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Heightened Enablement in the Unpredictable Arts

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HEIGHTENED ENABLEMENT IN THE UNPREDICTABLE ARTS

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A bedrock principle of patent law is that an applicant must sufficiently disclose the invention in exchange for the right to exclude. Essential to the disclosure requirement is enablement, which compels a patent applicant to enable a person having ordinary skill in the art (PHOSITA) to make and use the full scope of the claimed invention without undue experimentation. Enablement may be insufficient when the applicant claims an invention broadly with a dearth of supporting data or examples. This is problematic in unpredictable fields like chemistry because a PHOSITA often needs a specific and detailed teaching in order to practice the full scope of the claimed invention. Yet the current patent examination framework allows a patentee to obtain a broad claim encompassing millions of compounds enabled by a trivial amount of supporting disclosure. Such broad patent scope can have a chilling effect on other scientists who are seeking to make and use the claimed invention while the inventor does not know how to do so. In an effort to bridge the disconnect between patent law and the experimental sciences, I propose a new approach to establishing the prima facie case of nonenablement for patent applications in the unpredictable arts. After examining the PHOSITA's role in the enablement analysis, I elucidate the problems with the current framework for the enablement inquiry, propose a new framework, and explain why it mitigates problems with the current framework. I conclude by discussing some of the concerns raised by the proposed framework and explain how the proposed approach mitigates these concerns.

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INTRODUCTION

The claims are the most important part of a patent because they define the scope of the patentee's right to exclude.[1] Claim scope is central to every facet of patent law.[2] During patent prosecution,[3] applicants dicker with the

1. *See, e.g.*, Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent 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."); Rhone-Poulenc Specialties Chimiques v. SCM Corp., 769 F.2d 1569, 1572 (Fed. Cir. 1985) ("The claim defines the scope, or limits, of the right to exclude conferred by the patent.").

2. Donald Chisum explains the importance of claims and how they set forth the parameters of the invention:

> Claims measure the invention for determining patentability both during examination and after issuance when validity is challenged. They also determine what constitutes infringement. A claim recites a number of elements or limitations, and will cover or "read on" only those products (or processes) that contain all such elements or limitations. Effective claims must be neither too broad (i.e., cover the prior art or matter not adequately described in the specification) nor too narrow (i.e., fail to cover all possible embodiments of the applicant's invention).

1 DONALD S. CHISUM, CHISUM ON PATENTS, Glossary at Gl-3 (2008). Indeed, claims "are central to virtually every aspect of patent law." 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").

U.S. Patent and Trademark Office (PTO) to obtain an expansive exclusory right;[4] and in litigation the parties try to convince the court to construe the claims in their favor.[5]

A bedrock principle of patent law is that an applicant must sufficiently disclose[6] the invention in exchange for the right to exclude.[7] Thus, the scope

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3. Patent law consists of several branches. Patent prosecution describes the process by which an inventor, usually through the help of an attorney, files an application with the U.S. Patent and Trademark Office (PTO) for examination. The application contains essentially the same elements as an issued patent, including a written description, drawings, and claims. The patent prosecutor's interaction with the patent Examiner is ex parte. *See generally* ALAN L. DURHAM, PATENT LAW ESSENTIALS § 5 (2d ed. 2004) (explaining patent prosecution). Patent litigation focuses on issued patents. A patent owner whose rights have been infringed can compel an accused infringer to stop the infringing activity and pay for damages arising from the infringement that has already occurred. *See id.* § 11. On the other hand, a potential infringer can launch a "preemptive strike" against the patentee to seek a declaratory judgment that the patent is invalid. *Id.* Finally, patent licensing allows patent owners to generate royalty income by allowing others to practice the invention.

4. During patent prosecution the Examiner must afford claims their broadest reasonable interpretation. *See In re* Bass, 314 F.3d 575, 577 (Fed. Cir. 2002) ("In examining a patent claim, the PTO must apply the broadest reasonable meaning to the claim language, taking into account any definitions presented . . . .").

5. Claim construction is key in a patent infringement suit. A suit is often a bifurcated proceeding, where the court first determines the meaning and scope of the patent claims, and then compares the construed claims to the allegedly infringing device or method. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc) (finding that claim construction is a matter of law), *aff'd*, 517 U.S. 370 (1996); Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (articulating the principles of claim construction).

6. The statutory disclosure requirement has four parts, which appear in the first and second paragraphs of 35 U.S.C. § 112:

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

35 U.S.C. § 112 (2000) (emphasis added). Note that "specification" refers to the written description and the claims. *See id.* ("The specification shall contain a written description . . . [and] shall conclude with one or more claims . . . ."). Nevertheless, the terms "written description" and "specification" are often used interchangeably (and mistakenly) in patent law. DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 156 n.4 (3d ed. 2004).

7. The Court often describes disclosure as the quid pro quo for the inventor's right to exclude. *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."). In return for the right to exclude, the patent laws "impose upon the inventor a requirement of disclosure. To insure adequate and full disclosure so that upon the expiration of the [patent term] 'the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use.'" Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974) (quoting U.S. v. Dubliner Condenser Corp., 289 U.S. 178, 187 (1933)). Interestingly, the disclosure requirement can be traced back at least five centuries to the Venetian Patent Statute of 1474, which

of the claims is closely tied to the amount of information that the applicant discloses in the patent application. Essential to the disclosure requirement is enablement,[8] which compels a patent applicant to enable a person having ordinary skill in the art (PHOSITA) to make and use the full scope of the claimed invention without undue experimentation.[9] Enablement, therefore, places an outer limit on the scope of the claims.[10]

Enablement problems may arise when the applicant claims an invention broadly with a dearth of supporting data or examples. In such cases, the applicant often argues that the PHOSITA can rely on the ordinary level of skill in the art to fill in the gaps omitted from the disclosure.[11] This reasoning presents a problem in unpredictable fields like chemistry because a PHOSITA cannot fill in the gaps easily. For example, a chemist usually cannot extrapolate the result from one chemical reaction to predict how another chemical will react with any reasonable expectation of success.[12] Yet the current patent examination framework allows a patentee to obtain a broad claim encompassing millions of compounds enabled by a trivial amount of supporting disclosure.[13] And since a patentee never bears an affirmative burden of proving enablement,

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obliged "[a] person who shall build any new and ingenious device . . . not previously made . . . [to] give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated." Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC'Y 166, 177 (1948) (reprinting the statute); *see also* Craig Allen Nard & Andrew P. Morriss, *Constitutionalizing Patents: From Venice to Philadelphia*, 2 REV. L. & ECON. 223, 233–309 (2006) (examining the "constitutionalization" of patent systems, including the Venetian statute, the English Statute of Monopolies of 1624, the Intellectual Property Clause of the U.S. Constitution, and the U.S. Patent Act of 1790).

8. *See* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344 (Fed. Cir. 2005) (describing enablement as the essential aspect of the patent bargain). Although the enablement requirement is closely related to the "written description" requirement of § 112 ¶ 1, they are separate and distinct. *In re* Ruschig, 379 F.2d 990, 995–96 (C.C.P.A. 1967) (holding that when an applicant attempts to claim specific chemical compounds which were broadly disclosed, the question is not enablement, but "whether the specification discloses the compound . . . specifically, as something [the applicant] actually invented"). In any event, the two requirements often "rise and fall together" because "a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa." *LizardTech*, 424 F.3d at 1345.

9. *See infra* Part II.B.4 (discussing the judicially created undue experimentation requirement).

10. The scope of the claims must "be less than or equal to the scope of the enablement." Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). Accordingly, the scope of enablement is the sum of what is taught in the specification plus what is known by a person having ordinary skill in the art (PHOSITA) without undue experimentation. *Id.*

11. *See* Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) ("[T]he specification need not necessarily describe how to make and use every embodiment of the invention 'because the artisan's knowledge of the prior art and routine experimentation can often fill in the gaps.'").

12. *See infra* Part I.B.2 (discussing experimentation in the unpredictable arts).

13. *See infra* Part II.B (discussing the problems with the current framework).

neither in prosecution[14] nor in litigation,[15] he can sidestep the requirement. The problem here is that undue patent scope can have a chilling effect on other scientists who are trying to elucidate how to make and use the claimed invention while the inventor does not know how to do so.[16]

The issue I address in this Article, the inability of the patent laws to contend with enablement in the unpredictable arts, actually points to a broader disconnect between patent law and the experimental sciences. Unlike engineering and the applied technologies, unpredictable fields like chemistry do not lend themselves to speculation. Inventions in these fields often require confirmation through experiment, which means that a patent without working examples often becomes an invitation to experiment.

In an effort to bridge the disconnect between patent law and the experimental sciences, I propose a new approach to establishing the prima facie case of nonenablement for patent applications in the unpredictable arts. Part I begins by examining the PHOSITA's role in the enablement analysis. Here I also explain the distinction between the predictable and unpredictable arts. In Part II, I elucidate the problems with the current framework for the enablement inquiry, propose a new framework, and explain why it mitigates problems with the current framework.[17] Part III identifies potential concerns raised by the new framework and discusses how the proposal mitigates these concerns.

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14. During prosecution, the Examiner must prove nonenablement because the disclosure is presumed to be sufficient. *In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971).

15. During litigation, the patent challenger must prove nonenablement by clear and convincing evidence. Morton Int'l v. Cardinal Chem. Co., 5 F.3d 1464, 1470 (Fed. Cir. 1993) ("The court correctly required [defendant] to prove by clear and convincing evidence facts establishing lack of enablement."); *see also* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986) ("[T]he presumption [of validity] remains intact and [the burden of proof remains] on the challenger throughout the litigation, and the clear and convincing standard does not change.").

16. *See infra* Part II.B (exploring problems with the current framework).

17. This Article is the first to propose a new approach to the burden of proof required to make and to sustain a rejection for nonenablement in unpredictable technologies during patent prosecution. One commentator has discussed the policies and statutory requirements of disclosure as well as the complications particular to the unpredictable arts. *See* Brian P. O'Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure Within the Unpredictable Arts*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 147 (1996). Another commentator presents a pre-Federal Circuit doctrinal analysis of the sufficiency of disclosure challenges more generally, without emphasis on unpredictable technologies. *See* Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part I)*, 62 J. PAT. OFF. SOC'Y 217 (1980) (discussing burdens of proof); Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part V)*, 62 J. PAT. OFF. SOC'Y 387 (1980) (discussing enablement).

I. COMPARING THE ENABLEMENT INQUIRY IN THE PREDICTABLE AND THE UNPREDICTABLE ARTS

Although the patent statute does not distinguish between different fields of invention,[18] technology matters in patent law, particularly in the enablement context. Indeed, the level of skill in the relevant art "is [the] prism or lens through which a judge, jury, or the Board [of Patent Appeals and Interferences][19] views the prior art and the claimed invention."[20] Further, the judiciary encourages applicants to omit from the written description[21] that which is well known in the art.[22] But deciding what the PHOSITA knows, and whether the PHOSITA can fill in gaps omitted from the written description, lies at the heart of the enablement inquiry.

