the disclosure requirements of § 112(a), including enablement. *In re* Borst, 345 F.2d 851, 855 (C.C.P.A. 1965); Yasuko Kawai v. Metlesics, 480 F.2d 880, 886 (C.C.P.A. 1973); 3 CHISUM, *supra* note 58, § 10.05.

296. Ouellette, *supra* note 292, at 571. The scientific community evaluates the quality of the research, experimental results, and accompanying explanation through a legitimization process known as peer review. Peter Hernon & Candy Schwartz, *Peer Review Revisited*, 28 LIBR. & INFO. SCI. RES. 1, 1 (2006). It ensures that each research claim is reproducible, logical, independent, and satisfies other basic conditions for communal acceptability. JOHN M. ZIMAN, REAL SCIENCE 246 (2002).

297. Seymore, *Teaching Function*, *supra* note 25, at 625.

298. Sherkow, *supra* note 121, at 904; Holbrook, *Possession*, *supra* note 66, at 144; *see also* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 216–17 (1987) (explaining how application review at the Patent Office slows the dissemination of information in the scientific community).

299. Holbrook, *Possession*, *supra* note 66, at 142 ("The doctrine of willful infringement provides another structural infirmity to the ability of patents to perform a teaching function."); Fromer, *supra* note 66, at 588 ("[T]he rule of willful infringement hinders the patent system's disclosure function."); Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1886 (2016) (explaining how the willfulness infringement doctrine creates obstacles to reading patents).

300. Eisenberg, *supra* note 298, at 181–84; Lee, *supra* note 141, at 661; *see also* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 90 (1999) (explaining that in light of the strong norm in science that "scientific knowledge is ultimately a shared resource" for the public domain, "claiming property rights in invention is often seen as immoral.").

301. *See* Devlin, *supra* note 66, at 403 (explaining how the information disclosed in many patent documents is inadequate); Sherkow, *supra* note 121, at 852 ("[I]t seems clear that patents, especially for complex or statistically bound inventions, routinely disclose information that does not meet the strictures of scientific publishing); Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 746 (2012) ("[T]he fact that many of those patents obfuscate the technology at issue, deliberately or because we lack a clear language for communicating some types of inventions, means that the payoff from reading those applications is often dubious.").

Those reading the patent may need to look elsewhere to fill in gaps.[302]

Mechanistic enablement would be a significant step toward reducing or removing these obstacles. First, patents disclosing mechanism provide more detailed technical information than those that merely explain how to make and use the invention.[303] Mechanistic enablement fills a knowledge void that future innovators need not fill themselves.[304] This avoids duplicative research and promotes technological progress.[305] Second, the proposed disclosure inducements—broader claim scope and a third-party experimental use privilege—would encourage inventors to elucidate mechanism and disclose it.[306] Either scenario would encourage inventors and innovators to read patents.

B. Reducing the Information Deficit

What occurs during patent examination is crucial given the potential strength and scope of the exclusory rights at stake.[307] The patent system relies on examiners to serve as gatekeepers charged with the task of protecting the public from the burden of improvident patents.[308] Examiners carry out this task by ensuring that claims are "examined, scrutinized, limited, and made to conform to what [the applicant] is entitled to."[309]

But the examiner's task is hindered by an information deficit. To a large extent, the assurance of a good Patent Office examination is all about information.[310] Clearly, an examiner should have in hand as much technical

302. Note, *supra* note 52, at 2025–26; *see also* Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 6 (2012) (describing the teaching function of patents as "useless," "incomplete," and "opaque"). This is why some scholars view the statutory enablement requirement as weak. *See, e.g.*, Parchomovsky & Mattioli, *supra* note 142, at 230 (explaining that "[t]he Patent Act imposes a very modest enablement requirement"); Merges & Nelson, *supra* note 73, at 845 (explaining how the enablement requirement has been applied "rather loosely"); *cf.* Fromer, *supra* note 66, at 596 (observing that "disclosure norms and rules are lax.").

303. *See supra* note 13 and accompanying text.; discussion *supra* Part I.B.

304. *See supra* text accompanying notes 8–11.

305. *See* sources cited *supra* note 260.

306. *See supra* Part III.C.

307. *Cf.* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945) (regarding the public's interest in the patent grant as "paramount" given the social and economic consequences of a patent).

308. SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE COMM. ON THE JUDICIARY, 86TH CONG., THE EXAMINATION SYSTEM IN THE U.S. PATENT OFFICE 26 (Comm. Print. 1961); Jeffrey M. Kuhn, *Information Overload at the U.S. Patent and Trademark Office: Reframing the Duty of Disclosure in Patent Law as a Search and Filter Problem*, 13 YALE J.L. & TECH. 90, 92–93 (2011).

309. Keystone Bridge Co. v. Phx. Iron Co., 95 U.S. 274, 278 (1877).

310. *Cf.* Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 748 (2009) ("The assurance of a good patent quality is all about information . . . .").

information as possible to accurately gauge patentability.[311] But, for a variety of reasons, this does not happen.[312] To begin, the examiner is disconnected from mainstream science and technology.[313] Since the examiner is not an active researcher, one cannot expect this individual to know what is happening at the frontlines of theory and experiment in the technical field. And it is at the frontlines where patent protection is often sought.[314]

Further exacerbating the problem is the inventor's information advantage. The inventor is generally a person of extraordinary skill[315] who knows more about the invention and technical field than the examiner.[316] Sometimes this leads the inventor to be strategic—sharing no more information than is absolutely necessary to satisfy the patentability criteria.[317] Such behavior compromises patent (examination) quality.[318]

Disclosing mechanism would do much to close this information gap. Elucidating mechanism takes time and effort, which places the invention further down the R&D path—generating knowledge along the way.[319] Including mechanistic information in the patent application gives the examiner a more complete picture of the invention and the surrounding

311. *See* Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123, 124 (2006).

312. *See id.* (noting that examiners making patenting decisions based on "a limited subset of available information"); Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 GEO. L.J. 637, 647 (2013) ("[T]he PTO only has the information provided by the patent applicant and whatever limited information the patent examiner is able to discover on her own.").

313. Seymore, *Patently Impossible*, *supra* note 6, at 1512–14.

314. *See, e.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1504 (2001) (suggesting that a firm may obtain a patent to "stake their claim" in an area of technology to signal to investors and competitors that it operates at the cutting edge); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 647–49 (2002) (arguing that firms obtain patents to show their R&D acumen or technological capacity).

315. Unlike the PHOSITA, patent law presumes that inventors have extraordinary skill. Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

316. Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 733 (2004); Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1357 (Fed. Cir. 2008) ("[T]he patent practice includes recognition that the inventor usually knows more about the field than does the 'expert' patent examiner."); *see also* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 53 (2007) (explaining that examiners "have backgrounds roughly related to the technology at hand, but . . . are rarely experts on the precise details of the relevant invention").

317. ADELMAN ET AL., *supra* note 13, at 579 ("Experience teaches, however, that applicant obligations of candor may be tempered by the great incentive they possess not to disclose information that might deleteriously impact their prospective patent rights."); Holbrook, *supra* note 54, at 818 (exploring the incentives for applicants to behave strategically and withhold certain information from the examiner, particularly in the absence of an adversarial check).

318. Sean B. Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. 963, 991–92 (2016) [hereinafter Seymore, *Patent Asymmetries*]. Mark Lemley has argued that "the PTO issues many patents that would have been rejected had the examiner possessed perfect knowledge." Lemley, *supra* note 314, at 1500.

319. Cotropia, *Early Filing*, *supra* note 127, at 122.

technological landscape. This not only allows the examiner to do a better job,[320] but also may strengthen the inventor's case for patentability—particularly for inventions emerging from new, poorly understood, and paradigm-shifting technologies, as well as inventions from fields with a poor track record of success.[321] And it is worth reiterating that mechanistic enablement can *bolster statutory enablement*—particularly for embodiments that the inventor has not made or tested.[322] Finally, more transparency by the inventor would improve patent (examination) quality.[323]

C. Aligning Patent Law with Scientific Norms

Patent law and science promote technological progress through the dissemination of knowledge.[324] Indeed, the two spheres have much in common when it comes to the role of disclosure in achieving certain ends. For example, in both spheres there is hope that the disclosed information will enrich the public storehouse of technical knowledge and spur further creative activity.[325] This is why both patent law and science require a disclosure that indicates successful invention and teaches something that is novel, nontrivial, and reproducible by skilled artisans in the technical field.[326] However, different knowledge transfer paradigms—early disclosure in patent law[327] and peer review in science[328]—have created a divide between the spheres that the proposed regime seeks to bridge.