A. The Enablement PHOSITA

1. The Historical PHOSITA: An Unsophisticated "Plodder"

The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts.[23] Factors relevant to constructing

18. The U.S. Patent Act is essentially technology-neutral on its face, although several commentators argue that it is technology-specific in application. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1654–55 (2003) (exploring the pros and cons of a technology-specific system); William A. Drennan, *The Patented Loophole: How Should Congress Respond to This Judicial Invention?*, 59 FLA. L. REV. 229, 323–28 (2007) (same). But Congress added a technology-specific provision to the nonobviousness section of the statute in 1997. *See* 35 U.S.C. § 103(b) (2000) (addressing biotechnological processes). Interestingly, technological distinctions are prohibited by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which states that patent rights shall be "enjoyable without discrimination as to . . . the field of technology." TRIPS art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81, 93–94 (1994).

19. An applicant whose claims have been twice rejected by the Examiner may appeal to the Board of Patent Appeals and Interferences (Board). 35 U.S.C. § 134(a). The Board reviews adverse decisions of Examiners and determines priority of invention among contesting parties. *See* 35 U.S.C. § 6(b). The Board can affirm a rejection or reverse and remand to the examining corps. 37 C.F.R. § 1.197 (2007) (promulgating Patent Office regulations pertaining to the Board). An applicant dissatisfied with a Board decision can appeal to the Federal Circuit. 35 U.S.C. § 141.

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

21. The written description is the part of the patent application (or issued patent) that completely describes the invention.

22. *See* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art."). "He may begin at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings." Loom Co. v. Higgins, 105 U.S. 580, 586 (1881).

23. *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"). For an in-depth analysis of

the PHOSITA in a particular technical field include the sophistication of the technology and the educational level of active workers in the field.[24] Unlike inventors and patentees, whom the patent law presumes to have extraordinary skill,[25] the patent law views the PHOSITA as simply a user of the technology.

The enablement PHOSITA[26] has historically been viewed not an innovator, but rather a "plodder."[27] "If the enablement PHOSITA shows any problem-solving ability, it is in tapping the prior art to fill in gaps left by the inventor's disclosure."[28] But even under the plodder view, the educational background and experience imputed to a PHOSITA varies substantially within[29] and across[30] disciplines. Indeed, the PHOSITA's precise

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the PHOSITA concept, see generally John O. Tresansky, *PHOSITA—The Ubiquitous and Enigmatic Person in Patent Law*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 37 (1991); Joseph P. Meara, Comment, *Just Who Is the Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage*, 77 WASH. L. REV. 267 (2002).

24. *See* Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696–97 (Fed. Cir. 1983) (listing six factors relevant to a determination of ordinary skill which also include the educational level of the inventor, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made).

25. Judge Giles S. Rich describes the difference between a PHOSITA and an inventor:

> Inventors, as a class . . . possess something . . . which sets them apart from the workers of *ordinary* skill. . . . A person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate . . . .

Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985); *see also* N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1580 (Fed. Cir. 1993) (Rader, J., dissenting) (explaining that "inventors generally have extraordinary skill"); Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1189 (2002) ("Unlike the inventor, who almost by definition is presumed to be one of extraordinary skill, the PHOSITA standard contemplates some median or common level of skill." (internal citation omitted)); Dan L. Burk, *Feminism and Dualism in Intellectual Property*, 15 AM. U. J. GENDER SOC. POL'Y & L. 183, 189–90 (2006) ("Far from being one of ordinary skill, the inventor is by definition one of extraordinary skill, so that once the mental work has been completed, all that remains to be done has been characterized as the work of the mere artisan—not the work of an inventor." (internal citation omitted)).

26. There is also a nonobviousness PHOSITA. *See* 35 U.S.C. § 103(a) (2000). Unlike the enablement PHOSITA, the nonobviousness PHOSITA "is legally presumed to know all of the relevant prior art." *In re* Kleinman, 484 F.2d 1389, 1392 (C.C.P.A. 1973). For a discussion of other similarities and differences between the enablement PHOSITA and the nonobviousness PHOSITA, see Burk & Lemley, *supra* note 25, at 1185–1202, and Tresansky, *supra* note 23, at 52–54.

27. *See Standard Oil*, 774 F.2d at 454 (noting that a PHOSITA "is not one who undertakes to innovate"); *Edited & Excerpted Transcript of the Symposium on Ideas Into Action: Implementing Reform of the Patent System*, 19 BERKELEY TECH. L.J. 1053, 1060 (2004) (presenting Rebecca Eisenberg's views of the "plodder presumption" in case law); Douglas Y'Barbo, *Is Extrinsic Evidence Ever Necessary to Resolve Claim Construction Disputes?*, 81 J. PAT. & TRADEMARK OFF. SOC'Y, 567, 605 (1999) ("[I]t is bedrock proposition of patent law that the PHOSITA is not an innovator (but an applicator).").

28. Burk & Lemley, *supra* note 25, at 1190.

29. *Compare* Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1293 (Fed. Cir. 2006) (affirming the district court's finding that a PHOSITA in pharmacology has either "an advanced degree in pharmacy, biology, chemistry or chemical engineering and at least two years of experience [with the subject] . . . or a bachelor's degree in one (or more) of those fields plus five years of experience with such technology"), *with* Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1481 (Fed. Cir. 1997) (accepting the parties' contention that a PHOSITA formulating pharmaceutical compositions "is a person with an M.D. or Ph.D.").

identity is crucial to enablement because this legal concept is the prism through which one evaluates the adequacy of the disclosure.[31]

2. The PHOSITA After *KSR v. Teleflex*

As discussed above, the courts have viewed the enablement PHOSITA as an unimaginative and uncreative person. In the case of nonobviousness, on the other hand, the inquiry is traditionally what would lead a PHOSITA to combine teachings of the prior art in order to arrive at the claimed invention.[32] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and its predecessor court[33] resolved the question with the "teaching, suggestion, or motivation" (TSM) test, which deemed a patent claim obvious if some motivation or suggestion to combine the prior art teachings could be found in the prior art, the nature of the problem, or the knowledge of the PHOSITA.[34]

However, a unanimous U.S. Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* recently held that the Federal Circuit's rigid application of the TSM test is inconsistent with the "expansive and flexible" approach to the nonobviousness question set forth in prior precedent.[35] A critical flaw with

30. *See, e.g.*, Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1125 (Fed. Cir. 2000) (affirming the district court's finding that a PHOSITA in cigarette design has "a bachelor's degree in either engineering, chemistry, physics, or chemical engineering, and would have had at least five years experience in the field of cigarette design"); Dow Chem. Co. v. Am. Cyanamid Co., 816 F.2d 617, 618 (Fed. Cir. 1987) (noting that a PHOSITA in industrial chemistry "would be a Ph.D. chemist with industrial experience").

31. *See supra* text accompanying notes 19–20.

32. *See* Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356–57 (Fed. Cir. 2007) (recognizing that the U.S. Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, noted "the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination" (quoting KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1731 (2007))).

33. The Federal Courts Improvement Act of 1982 abolished the U.S. Court of Customs and Patent Appeals (C.C.P.A.). *See* Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). The successor court, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), adopted the 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) ("As a foundation for decision in this and subsequent cases in this court, we deem it fitting, necessary, and proper to adopt [the holdings of the C.C.P.A.] as precedent.").

34. *See, e.g.*, *In re* Rouffet, 149 F.3d 1350, 1355–56 (Fed. Cir. 1998) (explaining the TSM test); *In re* Bergel, 292 F.2d 955, 956–57 (C.C.P.A. 1961) ("The mere fact that it is possible to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.").

35. *See* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007). "We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way

the TSM test is the assumption that a PHOSITA lacks the creative ability to combine the teachings of the prior art:

> [The Federal Circuit erred] in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. . . . Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle . . . . *A person of ordinary skill is also a person of ordinary creativity, not an automaton.*
>
> . . . When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. . . .[36]

Thus, the post-*KSR* PHOSITA is not a plodder but a creative individual.[37]

If *KSR* also implicates the enablement PHOSITA's abilities, Examiners may have a harder time proving nonenablement. After all, an applicant could assert that the super-smart, post-*KSR* PHOSITA can readily fill in any gaps omitted from the disclosure. At least in the predictable arts,[38] it appears that the Federal Circuit will not embrace this view.[39] Nonetheless, the court's path in unpredictable fields remains uncertain.[40]

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the Court of Appeals applied its TSM test here." *Id.* (citing Graham v. John Deere Co., 383 U.S. 1 (1966); Hotchkiss v. Greenwood, 52 U.S. 248 (1851)).

36. *KSR*, 127 S. Ct. at 1742 (emphasis added).

37. For additional perspectives on the post-*KSR* PHOSITA, see Joseph Scott Miller, *Remixing Obviousness*, 16 TEX. INTELL. PROP. L.J. 237 (2008).

38. Predictable fields include applied technologies like electrical and mechanical engineering, and the unpredictable fields include the experimental sciences like chemistry and biotechnology. This classification presupposes that the electrical and mechanical arts lack unpredictable factors, and that the chemical arts lack predictability. Judge Giles S. Rich criticized this and advocated an alternative classification. *See In re* Bowen, 492 F.2d 859, 861–62 (C.C.P.A. 1974) (noting that "we do not think it hinges on whether the case is denominated 'chemical' or 'mechanical'").

39. *See infra* notes 47–50 and accompanying text.

40. Judge Moore's opinion in a recent nonprecedential opinion suggests that the court may adopt a "full scope" enablement framework in both predictable and unpredictable technologies. See *Pharmaceutical Res., Inc. v. Roxane Labs., Inc.*, 253 Fed. Appx. 26, 31 (Fed. Cir. 2007) (affirming the district court's grant of summary judgment that in the highly unpredictable field of making flocculated suspensions of megestrol acetate, three working examples did not provide an enabling disclosure commensurate in scope to cover a broad claim to "a surfactant," which was construed to cover any and all surfactants).

B. Distinguishing the Predictable and the Unpredictable Arts

1. The Predictable Arts

Historically, the judiciary has not required a specific and detailed teaching for inventions in applied technologies like electrical and mechanical engineering because they are rooted in well-defined, predictable factors.[41] In electrical engineering, for example, a PHOSITA can easily predict what will happen when circuits are combined.[42] Similarly, a PHOSITA in mechanical engineering can use thermodynamics to predict how much power a new engine will produce.[43] A simple hypothetical example illustrates this point:

> [A] specification for the invention of chopsticks would contain a description of two sticks of a given range of sizes, how sticks of appropriate dimensions could be made, and how the sticks would be positioned in the hand to be used for eating. Even if the claims were broad enough to include chopsticks with pointed and rounded tips, as well as other possible combinations of features, the above specification would be sufficiently enabling for the ordinary utensil manufacturer to produce the invention as claimed.[44]

Until recently, an applicant in the predictable arts rarely needed to show more than one embodiment to enable a broad claim.[45] The courts upheld the broad claim even if it read on other embodiments which were inadequately disclosed because applicants in predictable technologies, at least in the eyes of the court, could ordinarily rely on the knowledge of a PHOSITA to fill in gaps in the written description.[46]

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41. *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving predictable mechanical or electrical elements is less than that required for the unpredictable arts).

42. *See, e.g.*, JOHN D. CUTNELL & KENNETH W. JOHNSON, PHYSICS 577–619 (6th ed. 2004) (explaining electrical circuits).

43. *See id.* at 416–49 (explaining the laws of thermodynamics).

44. Karen S. Canady, *The* Wright *Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 457 (1994).

45. The patentee is "generally allowed [broad] claims, when the art permits, *which cover more than the specific embodiment shown*." *In re* Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944) (emphasis added); *see also* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement).

46. *In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971) (explaining that patent claims can and do cover vast numbers of inoperative embodiments "so long as it would be obvious to one of ordinary skill in the relevant art how to include those factors in such manner as to make the embodiment operative rather than inoperative").

Possibly as a result of *KSR*, however, the Federal Circuit has started to police enablement more carefully in the predictable arts.[47] For example, in *Automotive Techs., Int'l v. BMW*,[48] the court determined that a disclosure which enabled mechanical side-impact sensors was insufficient to support a broad claim encompassing both mechanical and electronic sensors because the two were "distinctively different."[49] This reflects a recent interest in "full scope" enablement which has appeared in other recent predictable-art cases, suggesting a single embodiment is no longer sufficient to enable a PHOSITA in these fields.[50]

2. The Unpredictable Arts

In contrast to the applied sciences, the judiciary has required more detailed disclosure in chemistry and the experimental sciences.[51] This requirement exists because the field of organic chemistry, for example, "is essentially an experimental science [where] results are often uncertain, unpredictable, and unexpected."[52] Indeed, a PHOSITA cannot predict if a reaction protocol which works for one compound will work for others.[53]

47. *See supra* note 40.

48. Auto. Tech. Int'l, Inc. v. BMW, 501 F.3d 1274 (Fed. Cir. 2007).

49. *Id.* at 1283–85.

50. *See, e.g.*, Sitrick v. DreamWorks, LLC, 516 F.3d 993, 1000–03 (Fed. Cir. 2008) (determining that a disclosure which enabled video games did not support a broad claim that covered movies as well as video games); Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (determining that a disclosure which enabled an injector with a pressure jacket was insufficient to support a claim that covered injectors both with and without a pressure jacket). The Federal Circuit intimated its adoption of full scope enablement a few years before *KSR*. *See* AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (explaining that a written description which only described a single embodiment of the invention, using aluminum with a certain percentage of silicon, failed to enable claims covering embodiments with other percentages of silicon).

51. The Federal Circuit has held that inventions in unpredictable technologies in early stages of development require "a specific and useful teaching." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1367–68 (Fed. Cir. 1997). This requirement exists because in these fields the PHOSITA often "has little or no knowledge independent from the patentee's instruction." Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004).

52. Schering Corp. v. Gilbert, 153 F.2d 428, 433 (2d Cir. 1946); *see also* 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.").

53. Attorney-scientist Karen Canady provides a hypothetical example from biotechnology:

> [A]n inventor develops a strategy for solving a class of problems, but has yet to demonstrate success in all applications within that class. Although the strategy may seem logical enough that one would expect it to succeed wherever applied, the unpredictability of biology raises doubts about this expectation. Difficulties arise because trial and error is normally required before a biologist can know which applications of a given strategy will succeed. Thus, it is difficult to distinguish between claimed inventions that solve an entire class of problems and those whose applicability is more limited.

Thus "the well-known unpredictability of chemical reactions [is] enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim."[54] There is a danger that embodiments not described either cannot be made or may require experimentation which is unduly extensive.[55]

The well-known case of *In re Fisher* illustrates this point.[56] The applicant in the case attempted to claim a hormone preparation which included all polypeptides having at least 24 amino acids of a specified sequence and purity.[57] The written description disclosed only a polypeptide with 39 amino acids and disclosed no products, inherently or expressly, containing other than 39 amino acids.[58] The C.C.P.A. affirmed the Board's conclusion that the written description did not enable a PHOSITA to make a hormone with other than 39 amino acids without undue experimentation:

> [T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. . . . In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.[59]

Canady, *supra* note 44, at 458. In the field of chemistry, a PHOSITA cannot even predict if a reaction protocol which works for one species will work for that same species on a larger scale. Laboratory chemists know that some reactions just do not scale up well, for reasons that are unknown.

54. *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971). An alternative test for enablement is to determine if a skilled scientist would have believed that the inventor's success with the described embodiment(s) "could be extrapolated with a reasonable expectation for success" to other embodiments encompassed by the broad claims. *In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993). One jurist explained the reasonableness in detail:

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

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

55. *See* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (explaining that "[e]nablement is lacking . . . because the undescribed embodiments cannot be made, based on the disclosure . . . without undue experimentation"); *In re* Prutton, 200 F.2d 706 (C.C.P.A. 1952) (holding that claims to a class of chemical compounds which were sufficiently broad to involve some speculation lack enablement notwithstanding the presence of the operative specific examples within the class).

56. *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970).

57. *See id.* at 835.

58. *Id.* at 836.

59. *Id.* at 839.

To hold otherwise would allow a patentee with nonenabled claims to dominate the future patentable inventions of others.[60] But even though the judiciary recognizes the unique challenges that inventions in the unpredictable arts bring to the patent system, it has struggled to adapt the old doctrinal framework of the patent laws to meet these challenges.

II. RETHINKING THE PRIMA FACIE CASE OF NONENABLEMENT

A. The Current Framework

As an initial matter, a patent application is presumed to be enabled when it is filed.[61] The burden of proof is on the PTO to show unpatentability, not on the applicant to establish patentability, and "it remains on the PTO even if the [Examiner] has made a prima facie case" of unpatentability.[62]

60. *See id.* Similarly, *In re Wright*, 999 F.2d 1557, 1564 (Fed. Cir. 1993), illustrates the potential impact of an insufficiently supported claim on science and medicine. The written description included a single working example that taught the production of a vaccine-conferring immunity in chickens against a RNA tumor virus. However, the applicant attempted to claim "*any and all* live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in *any* animal for toward *any* RNA virus." *Id.* at 1562. The court determined that the appealed claims would have provided broad patent rights for vaccines directed toward AIDS and leukemia. In affirming the Board's rejection, Judge Giles S. Rich noted that the disclosure of a single working example should be viewed as an invitation to experiment to determine whether the applicant's teaching could be extrapolated to other RNA viruses. *Id.* at 1560–62; *cf. In re* Gardner, 427 F.2d 786, 789 (C.C.P.A. 1970) (determining that the applicant's disclosure, which lacked a single specific example or embodiment, fell into the category of "an invitation to experiment" in order to determine how to make the alleged invention).

61. *See In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining that the PTO must accept the applicant's disclosure "as in compliance with the enabling requirement of [§ 112 ¶ 1] *unless* there is reason to doubt the objective truth of the statements contained therein that must be relied on for enabling support"); *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("Accordingly, applicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112."). Judge S. Jay Plager suggests that the presumption of enablement emanates from the judiciary's liberal interpretation of the patent statute:

> Logic would dictate that when an applicant seeks a grant of property from the government the applicant bears the burden of establishing entitlement to that grant. That, however, is not the rule in patent law; the rule is that the burden of persuasion is on the PTO to show why the applicant is not entitled to a patent . . . .
>
> Perhaps the explanation lies in the way that the statute is written: "A person shall be entitled to a patent unless—." 35 U.S.C. § 102 (1988). Whether a different rule would prevail if the statute said, "To be entitled to a patent, an applicant shall establish . . . " is a question that purists can debate. Whatever the case, the rule is now well established.

In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring).

62. Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1249 (1994) (citing *In re* Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (explaining that an Examiner must affirmatively prove unpatentability); *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (same)). Therefore, "[i]f the claimed invention is patentable, the applicant is entitled to a patent (because the statute says so)—not eventually, but as soon as patentability can be determined." *Id.*

If the Examiner suspects that one or more claims lack enablement, he or she must first construe the claims to determine their scope.[63] Claim construction includes defining terms that are ambiguous or are not well known in the art, while simultaneously giving the claims the broadest reasonable interpretation consistent with the written description.[64] In the rejection, the Examiner must explicitly set forth the meaning of the terms and the scope of the claim.[65] Further, the Examiner must establish that the rejection is proper by a preponderance of the evidence.[66]

To establish a prima facie case of nonenablement, the Examiner "bears an initial burden of setting forth a reasonable explanation as to why [he or she] believes that the scope of protection [sought in] that claim is not adequately enabled by the description of the invention provided in the" written description.[67] The Examiner must "explain why [he or she] doubts the truth or accuracy of any statement" and "back up [these assertions] with acceptable evidence or reasoning which is inconsistent with the contested

63. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 2164.04 (8th ed. 6th rev. 2007) [hereinafter MPEP] (instructing Examiners to construe claims before analyzing enablement); *see also In re* Volk, 634 F.2d 607, 610 (C.C.P.A. 1980) ("Though an applicant has a right to claim what 'he' regards as his invention under 35 U.S.C. § 112, it is a function of the examiner to construe the claims presented.").

64. *See supra* note 4 and accompanying text.

65. MPEP, *supra* note 63, § 2164.04.

66. *In re* Caveney, 761 F.2d 671, 674 (Fed. Cir. 1985) (explaining that patent applications are not entitled to the procedural advantages of the 35 U.S.C. § 282 statutory presumption of validity, which means that the standard of proof required to reject a patent claim is lower than that required to invalidate a patent).

67. *In re* Wright, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993); *see also In re* Armbruster, 512 F.2d 676, 677 (C.C.P.A. 1975). Judge Pauline Newman describes the burden shifting that takes place in patent prosecution:

> The *prima facie* case is a procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant. The term "*prima facie* case" refers only to the initial examination step . . . . [T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.
>
> If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.
>
> In reviewing the examiner's decision on appeal, the Board must necessarily weigh all of the evidence and argument. An observation by the Board that the examiner made a *prima facie* case is not improper, as long as the ultimate determination of patentability is made on the entire record.