One shared goal is to push back technological frontiers by emphasizing original, challenging research endeavors.[329] In patent law, the nonobviousness requirement explicitly denies patents for trivial inventions that would have come about through ordinary technological progress.[330] This induces inventors to explore challenging endeavors rather than easy ones.[331] Scientific research works the same way, giving a nod to researchers

320. Seymore, *Teaching Function*, *supra* note 25, at 653.

321. *See* Seymore, *Patently Impossible*, *supra* note 6, at 1494 (explaining the patentability hurdles for such inventions).

322. For an illustration, see *supra* Part III.B.2(a).

323. Seymore, *Patent Asymmetries*, *supra* note 318, at 1010.

324. Eisenberg, *supra* note 298, at 181.

325. *See supra* note 49 and accompanying text.

326. Seymore, *Teaching Function*, *supra* note 25, at 663.

327. *See* discussion *supra* Part II.B.

328. *See supra* note 296 and accompanying text.

329. *See supra* notes 51 and 65; CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION TO PATENT LAW 302 (2010) (explaining how, as a matter of public policy, patent law seeks to encourage scientific breakthroughs).

330. *See supra* notes 58–60 and accompanying text.

331. Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 137 (2000); Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547, 549 (2008).

who pursue difficult, risky endeavors or those with uncertain outcomes.[332] It balks at research endeavors that are "overly conservative, [and] perhaps even wasting societal resources on too-safe technology that might be spent on other human endeavors or social needs."[333]

The corollary is that challenging inventions are the ones that drive technological progress.[334] By nature challenging inventions involve uncertain outcomes; but this type of uncertainty is good for creativity.[335] Uncertainty drives innovative activity because the inability to sufficiently predict a project's outcome provides the motivation to dive in and figure it out.[336] So, if the nondisclosure rule endures out of fear that some inventions might prove too difficult to understand,[337] such reasoning undervalues uncertainty and unpredictability. As explained by one scientist:

> Every important discovery in science is by definition unpredictable. If it were predictable, it would not be an important discovery. The purpose of science is to create opportunities for unpredictable things to happen. When nature does something unexpected, we learn something about how nature works . . . . [It is] accurate to define science as organized unpredictability.[338]

The broader point is that meaningful science is, by its very nature, difficult.[339] In the realm of patent law, efforts to elucidate mechanism, and the information that flows from such efforts, could do much to promote technological progress.[340]

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332. *See* PAUL R. BEIJE, TECHNOLOGICAL CHANGE IN THE MODERN ECONOMY: BASIC TOPICS AND NEW DEVELOPMENTS 97 (1998) (discussing technological uncertainty and innovation); Göran Ekvall, *Creative Climate*, *in* 1 ENCYCLOPEDIA OF CREATIVITY 403, 407 (Mark A. Runco & Steven R. Pritzker eds., 1999) ("Innovation involves risk.").

333. Henry Petroski, *The Success of Failure*, 42 TECH. & CULTURE 321, 328 (2001).

334. Included here are serendipitous inventions—those where the inventor set out to make *X* but instead made *Y*. FIRESTEIN, *supra* note 102, at 44–45. They tend to promote technological progress particularly well because scientific principles that were seemingly well understood and settled are suddenly thrust wide open, thereby "enabl[ing] science to advance into domains of understanding that were not previously imagined." ZIMAN, *supra* note 296, at 217. After the initial bewilderment, the discovery tends to spawn two types of inquiry: basic research, which seeks to understand what happened; and applied research, which opens new frontiers for exploration. Seymore, *supra* note 102, at 210.

335. "[U]ncertainty leads to choice, and choice favors mindfulness, which paves the way for creativity." Becca Levy & Ellen Langer, *Aging*, *in* 1 ENCYCLOPEDIA OF CREATIVITY, *supra* note 332, at 45, 46.

336. *See* LEWIS M. BRANSCOMB & PHILIP E. AUERSWALD, TAKING TECHNICAL RISKS: HOW INNOVATORS, EXECUTIVES, AND INVESTORS MANAGE HIGH-TECH RISKS 44–45 (2001); *see also* GUY CLAXTON & BILL LUCAS, BE CREATIVE: ESSENTIAL STEPS TO REVITALIZE YOUR WORK AND LIFE 24 (2004) ("[U]ncertainty requires . . . creativ[ity], and creativity requires uncertainty.").

337. For a discussion of the nondisclosure rule, see *supra* Part II.A.

338. FREEMAN DYSON, FROM EROS TO GAIA 68 (1992).

339. *Cf.* ZIMAN, *supra* note 296, at 42 ("Original research is difficult.").