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

statement."[68] The Examiner bears this burden "even when there is *no evidence* in the record of operability[69] without undue experimentation."[70]

The Examiner must write the rejection to point out specifically how the written description fails to teach a PHOSITA how to make and use the claimed invention without undue experimentation,[71] or how the enablement provided is not commensurate in scope with the protection sought by the claims.[72] The Examiner must support rejections with references.[73] In certain cases the Examiner can even use a post-filing date reference as evidence of nonenablement. For example, the Examiner can use a post-filing date reference as evidence to support his contention that a PHOSITA could not possibly practice the disclosed invention until months

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68. *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971); *see also In re* Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) ("One function of the PTO's prima facie case practice is to force the PTO examiners to set forth specific objections, which can be met by the applicant, and not just to make a general rejection.").

69. The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be "operable." *See* Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983) (explaining that a claim is inoperative when it requires an unattainable result). Lack of utility or operability and lack of enablement are closely-related grounds of unpatentability. *See* Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358–59 (Fed. Cir. 1999) (providing illustrations). Nonetheless, an applicant's assertion of operability creates a presumption that is sufficient to satisfy the statutory requirement. *In re* Langer, 503 F.2d 1380, 1391 (C.C.P.A. 1974); *accord In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

70. MPEP, *supra* note 63, § 2164.04 (emphasis added) (citing *In re* Brana, 51 F.3d at 1566) (explaining burden shifting in the utility context, which mirrors the enablement analysis). These cases make clear that neither the unpredictable nature of the art nor the possibility that the claims read on a substantial number of inoperative embodiments lowers the Examiner's initial burden:

> In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts . . . . [In any case,] it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement [with evidence or reasoning]. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

Marzocchi, 439 F.2d at 223–24 (citations omitted).

71. *See In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) ("Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation'." (quoting *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988))); *see also infra* Part II.B.4 (discussing the judicially created undue experimentation requirement).

72. *In re* Moore, 439 F.2d 1232, 1236 (C.C.P.A. 1971) ("The relevant inquiry may be summed up as being whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims.").

73. *Marzocchi*, 439 F.2d at 224; *see also In re* Brebner, 455 F.2d 1402, 1405 (C.C.P.A. 1972) (holding that the PTO must provide a factual basis for a lack of enablement rejection, rather than conclusory statements as to the level of ordinary skill in the art).

or years after the filing date.[74] However, in the case of an application which claims priority to an earlier-filed application, the Examiner cannot use a reference to show lack of enablement based on later developments in the art.[75]

Next, after the Examiner establishes a prima facie case of nonenablement, the burden shifts to the applicant to rebut the prima facie case with "persuasive arguments, supported by suitable [evidence] where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide."[76] As previously noted, the claims must be enabling as of the filing date of the application,[77] which means that the applicant cannot supplement an insufficient disclosure.[78] However, the applicant can supply post-filing date references as evidence of the level of predictability in the art as of the filing date.[79]

Finally, the Examiner "must then weigh all the evidence before [him], including the specification and any new evidence supplied by [the] applicant with the evidence and/or sound scientific reasoning previously presented in the initial rejection and decide whether the claimed invention is enabled."[80] Examiners must make the determination on the weight of all the evidence and not on personal opinion.[81] An applicant who has been twice rejected can appeal.[82]

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74. MPEP, *supra* note 63, § 2164.05(a); *In re* Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (affirming the Board's decision that an article published five years after the effective filing date established that the art was sufficiently unpredictable that a PHOSITA would not believe that the applicant's success with one embodiment could be extrapolated to others).

75. *See In re* Hogan, 559 F.2d 595, 605 (C.C.P.A. 1977) (explaining that since the applicant's effective filing date establishes enablement, references supplied to demonstrate later changes in the state of the art are impermissible).

76. MPEP, *supra* note 63, § 2164.05 (citation omitted); *see also Marzocchi*, 439 F.2d at 223.

77. *See In re* Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974) (holding that sufficiency is judged as of an application's filing date); *see also* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (explaining that in both patent prosecution and litigation the enablement determination "is made *retrospectively*, *i.e.*, by looking back to the filing date of the patent application and determining whether undue experimentation *would have been* required to make and use the claimed invention at that time").

78. *Glass*, 492 F.2d at 1232 (explaining that an applicant cannot supplement an application with later publications that add to the knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention).

79. *See Hogan*, 559 F.2d at 605 ("This court has approved use of later publications as evidence of the state of art existing *on the filing date* of an application." (citation omitted)); *Enzo*, 188 F.3d at 1374 n.10 ("In view of the rapid advances in science, we recognize that what may be unpredictable at one point in time may become predictable at a later time." (citation omitted)).

80. MPEP, *supra* note 63, § 2164.05.

81. *Id.*

82. *See supra* note 19 (explaining appeal procedures).

B. Identifying the Problem With the Current Framework

1. Constructive Reduction to Practice

In contrast to the canons for scientific research and publishing, an inventor can obtain a patent without conducting a single experiment.[83] It is well settled in U.S. patent law that conception,[84] and not any physical act, is the "touchstone" of inventorship.[85] Thus, an applicant who constructively reduces an invention to practice by merely filing a patent application presumably has complied with the disclosure requirements of 35 U.S.C. § 112.[86] This legal fiction is an artifact of the patent law's historical roots in predictable technologies.[87]

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83. Judge Pauline Newman has described the role of constructive reduction to practice in patent law:

> "Constructive reduction to practice" is a legal status unique to the patent art. Unlike the rules for scientific publications, which require actual performance of every experimental detail, patent law and practice are directed to teaching the invention so that it can be practiced. The inclusion of constructed examples in a patent application is an established method of providing the technical content needed to support the conceived scope of the invention.

Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354, 1377 (Fed. Cir. 2003) (Newman, J., dissenting); *cf.* 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)).

84. Conception "is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998).

85. Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship, the completion of the mental part of invention."). According to the Supreme Court:

> The primary meaning of the word "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented. Neither the statutory definition of the term in § 100 nor the basic conditions for obtaining a patent set forth in § 101 make any mention of "reduction to practice."

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

86. *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) ("Constructive reduction to practice occurs when a patent application on the claimed invention is filed."). The courts admit that constructive reduction to practice is legal fiction. *See, e.g.*, Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1055 (Fed. Cir. 2003) (quoting *In re* Borst, 345 F.2d 851, 855 (C.C.P.A. 1962)). Nevertheless, constructive reduction to practice is an established method of disclosure. *See, e.g.*, Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366–67 (Fed. Cir. 2006); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004).

87. *See* William D. Noonan, *Patenting Medical Technology*, 11 J.L. MED. 263, 264–69 (1990) (presenting a historical perspective of the patent system's "engineering bias").

Implicit in this legal fiction is the assumption that a PHOSITA can use the written description to practice the invention:

> [T]he inventor is in some sense speculating or guessing about the features of an invention not yet built. But even [so], the underlying assumption in patent law is that the inventor "has" the invention mentally, and so can give a sufficiently detailed description of that inventive conception—physically creating the invention is straightforward.[88]

However, unlike engineering and the applied sciences, unpredictable fields like chemistry do not lend themselves to speculation. Accepted scientific practice dictates inventions in these fields often require confirmation through experiment, which means that the written description without working examples often becomes an invitation to experiment.[89]

2. Prophetic Examples

As noted above, under the current framework, compliance with the enablement requirement does not turn on whether an inventor discloses working examples.[90] This presents a problem in unpredictable fields like chemistry where the array of chemical compounds which are structurally similar may differ radically in their properties.[91] As an alternative to working examples, courts allow inventors to satisfy enablement in other ways, including the disclosure of "prophetic" examples: These are "forms of the invention that the patentee did not actually invent but which would be within the scope of [his or] her disclosure."[92]

Prophetic examples present several problems for enabling inventions in unpredictable fields. First, in the experimental sciences, a PHOSITA cannot extrapolate a result from one particular embodiment across a broad genus

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88. Burk & Lemley, *supra* note 25, at 1174 n.77.

89. *See supra* note 60 and accompanying text.

90. *See In re* Borkowski, 422 F.2d 904, 908 (C.C.P.A. 1970) (explaining that there is no statutory basis for a working example requirement); *In re* Long, 368 F.2d 892, 894–95 (C.C.P.A. 1966) (same).

91. In cases involving "chemical compounds, many of which of course differ radically in their properties, it must appear in the specification . . . that 'the chemicals or chemical combinations included therein were generally capable of accomplishing the desired result.'" *In re* Walker, 70 F.2d 1008, 1011 (C.C.P.A. 1934) (citation omitted).

92. Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006). Prophetic examples do not automatically make a patent nonenabling. Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1577 (Fed. Cir. 1984). The key benefit of prophetic examples is their use in provisional patent applications, which are applications used to obtain an early filing date for an invention before the applicant is ready to draft a claim. *See* 35 U.S.C. § 111. But the provisional application must include a specification which satisfies the requirements of § 112. *See* New Railhead Mfg. v. Vermeer Mfg., 298 F.3d 1290, 1294–95 (Fed. Cir. 2002).

with a reasonable expectation of success.[93] This is true, for example, because minor changes in structure can result in large changes in reactivity.[94] Second, when no actual experiments are disclosed, there is a danger that the claimed invention cannot be made or is inoperative.[95] Third, a patent supported with prophetic examples poses the danger of rewarding an inventor with undue patent scope. As Timothy Holbrook points out, "[u]ndue patent scope could have a chilling affect on others who may actually be investigating how to create the prophetically claimed invention when the inventor herself may not be able to do so."[96] The chilling effect also ripples downstream because the patent becomes prior art, which is presumptively enabled.[97]

3. Generic Claims

A generic claim uses structural formulas[98] or functional language to cover embodiments that share a common attribute.[99] This style of claiming pervades the chemical and pharmaceutical arts,[100] and affords the broadest

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

94. *See supra* note 91 and accompanying text.

95. Claims are not necessarily invalid if they read on inoperative embodiments because "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances." *Atlas Powder*, 750 F.2d at 1576 (quoting *In re* Dinh-Nguyen, 492 F.2d 856, 858–59 (C.C.P.A. 1974)). But, "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." *Id.* at 1576–77 (citation omitted); *see also* Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306–07 (Fed. Cir. 2001) (determining that if the accused infringer could have shown that a "significant percentage" of embodiments with the scope of claims were inoperable, "that might have been sufficient to prove invalidity").

96. Holbrook, *supra* note 92, at 158.

97. *See In re* Sasse, 629 F.2d 675, 681 (C.C.P.A. 1980) (holding that a reference to a patent as prior art is presumptively enabled and operable, and describing how an applicant can rebut the presumption), *cited with approval in* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003) ("In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled. . . .").

98. *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 is called Markush practice. *See In re* Harnisch, 631 F.2d 716, 719–20 (C.C.P.A. 1980) (explaining the history and current law of Markush practice). A Markush claim is an alternative claim format which allows an applicant to define a genus or subgenus by enumeration of species. *See generally* V.I. Richard, *Claims Under the Markush Formula*, 17 J. PAT. OFF. SOC'Y 179 (1935) (presenting a pre-*Harnisch* comprehensive reviews of the history of Markush claiming); Richard L. Kelly et al., *Markush Claims*, 37 J. PAT. OFF. SOC'Y 164 (1955) (same); Edward C. Walterscheid, *Markush Practice Revisited*, 61 J. PAT. OFF. SOC'Y 270 (1979) (same).

99. *See* MPEP, *supra* note 63, § 806.04(d) (defining a generic claim).

100. Applicants often draft broad claims to sweep within their ambit every conceivable functionality that might show the desired reactivity. *See generally* Lucille J. Brown, *The Markush Challenge*, 31 J. CHEM. INFO. COMPUTER SCI. 2 (1991) (discussing the widespread use of Markush structures in chemical patents);

claim scope under the patent laws.[101] Indeed, a single generic claim can easily encompass millions,[102] billions,[103] or novemdecillions[104] of compounds.

Generic claims create several problems which the current framework cannot solve. First, when a generic method claim covers millions of embodiments, as they frequently do, enablement across the entire genus becomes suspect:

> 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.[105]

Yet the patentee never bears the burden of specifically identifying which species work.[106]

Second, generic claims are hard to examine. They often read on a genus where the species have disparate properties or lack a common core structure.[107] This disparity complicates and necessarily lengthens the Examiner's search, which in turn delays prosecution.[108] In the words of one experienced Examiner, dealing with generic claims is like "living under the national debt

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G.W.A. Milne, *Very Broad Markush Claims; A Solution or Problem? Proceedings of a Round-Table Discussion Held on August 29, 1990*, 31 J. CHEM. INFO. COMPUTER SCI. 9 (1991) (same).

101. *See* Brown, *supra* note 100, at 2–3 (discussing the widespread use of generic structures in chemical patents and the broad protection they convey).

102. *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. All together, this claim covers 10,235,904 formulations of a peptide.

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

104. For an extreme example, see Bis-Benzo or Benzopyrido Cyclo Hepta Piperidene, Piperidylidene & Piperazine Compounds & Compositions, European Patent No. 0,535,152 (filed June 21, 1991). One commentator conservatively calculates that the number of compounds covered by the patent is at least one novemdecillion (which is 10 followed by 60 zeroes). *See* Mario Franzosi, *Markush Claims in Europe*, 25 EUR. INTELL. PROP. L. REV. 200, 200 (2003).

105. Brown, *supra* note 100, at 3.

106. *See supra* Part II.A.

107. *See* Milne, *supra* note 100, at 11–12 (explaining the difficulty in examining Markush-type generic claims).

108. The slowdown drains the resources of the PTO, delays the prosecution of other applications in queue, and consequently postpones the introduction of the claimed invention and other inventions into the marketplace. Some possible solutions include charging applicants incrementally for the Examiner's search time or for the number of embodiments encompassed by the claims. *See id.* (presenting various solutions to generic claiming).

or with [a] teenager."[109] He further explains that the courts and the patent bar have struck down inventive solutions which have emerged from the examining corps:

> Beginning about 1970, we tried to apply the appropriate statutes .... [For example,] we rejected the claims in many applications for not having an enabling disclosure for making all of the compounds ....
>
> There is a strong presumption of [enablement, which favors the applicant]. ... Over the decade of 1970–1980, the courts pretty much went against us. *It is rare now for an examiner to be sustained for making enablement-type rejections against a broad [generic] claim.*
>
> Around 1980, we decided to change our approach .... [For example, in 1986 we proposed raising examination fees to be commensurate in scope with the work involved, which the patent bar rejected.] We are now left with a situation where we don't have many tools to handle these [generic] claims.[110]

As I discuss below, time pressures and the PTO's incentive system makes it nearly impossible for an Examiner to rigorously examine a complex generic claim.[111]

Third and relatedly, the cumulative effect of the PTO's burden of proof, constructive reduction to practice, prophetic examples, and the Examiner's time pressures, and is that the present system is hard pressed to prevent a patentee from using generic claims to obtain protection which far exceeds the disclosure provided. From a scientific standpoint, as discussed above, undue patent scope can have a chilling effect on other scientists who are trying to elucidate how to make and use the claimed invention while the inventor does not know how to do so.[112]

4. What Constitutes "Undue Experimentation"

An enabling disclosure must teach a PHOSITA how to practice the claimed invention without "undue experimentation."[113] This judicially created doctrine seeks to determine if undue experimentation is required to practice the invention as of the filing date of the patent application.[114] The

109. *Id.* at 11.

110. *Id.* at 11–12 (emphasis added).

111. *See infra* Part II.B.6.

112. *See* text accompanying *supra* note 96.

113. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("The term 'undue experimentation' does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation." (citation omitted)); *accord In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) (citing *Wands*, 858 F.2d at 737).

114. *See supra* note 77 and accompanying text.

Federal Circuit considers a nonexhaustive list of factors to answer this question. These factors include (1) the nature of the invention, (2) the breadth of the claims, (3) the level of predictability of the art, (4) the quantity of experimentation necessary, (5) the presence or absence of working examples, (6) the amount of direction presented, (7) the prior art, and (8) the relative skill of those in the art.[115] These factors are, at least in principle, quite sensitive to the nature of the art. The presence of factors (2), (5), and (8) make it clear that elucidating what constitutes undue experimentation is the linchpin of the enablement inquiry in the experimental sciences.

This view of what constitutes undue experimentation fails to recognize the realities of the experimental sciences and points to the larger issue of the disconnect between the judicial bench and the laboratory bench. To illustrate the nature of this disconnect, consider first that in the eyes of the judiciary, a large quantity of experimentation is not necessarily undue:

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . . .[116]

In re Angstadt further illustrates this point.[117] The broad claims at issue, which read on thousands of species, covered a method for catalytically transforming a class of organic compounds. Although the applicant disclosed forty examples, the Board agreed with the Examiner that the specification left "too much to conjecture, speculation and experimentation" and was insufficient to support the broad claim because: (1) the forty examples did not teach across (and were not representative of) the entire genus; and (2) the written description did not disclose those factors which would allow a PHOSITA to produce the claimed product.[118] Yet the panel majority reversed, explaining that requiring a more detailed disclosure had drawbacks:

> To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of

115. *See Wands*, 858 F.2d at 737. In subsequent cases, the court determined that the *Wands* factors are illustrative and not mandatory. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) ("[I]t is not necessary that a court review all the *Wands* factors to find a disclosure enabling . . . ."). "What is relevant depends on the facts . . . ." *Id.*

116. *Wands*, 858 F.2d at 737 (citations omitted).

117. *In re* Angstadt, 537 F.2d 498 (C.C.P.A. 1976).

118. *Id.* at 501–02.

> examples . . . . More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.[119]

The unfortunate consequence is that a PHOSITA wanting to practice the invention must bear the task of engaging in time-insensitive experiments to figure out which catalysts work and which catalysts do not work.

Second, within the realm of unpredictable arts, the Federal Circuit's willingness to deem experimentation undue appears to vary across the experimental sciences.[120] In newer fields like biotechnology, the Federal Circuit appears more willing to deem experimentation undue,[121] possibly because the judges themselves do not understand the underlying science.[122]

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119. *Id.* at 502–03 (citation omitted).

120. In other words, there are degrees of unpredictability. *See, e.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1377 (Fed. Cir. 1999) (affirming a district court's determination that antisense technology was highly unpredictable and that the teachings provided virtually no disclosure of the practice of antisense in cells other than E. coli, and concluding that the breadth of enablement was not commensurate in scope with the claims because the quantity of experimentation required to practice antisense in cells other than E. coli as of the filing date would have been undue).

121. *See* Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1367–68 (Fed. Cir. 1997) ("Where, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching."); 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."); *In re* Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (affirming the Board's determination that as of the applicant's filing date, the claimed methods for the biotechnological invention were "fraught with unpredictability" and "would have required extensive experimentation that would preclude patentability"); *In re* Vaeck, 947 F.2d 488, 495–96 (Fed. Cir. 1991) (affirming the Board's determination that the applicant's limited disclosure could not teach a PHOSITA how to practice the invention with undue experimentation due to the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, the corresponding high level of unpredictability, and the breadth of the claims).

122. Several commentators suggest that the Federal Circuit and other courts hearing patent cases may not understand the science that they encounter. *See* Burk & Lemley, *supra* note 25, at 1197 ("Even the Federal Circuit, which does not suffer nearly so much from these limitations, is not in a position to fully understand all of the science it encounters."). One jurist openly described the problem faced by the appellate bench:

> Appellant's specification is long and complicated, and such explanation of operation as is given is expressed in language which . . . is not comprehensible, although the physical structure itself is capable of being understood. The specification does not conform to any scientific or engineering principles of which we have been able to obtain any knowledge. Should we reverse the experts and grant the patent sought, it would be a "leap in the dark," so far as this court is concerned, and we would be entirely unable to say what the patent is really for, or what measure of protection appellant is receiving. We have no way of ascertaining whether the device . . . will do the things claimed for it.

By contrast, the court seems more willing to permit a high level of experimentation in older technologies like chemistry.[123] Whether this is due to the judiciary's comfort with chemistry or the accumulation of a substantial body of chemical patent cases, the inherent unpredictability of science and the trial-and-error approach to research must be accounted for in any enablement analysis.

5. The Inability to Test Enablement Post-Issuance

A PHOSITA cannot test enablement in a patent post-issuance without risking infringement. Although a common law experimental-use exception to infringement for testing and verifying the patented invention can be traced back to the early nineteenth century,[124] in a handful of opinions the Federal Circuit has essentially nullified the doctrine.[125] As a result, a PHOSITA probably cannot experiment with the patented technology without

In re Perrigo, 48 F.2d 965, 966 (C.C.P.A. 1931). Arti Rai suggests that the Federal Circuit should defer to the technical expertise of the PTO in certain circumstances:

> The amount of technical knowledge that an appellate court can wield—even a specialized court like the Federal Circuit—is quite limited. To be sure, the Federal Circuit has a few judges who are technically trained. Federal Circuit judges are also assisted by a small technical staff and by law clerks who generally have both legal training and some technical background. Nonetheless, technically adept judges, a small technical staff, and technically adept clerks are not—and indeed could not be—trained in every area of science or technology in which patent disputes might arise. Moreover, because scientific knowledge is highly localized, training in one area of science or technology simply does not transfer into other areas. By contrast, the PTO has thousands of patent examiners with training in multiple different fields of technology. In the area of biotechnology alone, for example, the PTO has over 150 Ph.D.s.

Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1068–69 (2003) (internal citations omitted).

123. Indeed, the court has stated that "[i]n view of the rapid advances in science, we recognize that what may be unpredictable at one point in time may become predictable at a later time." *Enzo*, 188 F.3d at 1374 n.10.

124. The doctrine has been traced back to Justice Joseph Story's opinion in *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813), in which 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."

125. In *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), the court held that the experimental use exception is "truly narrow" and does not protect experiments which further the legitimate business interests of the alleged infringer. Congress subsequently carved out an additional exception for generic drugmakers that submit information to the FDA for approval. *See* 35 U.S.C. § 271(e) (2000). In *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), Judge Arthur J. Gajarsa wrote that "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, 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." For a deeper discussion of the role of the eviscerated experimental use defense in the disclosure function of patents, see Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 139–46 (2006).

seeking a license. Therefore, it is even more imperative that the PTO scrutinize the disclosure carefully at the outset. Otherwise nonenabled, invalid patents will proliferate.

6. Additional Considerations

Finally, identifying the problems with the current framework requires consideration of specific challenges faced by the Examiner. First, the decisional law and PTO policies resolve doubts as to patentability in favor of the applicant,[126] which provides an Examiner little incentive to assemble the substantial evidence required to support a nonenablement rejection.[127]

126. *See, e.g.*, Carl Shapiro, *Patent System Reform: Economic Analysis and Critique*, 19 BERKELEY TECH. L.J. 1017, 1019 (2004) ("[T]the systems for patent issuance and patent litigation are tilted in favor of patent applicants and patent holders."). Christopher Leslie describes how a Federal Trade Commission (FTC) report reached a similar conclusion:

> Evidentiary standards provide an additional obstacle to PTO examiners denying patent applications. The examiner essentially has the burden of proving nonpatentability rather than the applicant being compelled to establish patentability. The FTC concluded in its report that "[t]he allocation of burden, coupled with examiners' limited ability to probe applicants' assertions, may explain the significant presumptions that favor applicants during patent examinations. Many of the key issues are rebuttably presumed in the applicant's favor." Yet the presumption is extremely difficult to rebut because "the PTO lacks testing facilities, and assertions that cannot be overcome by documentary evidence promptly identifiable by the examiner often must be accepted. . . ." [T]he constraints of time, information, and evidentiary standards create a situation where "[t]he PTO's evaluation of a patent may be so poor or hurried as to be near meaningless." The result is the issuance of invalid patents.

Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 108–09 (2006) (quoting FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch.5, at 9 (2003), and Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 667–68 (2002)). During its early years the Federal Circuit took the opposite position: "[T]he premise that doubts as to patentability should be resolved in favor of a patent applicant is now defunct. . . . Indeed, if patents were issued based on resolving doubts in an applicant's favor, the presumption of validity would lose its legitimacy." *In re* Andersen, 743 F.2d. 1578, 1580 (Fed. Cir. 1984) (per curiam).

127. As one commentator observes, "an examiner faced with a determined applicant has every incentive to give in and allow the patent." Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 75 (2004); *see also* Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 944 (2004) (mentioning the strategy of "wearing down the examiner" to obtain a patent).

Second, the PTO's compensation system emphasizes throughput[128] and favors allowance.[129] Current PTO practices reward Examiners for certain activities and not for others.[130] For example, the first Office Action[131] and a final allowance or rejection "count" toward the Examiner's productivity quota, but searching the prior art, applicant interviews, other correspondence with the inventor, and subsequent (including the final) Office Actions do not.[132] Indeed, one commentator notes that a savvy Examiner maximizes his monetary and performance rewards in a particular case by rejecting the application once, issuing one Office Action, and then allowing it.[133]

Third, the likelihood of Board reversal likely influences Examiner behavior. For example, in 2005 the Board affirmed the Examiner in about 55

128. The amount of time the PTO allots for an Examiner to dispose of a case depends on factors like seniority and the technology involved. *See* John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314 (2001) (explaining Examiner time management). Thomas estimates that the average time allotment is between 16 and 17 hours. *See id. But see* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 n.19 (2001) (providing time estimates from other commentators and PTO officials which range from 8 to 32 hours, depending on the technology).

129. *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT? 34–35 (2004) ("[The PTO] has become so overtaxed, and its incentives have become so skewed towards granting patents, that the tests . . . that are supposed to ensure that the patent monopoly is granted only to true inventors have become largely non-operative."); Farrell & Merges, *supra* note 127, at 944–45 (discussing biased procedures at the Patent Office which favor hasty Examiner analysis and skewed incentives); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 609 (1999) (observing that "[t]he current bonus system is believed to skew incentives in favor of granting patents").

130. *See generally* MPEP, *supra* note 63, § 1705 (describing the procedures for crediting an Examiner's activities on the Examiner's Case Action Worksheet and the Biweekly Examiner Time and Activity Report).

131. An Office Action is an official communication from the PTO stating the Examiner's position on patentability and the basis for any claim rejections. *See* 37 C.F.R. § 1.104 (2007).

132. *See* David Hricik, *Aerial Boundaries: The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage*, 44 S. TEX. L. REV. 205, 228 (2002) (explaining that Examiners have a monetary incentive to grant applications and a disincentive to engage in an extensive prior art search).

133. *See* Nikolas J. Uhlir, Note, *Throwing a Wrench in the System: Size-Dependent Properties, Inherency, and Nanotech Patent Applications*, 16 FED. CIR. B.J. 327, 340 n.88 (2006) (explaining the "count" system). Although final allowances and rejections both count, the incentive system favors allowance. As Mark Lemley observes, "[E]xaminers must write up reasons for rejection, but not reasons for allowance, giving them more incentives to allow rather than reject an application." Lemley, *supra* note 128, at 1496 n.3; *see also* Thomas, *supra* note 128, at 324–25 ("The belief is widely held that this regime encourages examiners to allow rather than to reject applications."). Thomas suggests that the current regime represents an effort to close prosecution in a timely fashion. *Id.* at 325.

percent of cases.[134] Attorney-Examiner Jeffrey Friedman calculates that there has been about a 25-fold reduction in the likelihood of affirmance between 1960 and 2002.[135] Fear of reversal may lead an Examiner to allow marginal patent applications, which reduces patent quality.[136] It may also induce applicants to appeal more frequently, or at least to threaten to do so.[137]

Fourth, even if the Board sustains an enablement rejection, the level of deference that the Federal Circuit should afford the PTO's determination of enablement remains unsettled.[138] Although the PTO's incentive structure and the Examiner's time pressures suggest that the facts underlying a patent grant should be viewed with caution, for a patent denial "the fact-finding associated with the [Examiner's] analysis is much more likely to be accurate."[139] This result occurs because the Examiner must support the denial with technical evidence, which is reviewed by the Board whose members are often

134. Jeffrey Fredman, *Silence Is Not Always Golden: Why Decisions of the Board of Patent Appeals and Interferences Should Be Precedential*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 859, 865 (2006) (presenting empirical data).

135. *See id.* Fredman argues that since the Federal Circuit tends to affirm the handful of Board decision it reviews, it is clear that the Board "has incentives to reverse examiners apart from the merits of the particular case." *Id.* at 872. These incentives include "reducing the backlog of appeals by discouraging examiners from responding to appeal briefs, achieving production goals, and increased likelihood of affirmance at the [Federal Circuit]." *Id.*

136. *See id.*

137. *See* Lemley & Moore, *supra* note 127; Farrell & Merges, *supra* note 127.

138. Enablement is a question of law based on underlying factual determinations. *In re* Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000). The court reviews the Board's underlying findings of fact for substantial evidence and reviews its ultimate conclusion whether a disclosure is enabling de novo. *Id.*; *see also In re* Gartside, 203 F.3d 1305, 1311–16 (Fed. Cir. 2000) (per curiam) (discussing the standards of review for PTO determinations (citing Dickinson v. Zurko, 527 U.S. 150, 161–65 (1999) (holding that the Federal Circuit must use the standards set forth in the Administrative Procedures Act when reviewing findings of fact made by the Patent Office))). Some commentators argue that the Federal Circuit should apply the framework set forth in *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), to adjudicate mixed questions of law and fact. *See, e.g.*, Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199, 221–26 (2000). Nonetheless, the Federal Circuit recently noted that "the Board does not earn *Chevron* deference on questions of substantive patent law." Brand v. Miller, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 650 (2007). The Federal Circuit's nondeferential view has emerged over the past two decades:

> As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings before the [PTO]; it does NOT grant the Commissioner the authority to issue substantive rules. . . . [Since] Congress has not vested the Commissioner with any general substantive rulemaking power . . . , the rule of controlling deference set forth in *Chevron* does not apply.

Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (quoting *Animal Legal Def. Fund*, 932 F.2d at 930).

139. Arti K. Rai, *Allocating Power Over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L.J. 907, 912 (2004).

skilled in the relevant law and science.[140] As Arti Rai argues, this review "is hardly a rubber stamp for examiner decisions to deny a patent."[141]

C. The Proposed Framework

1. The Examiner as Gatekeeper

I propose a new approach to establishing the prima facie case of nonenablement for patent applications in the unpredictable arts.[142] This approach maintains elements of the present framework but allows the Examiner to more easily satisfy his initial burden under certain conditions. One question that must be answered at the outset is whether the PTO is the best institutional candidate to contend with nonenablement. I contend that the Examiner, as the gatekeeper of the patent system,[143] is uniquely poised to derail nonenabled patents for two reasons. First, as I previously discussed, a PHOSITA cannot test enablement in a patent post-issuance without risking infringement.[144] Consequently, the Examiner becomes the key safeguard in preventing the issuance of nonenabled (and per se invalid) patents.[145] Second and relatedly, the PTO as gatekeeper has

140. "Many Board members . . . are experienced former senior examiners. Due to their technical expertise as well as their opinion writing experience as administrative judges, they are more than capable of providing the adequate fact finding required by our cases . . . ." Gechter v. Davidson, 116 F.3d 1454, 1459 (Fed. Cir. 1997); *see also In re* Moore, 444 F.2d 572, 574 (C.C.P.A. 1971) ("We also acknowledge the technical expertise of the individual members of the [B]oard in making findings of technical fact based upon their own knowledge and experience.").

141. Rai, *supra* note 139, at 912.

142. I agree with Judge Giles S. Rich that the enablement inquiry is highly dependent on the facts of a particular case. *See In re* Metcalfe, 410 F.2d 1378, 1382 (C.C.P.A. 1969) ("[W]hether a given disclosure which identifies a material to be employed in the practice of the claimed invention is 'enabling' within the meaning of 35 U.S.C. § 112, must be decided by a rule of reason applied to the facts of the case.").