340. This is true even if there is a significant time lag between figuring out how to make and use the invention (statutory enablement) and how and why it works (mechanistic enablement). Perhaps the best example is aspirin, patented by Bayer in 1900. *See* Acetyl Salicylic Acid, U.S. Patent No. 644,077

D. Tensions

One potential concern of the proposed regime is that it asks the patent system to do too much. Even if all agree that understanding mechanism is an activity that should be encouraged,[341] one could argue that it can be done outside of the patent system.[342] It is certainly true that a considerable amount of basic research at universities has been produced and disclosed without patents.[343] And non-patent inducements like reputation, publication, or intellectual curiosity can lead to mechanistic disclosure.[344]

A related concern is whether the patent system is equipped to handle mechanistic enablement. Evaluating it would add an administrative burden to the Patent Office—an agency that is already strained for resources.[345] To be sure, an enablement analysis is the most formidable task that a patent examiner can undertake.[346] And it becomes more formidable for complex inventions.[347] So it is fair to ask if the examiner has the time, incentive,

(filed Aug. 1, 1898) (issued Feb. 27, 1900). It was used as a pain reliever for over 70 years before Sir John Vane elucidated the mechanism. John R. Vane, *Inhibition of Prostaglandin Synthesis as a Mechanism of Action for Aspirin-like Drugs*, 231 NATURE NEW BIOLOGY 232, 232–35 (1971). Vane's Nobel Prize-winning discovery spawned an incredible amount of aspirin research, including its use to prevent heart disease and stroke. *See* DIARMUID JEFFREYS, ASPIRIN: THE REMARKABLE STORY OF A WONDER DRUG 235–77 (2004). To the extent that the proposed paradigm could narrow the time lag, the end result would be speedier follow-on innovation and public benefit. *See* source cited *supra* note 290 and accompanying text.

341. *See* discussion *supra* Part II.C.

342. It is certainly true that in some cases, the peer-reviewed literature provides sufficient mechanistic information. *See* Ouellette, *supra* note 292, at 572 (explaining that one reason why researchers ignore patents is because the information disclosed therein is duplicative of what is available in the scientific literature).

343. Rai, *supra* note 300, at 119; *see also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1667 (1996) (arguing that patent incentives are unnecessary for federally-sponsored research since the government has already paid for it). But "it bears mention that the type of research that emerges as a result of patent incentives may be quite different from the research that would emerge in the absence of such incentives." Rai, *supra* note 300, at 119–20.

344. *See* Rantanen, *supra* note 302, at 19–20 (providing various reasons why inventors may choose to disclose, including reputational benefits). Of course, a patent might provide an additional inducement. *See* Holbrook, *Possession*, *supra* note 66, at 146 ("An inventor who anticipates obtaining a patent on an invention will be more willing to publish a scientific article or other sort of disclosure to the public, because she knows her invention will eventually be protected by a patent and not by a trade secret."). *But see* Devlin, *supra* note 66, at 416–22 (criticizing patent law's disclosure theory).

345. *See* JAFFE & LERNER, *supra* note 148, at 22 (explaining that the Patent Office lacks the resources to effectively evaluate applications); COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 81–83 (Stephen A. Merrill et al. eds., 2004) (describing the additional resources that the Patent Office will need to improve its performance).

346. Sean B. Seymore, *Reinvention*, 92 NOTRE DAME L. REV. 1031, 1034 (2017).

347. Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 67 (2010). To be sure, it is easier to gauge enablement in simple inventions like paper clips and broom rakes than in more complex inventions like chemical compounds. Seymore, *Presumption*, *supra* note 25, at 1019.

expertise, and resources to adequately evaluate mechanistic enablement.[348]

There are several responses to these concerns. First, while it is true that mechanistic enablement *can* be provided through other media, it must be remembered that some inventions are *only* disclosed in patent documents.[349] Details about many inventions never appear in the non-patent technical literature.[350] So one interested in understanding them must rely solely on the patent's disclosure.[351] If mechanistic enablement is not provided, an interested researcher must fill this knowledge void.[352] Again, the proposed regime would induce inventors to elucidate and disclose mechanism *in the patent document*, thereby avoiding duplicative third-party experimentation and allowing quicker entry into the public storehouse of technical knowledge.[353]