143. The patent examiner is a quasi-judicial official. United States v. Am. Bell Tel. Co., 128 U.S. 315, 363 (1888) ("The patent . . . is the result of a course of proceeding, *quasi*-judicial in its character . . . ."); Butterworth v. United States, 112 U.S. 50, 67 (1884) ("That it was intended that the Commissioner of Patents, in issuing or withholding patents . . . should exercise *quasi*-judicial functions, is apparent from the nature of the examinations and decision he is required to make . . . ."). Several commentators have recognized the gatekeeping function of the PTO. *See, e.g.*, Craig A. Nard, *Legitimacy and the Useful Arts*, 10 HARV. J.L. & TECH. 515, 541 (1997) (arguing that the PTO rather than the courts "is better positioned to act as a gatekeeper of the patent and technological lexicons, with each examiner . . . assuming the role of lexicologist"); John R. Thomas, *On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation*, 47 UCLA L. REV. 183, 219 (1999) ("Examiners serve as the initial gatekeeper to the patent system by judging the novelty and nonobviousness of claimed inventions.").

144. *See supra* Part II.B.5.

145. Admittedly, however, the Examiner must deal with nonprocedural issues which adversely affect claim scope. *See, e.g.*, Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 765 (2002). "It is widely suggested that the Patent Office issues patents that are either 'facially' invalid or broader than the actual innovation disclosed in the patent

the ability to prevent the public from bearing the cost and burden of litigation to determine if the disclosure adequately enables the claimed invention.[146]

The current examination framework is derived from judicial precedent, which means that change must originate with the Federal Circuit. Assigning some responsibility to the judiciary is not new or radical, as numerous judges have hinted over the years at the difficulty in wrestling with unpredictable fields like chemistry.[147] This difficulty is an artifact of the judiciary's efforts to fit chemical inventions into the mold of mechanical-electrical inventions.[148] My proposed framework mitigates this artifact by shifting the burden of proof to the applicant when the written description lacks actual experimental details. I adopt the view that applicants should provide sufficient disclosure through true testing and experimentation that enables the reproduction of each claimed embodiment of the invention unless the applicant can show with clear and convincing evidence that the level of skill in the art would allow a PHOSITA to achieve the claimed result.[149]

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application. Both problems result from the Patent Office's inability to accurately determine the scope of information that is already in the public domain or is the subject of other patents (i.e., the relevant prior art) when examining patent applications." *Id.*

146. *Cf.* Giles S. Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 501 (1990) ("[T]he function of claims is to enable everyone to know, without going through a lawsuit, what infringes the patent and what does not."). Mark Lemley concisely presents an argument (contrary to his own) for early resolution of the validity question:

> Having to go through litigation to determine validity not only costs a great deal of money, but it takes quite a bit of time. Indeed, the average time between the issuance of a patent that would later be litigated and a final decision on its validity in litigation was 8.6 years. For many patents, the validity decision was not made until thirteen or fourteen years after the patent issued. During this period, both the patentee and potential infringers . . . are uncertain about their legal rights. Surely we would be better off knowing sooner rather than later whether a patent is valid.

Mark A. Lemley & Kimberly A. Moore, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1520 (2001) (citing Craig Allen Nard, *Certainty, Fence Building and the Useful Arts*, 74 IND. L.J. 759, 795 (1999) (advocating a post-patent grant opposition proceeding, which would provide greater proprietary and competitive certainty ex ante)); *see also* Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 42–43 (2007) (explaining that even in cases where the probability that a patent is invalid is very high, the overall incentive to challenge a patent is weak due to certain structural features of modern patent litigation).

147. *See, e.g.*, Capon v. Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005) (noting "that in the 'unpredictable' fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled").

148. *See infra* note 165 and accompanying text.

149. Under this approach, a PHOSITA should be able to look to the written description in order to "determine, *with reasonable certainty before performing the reaction*, whether the claimed product will be obtained." *In re* Angstadt, 537 F.2d 498, 502, 507 (C.C.P.A. 1976) (Miller, J., dissenting) (emphasis added) (citing Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916)). Although the law should permit some experimentation, "nothing must be left to speculation or doubt." *In re* Eltgroth, 419 F.2d 918, 921 (C.C.P.A. 1970) (affirming the rejection of claims

2. Shifting the Burden of Proof and the Primacy of Working Examples

First, I propose that an application which lacks working examples or is supported by prophetic examples is prima facie nonenabled because it raises an inference that undue experimentation is required in order to practice the invention.[150] In such a case the burden should shift to the applicant to establish patentability. While the lack of working examples would not absolutely preclude patentability,[151] in order to rebut the prima facie case, the applicant would have to show that the written description provides some technique which enables the scope of protection sought by the claims, unless such knowledge is reasonably accessible to the PHOSITA.[152] If the applicant fails to rebut the prima facie case, the applicant would be required to amend the claims to remove the nonenabled subject matter.[153]

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which lacked working examples or any "tangible disclosure"); *see also* Carlos M. Correa, *Pharmaceutical Inventions: When Is the Granting of a Patent Justified?*, 1 INT'L. J. INTELL. PROP. MGMT. 4, 12 (2006) (advocating true testing and experimentation).

150. In *In re Strahilevitz*, 668 F.2d 1229 (C.C.P.A. 1982), the applicant disclosed no operative examples in an invention directed to methods and devices for removing antigens from blood. The Board, in affirming the Examiner's nonenablement rejection, recognized that "[while] specific examples are not necessary to meet the requirements of Section 112, when present, *they do provide good evidence that the disclosure is enabling and that the invention may be performed without undue experimentation*." *Id.* at 1231 (emphasis added) (citing *In re* Gay, 309 F.2d 769 (C.C.P.A. 1962)). The court did not adopt the Board's heightened standard of review and reversed, but "recognize[d] that working examples are desirable in complex technologies and that detailed examples can satisfy the statutory enablement requirement. Indeed, the inclusion of such examples here might well have avoided a lengthy and, no doubt, expensive appeal." *Id.* at 1232; *see also Capon*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

151. The applicant might be able to draft a written description in which enablement is "so apparent as to virtually jump off the page and slap [a PHOSITA] in the face." *See* Ash v. Tyson Foods, Inc. 546 U.S. 454, 456–57 (2006) (per curiam) (quoting Cooper v. Southern Co., 390 F.3d 695, 732 (11th Cir. 2004)) (evaluating the "jump off the page" standard in the context of an employment discrimination suit).

152. This language is based in part on an old C.C.P.A. decision:

> [T]he inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use some technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

In re Fouche, 439 F.2d 1237, 1242 (C.C.P.A. 1971). Further, "where an applicant undertakes to define his invention by the recitation of a Markush group, he must enable one skilled on the art to make and use at least one composition employing each member of the Markush group." *Id.*

153. However, the applicant could not then amend the written description to introduce new matter into the application. 35 U.S.C. § 132(a) (2000). The new matter prohibition of 35 U.S.C. § 132 and its corollary, the written description requirement of 35 U.S.C. § 112 "both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001).

Similarly, generic claims supported by a single working example[154] or a set of nonrepresentative examples[155] should raise an inference of undue experimentation. The Examiner should allow the subgenus claims specifically enabled by the single working example and reject the unsupported claims because in unpredictable fields, a PHOSITA cannot extrapolate a result from one particular embodiment across a broad genus with a reasonable expectation of success.[156] To rebut the prima facie case, the applicant would be required to show that the written description provides some technique which enables the scope of protection sought by the claims, unless such knowledge is reasonably accessible to the PHOSITA.[157] If the applicant fails to rebut the prima facie case, the applicant would have to amend the claims to remove the nonenabled subject matter.[158]

A hypothetical example will illustrate the operation of the proposed framework. Consider a hypothetical patent application directed toward a new class of pharmaceuticals. The application includes a generic method of use claim which, by using a structural formula including an array of variables allowing for the substitution of a countless number of organic functional groups,[159] reads on millions of chemical compounds.[160] However, the only

154. The case of *In re Soll*, 97 F.2d 623 (C.C.P.A. 1938), illustrates how a single working example can be insufficient to enable a (small) genus of four compounds. The halogens are a four-member class of chemical elements (fluorine, chlorine, bromine, and iodine) familiar to most laboratory scientists. *Id.* at 624. The applicant attempted to claim the product and process of reacting a butadiene moiety with a hydrogen halide. *Id.* at 623. The written description disclosed the reaction of natural rubber (which contains a butadiene moiety) with hydrogen fluoride. *Id.* at 624. After noting that the application dealt with an obscure and complex reaction, the Examiner rejected several broad claims for lack of support "since no implied or direct statements can be found in the application, as originally filed, that the other hydrogen halides will react similarly to give the same product." *Id.* The applicant contended the disclosure of one member of a well-known small group was sufficient to enable claims covering the entire group. *Id.* The court affirmed the Board's rejection, noting that "[c]ertain members of a well-defined group of chemicals may be equivalents for one purpose and not equivalents for another. Experimentation is required to ascertain the particular action of a member of the group upon the particular material to be treated . . . ." *Id.* at 625.

155. For example, if a claim reads on 100 species, the applicant may provide numerous examples which only enable one or two species. These examples, though many in number, are "nonrepresentative" of the genus claimed. This is why compliance with the enablement requirement is not a numbers game. *See In re* Borkowski, 422 F.2d 904, 910 (C.C.P.A. 1970) (explaining that in satisfying enablement "there is no magical relation between the number of representative examples and the breadth of the claims").

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

157. *See supra* note 152.

158. *See supra* note 153.

159. *See supra* note 98 (describing the Markush-type claim).

160. A functional group is a group of atoms within a molecule that represents a potential reaction site in an organic compound. Functional groups are responsible for the chemical reactions of these molecules. *See generally* RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS: A GUIDE TO FUNCTIONAL GROUP PREPARATIONS (Wiley 1999).

teaching provided in the written description is a handful of working examples in which only a few of functional groups are substituted. After construing the claims and assessing the level of skill in the art,[161] under the proposed framework the Examiner would reject the generic claim and only allow a narrower claim covering the subgenus because:

> [R]eplacing a functional group on a chemical compound can often have highly unpredictable results. . . . [E]ven a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group . . . could result in either a significant improvement or reduction in the activity of the compound against a particular biological target.[162]

The point here is that a PHOSITA cannot extrapolate a result from a few embodiments across a broad genus with a reasonable expectation of success.[163] As stated above, the applicant could rebut the prima facie case of nonenablement with sound scientific reasoning or, alternatively, amend the claims to remove the nonenabled subject matter.[164]

Admittedly this proposal substantially heightens the threshold required to enable a typical claim in unpredictable fields like chemistry and biology. It incorporates a rethinking of the presumption of enablement and the doctrine of constructive reduction to practice. This rethinking is crucial in order to mitigate the disconnect between patent law and science. As I set forth below, the benefits of this framework outweigh its costs.