Second, it is certainly true that evaluating mechanistic enablement would be more demanding than statutory enablement. One concern is whether an examiner can competently evaluate mechanisms. Even though the examiner is not an active researcher,[354] the examiner has expertise in a specific technological field.[355] One would think that this expertise should be sufficient to detect implausible mechanisms. Another concern is time—examiners face time pressures and production goals.[356] The Patent Office is aware of this problem and seeks to solve it.[357] But there is another side to

348. *See* MIELE, *supra* note 168, at 97–98 (discussing examiner concerns and incentives); Noveck, *supra* note 311, at 132 (discussing examiner time and resource constraints); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 23 (2009) ("[A]n examiner has no incentive to spend more time on harder cases."). Examiners have between eight and twenty-five hours to evaluate an application. FTC REPORT, *supra* note 69, ch. 5, at 5. Examiner incentives are complicated; certain tasks "count" more for production goals, promotion, and bonus decisions than others. Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. & STAT. 817, 818 (2012).

349. Seymore, *Teaching Function*, *supra* note 25, at 656.

350. This is particularly true in industrial settings, where scientists publish relatively little. *See generally* Benoît Godin, *Research and the Practice of Publication in Industries*, 25 RES. POL'Y 587 (1996) (presenting various explanations and using bibliometrics to assess the usefulness of publication in industry). The highest priority for an industrial inventor is to generate results that show commercial promise and will ultimately find their way into a marketable product. Partha Dasgupta & Paul A. David, *Information Disclosure and the Economics of Science and Technology*, *in* ARROW AND THE ASCENT OF MODERN ECONOMIC THEORY 519, 522 (George R. Feiwel ed., 1987); *see also* Diana Hicks, *Published Papers, Tacit Competencies and Corporate Management of the Public/Private Character of Knowledge*, 4 INDUS. & CORP. CHANGE 401, 412–14 (1995) ("After all, writing papers makes no money and consumes time.").

351. Seymore, *Teaching Function*, *supra* note 25, at 664–66.

352. *See supra* text accompanying notes 8–11.

353. *See supra* notes 259–261 and accompanying text.

354. *See supra* text accompanying notes 313–314.

355. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2136–37 (2016); *see also In re* Berg, 320 F.3d 1310, 1315 (Fed. Cir. 2003) (describing patent examiners as "persons of scientific competence in the fields in which they work").

356. *See supra* note 348.

357. *See, e.g.*, Press Release, U.S. Patent & Trademark Office, Recently Announced Changes to USPTO's Examiner Count System Go into Effect (Feb. 18, 2010), http://www.uspto.gov/news/pr/2010/

the story. As previously discussed, critics have long argued that a major contributor to the patent quality problem is that examiners lack adequate technical information to conduct a rigorous examination.[358] Providing mechanistic enablement would give the examiner a more complete picture of the invention and do much to solve the information deficit.[359] This additional information might require more time to evaluate; however, this might be an appropriate tradeoff to improve patent (examination) quality.[360] So I would argue that any additional burden required for the Patent Office to evaluate mechanistic enablement would be slight in comparison to the benefits that would flow from it.

CONCLUSION

Disclosure is often touted as a principal benefit of the patent system, giving the public access to knowledge that can stimulate ideas and promote technological progress. Yet the disclosure function falls short in achieving these goals because patent law only requires minimal disclosure from the inventor. Indeed, an inventor can obtain a patent without disclosing how or why the invention works. The resulting patent has limited technical value because follow-on researchers must figure out the omitted information. This problem has intensified as inventions have become more complex over time. This Article argues that encouraging inventors to fill this knowledge void will produce more technically-robust patent documents that will allow follow-on innovators to more easily and quickly improve on current technologies and will foster the diffusion of knowledge and more creative innovation within and across disciplines. Inducing inventors to provide mechanistic disclosures would do much to bridge the gap between patent law and scientific norms. And by reinvigorating the teaching function of patents, mechanistic disclosure would allow the patent system to truly fulfill its broader mission of promoting scientific progress and extending the frontiers of knowledge.

10_08.jsp [https://perma.cc/7N6P-RVEV] (announcing changes that will give examiners more time to review applications, rebalance incentives, and improve morale).

358. *See supra* notes 316–318 and accompanying text; BURK & LEMLEY, *supra* note 348, at 51 (explaining that while the Patent Office's accessible information sources might be sufficient to gauge patentability for mechanical and chemical fields, this may not be true in fields like software where the relevant information is inaccessible to the agency).

359. For a deeper discussion of the information deficit in patent examination, see Seymore, *Patent Asymmetries*, *supra* note 318, at 991–96.

360. *See supra* Part IV.B.