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161. Various legal actors disagree about where the enablement analysis should begin. In a recent opinion, Judge Moore noted that it begins with the disclosure in the specification. Sitrick v. DreamWorks, LLC, 516 F.3d 993, 1000 (Fed. Cir. 2008). On the other hand, Dennis Crouch contends that "enablement should begin with the knowledge of one skilled in the art and move forward from there." Dennis Crouch, *CAFC Continues to Expand Doctrine of Full Scope Development*, PATENT LAW BLOG (PATENTLY-O), Feb. 4, 2008, http://www.patentlyo.com/patent/2008/02/establishment-cont.html. In either case, the ultimate question is whether the enablement provided is commensurate in scope with the protection sought by the claims. *See supra* note 72 and accompanying text.

162. Singh v. Brake, 317 F.3d 1334, 1344 (Fed. Cir. 2003) (citation omitted); *see also* Yasuko Kawai v. Metlesics, 480 F.2d 880, 891 (C.C.P.A. 1973) (explaining that with respect to the enablement of a method-of-treatment claim, a PHOSITA "is well aware that subtle changes in chemical compounds can radically alter the effects on a human body").

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

164. One commentator explains how a series of narrower claims can solve the problem in Markush practice: If an applicant's broad claim is rejected,

> even if perhaps it covers things that are not operative or because it is so broad that it inadvertently reads on the prior art, the remedy for that is to have a whole series of dependent claims. That is why patent applications generally have a number of claims of decreasing scope.

Milne, *supra* note 100, at 12.

D. How the Proposed Framework Mitigates the Problems

1. Reconciling Patent Law With Scientific Norms

The issue I address in this Article, the inability of the patent laws to contend with enablement in the unpredictable arts, actually points to a broader conflict between patent law and the experimental sciences.[165] As several commentators have noted, the conflict arose shortly after World War II when the rapid increase in inventions emerging from the chemical and pharmaceutical industries forced the patent system to accommodate these technologies.[166] Yet the basic doctrinal framework, rooted in the applied arts, had already been set; one commentator has aptly described patents in the experimental sciences as "a child (or orphan) of mechanical patent law."[167]

By requiring true testing and experimentation as proof of enablement, this proposed framework resolves a striking incongruity between the patent laws and the norms of scientific research.[168] In science, claims to new compositions unsupported with actual experimental results are rarely believed. Stemming in part from the community's duty to exercise critical vigilance over the claims of its members, a scientist must support findings with actual experimental details and results, which are usually proffered in replicate.[169]

165. *See, e.g.*, Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries*, 61 N.Y.U. ANN. SURV. AM. L. 317, 347 (2005) (exploring the extent to which the doctrinal framework of the U.S. patent system is capable of dealing with new sciences and evolving technologies, and proposing that the courts and the PTO "focus their efforts on understanding the nature and processes of discovery in various evolving technologies. . . ."); Jackie Hutter, Note, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 713–25 (1995) (describing the inherent differences between engineering-related inventions and chemical-biological inventions).

166. *See* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 87–94 (2002) (presenting a historical perspective of the judiciary's response to the evolution of inventions from agricultural-mechanical to chemical); John Hoxie, *A Patent Attorney's View*, 47 J. PAT. OFF. SOC'Y 630, 636 (1965) (contending that the judiciary's interpretation of the patent statute did not change even when chemical inventions became more frequent); William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 264–69 (1990) (exploring the historical role of the patent system's engineering bias in the examination of patent applications in biological systems and pharmaceutical compounds). Quite curiously, the first patent was granted to Samuel Hopkins in 1790 for an improved method for making potash (potassium carbonate), America's first industrial chemical. *See* U.S. Patent No. X1 (issued July 31, 1790).

167. Paul H. Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 51 J. PAT. OFF. SOC'Y 768, 783 (1969); *see also* Hoxie, *supra* note 166, at 636 (explaining that the judiciary tries to fit chemical inventions into the "mold" of mechanical-electrical inventions).

168. *See* Shi, *supra* note 165, at 347.

169. *See generally* JOHN M. ZIMAN, RELIABLE KNOWLEDGE: AN EXPLORATION OF THE GROUNDS FOR BELIEF IN SCIENCE (Cambridge 1978) (investigating the credibility of scientific knowledge across a range of disciplines).

Policing occurs through the rigorous scrutiny of peer review,[170] which the Supreme Court even recognizes "is [a] component of 'good science.'"[171] Although peer review, which has its own shortcomings in the patent examination context,[172] is not a part of my proposal, peer review and the enablement requirement likely share at least one goal: to ensure that a skilled artisan can replicate and practice that which is disclosed.[173]

2. Lessening the Administrative Burden of Patent Examination

A key benefit of the new framework is that it would reduce the pendency of an application in the PTO and accelerate prosecution. First, the Examiner would require less time to conduct the initial search and to issue the first Office Action because the Examiner can more easily determine the outer limits of claim scope when working examples are provided.[174] Stated differently, gauging enablement with actual embodiments saves time because the Examiner does not need to figure out if the PHOSITA can fill in gaps omitted from the written description.[175]

Second and relatedly, limiting the presumption of enablement and narrowing the doctrine of constructive reduction to practice should induce

170. Peer review "is quite efficient at screening out papers that are too speculative or where there are serious errors in the design of the study or in the analysis of data." KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS 171 (1997). For a more in-depth discussion of peer review in science, see ELIZABETH WAGER ET AL., HOW TO SURVIVE PEER REVIEW 1 (2002) (describing the concept of peer review, noting that although it is an "important milestone[ ] of funding and publication, the concept of critical discussion of ideas and findings runs through the entire scientific process"). *See generally* PEER REVIEW IN HEALTH SCIENCES (Fiona Godlee & Tom Jefferson eds., 2d ed. 2003).

171. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593 (1993) (citations omitted).

172. For example, one commentator argues that peer review suppresses innovation. *See* David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J. AM. MED. ASS'N 1438, 1438–41 (1990) (arguing that peer review fails to recognize the work of innovators who are often erratic, unsystematic, and difficult to work with).

173. One commentator makes a strong argument for peer review in the patent process. *See* Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123, 125 (2006) (asserting that the patent examiner's inability to communicate with the scientific community leads to institutionalized isolation of expertise which adversely affects patent quality). However, a key distinction between peer review and the current framework is that peer review focuses on work that has been done, not on speculative results. Nonetheless, even research grant proposals, which are inherently speculative because they propose research, often include some actual experimental results because "it is virtually impossible to obtain a favorable review without strong preliminary data." National Cancer Institute: Quick Guide for Grant Applications, http://deainfo.nci.nih.gov/extra/extdocs/gntapp.htm#9 (last visited June 19, 2007).

174. *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (holding that "[t]he scope of the claims must 'be less than or equal to the scope of the enablement'").

175. *See supra* Part I.A (discussing the PHOSITA's ability to fill in gaps in unpredictable technologies).

applicants to draft claims more precisely, meaning that there should be a closer correspondence between the disclosed embodiments and claim breadth. Applicants will be less inclined to draft claims reading on millions or billions of embodiments because it is unlikely that the applicant can provide enough working examples to support claims of that breadth. This should result in a shift toward narrower claiming, which would simplify and shorten the Examiner's search.

III. POTENTIAL CRITICISMS OF THE PROPOSED FRAMEWORK

A. The Incentive to Innovate

One oft-cited justification for the current enablement standard is that it fosters innovation. Judge Newman, for example, argues that a patentee's obligation to disclose should not destroy the incentive to innovate:

> As implemented by the patent statute, the grant of the right to exclude carries the obligation to disclose the workings of the invention, thereby adding to the store of knowledge without diminishing the patent-supported incentive to innovate.
>
> But the obligation to disclose is not the principal reason for a patent system .... The reason ... is to encourage innovation and its fruits ....[176]

Supporters of this view believe that the patent system must offer companies sufficient incentives to develop new products, to attract investors, and to earn a profit.[177] To that end "the patent law[s] place[ ] strong pressure on filing the patent application early in the development of the technology, often before the commercial embodiment is developed or all of the boundaries [are] fully

176. Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc); *see also* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1568 (Fed. Cir. 1990). "There cannot, in an effective patent system, be such a burden placed on the right to broad claims. To restrict appellants to the [specific embodiment] disclosed ... would be a poor way to stimulate invention, and particularly to encourage its early disclosure." *Id.* (quoting *In re* Hogan, 559 F.2d 595, 601–06 (C.C.P.A. 1977)). *But see* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974) (explaining that the purpose of the patent system is trifold, including promoting disclosure of inventions, which stimulates further innovation, and permitting the public to practice the invention once the patent expires); *see also* Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007 (2005) (examining the value of the patent system's disclosure function).

177. *See* Lita Nelsen, *The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries*, 3 YALE J. HEALTH POL'Y, L. & ETHICS 301, 301 (2003) (arguing that patent protection is necessary "to provide the incentive for industrial participation" in drug discovery); Dana Rohrabacher & Paul Crilly, *The Case for a Strong Patent System*, 8 HARV. J.L. & TECH. 263, 271 (1995) (explaining that the patent system acts as a strong shield to protect pharmaceutical and biotechnological innovation and "thus maintaining the incentive for the investment of venture capital in research and development").

explored."[178] Admittedly the patent laws actually penalize inventors who fail to file promptly.[179] Thus, it is a concern that a heightened enablement standard would delay entry into the patent system because the inventor would require more time in research and development.[180]

Another concern is that allowing the applicant to claim only those embodiments actually realized would decrease the value of patents:

> At first blush it might seem to make sense to limit the rights of a patentee to only those embodiments of the invention . . . that she has actually created at the time the patent application is filed. But imitators would soon find some minor variation over the disclosed embodiments . . . [which would give them] a nonenablement defense

178. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (en banc) (per curiam) (Newman, J., concurring), *rev'd on other grounds*, 520 U.S. 17 (1997); *see also* Edlyn S. Simmons, *Prior Art Searching in the Preparation of Pharmaceutical Patent Applications*, DRUG DISCOVERY TODAY, Feb. 1998, at 52, 52 (explaining the importance of drafting broad generic claims which includes hypothetical related compounds in order to prevent competitors from developing them). Drug companies, for example, often seek broad patents early in the drug discovery process, long before a marketable form of the drug is identified or tested. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 349 (2007) (discussing the role of the patent system in drug development). However, it is true that pharmaceutical and biotech companies "must file patent applications early in the development stage to avoid the statutory bar effect of their public use clinical trials." Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System With Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 557 (2006). Early patenting has drawbacks, which include loss of patent term and market erosion. *See* Bryan L. Walser, *Shared Technical Decisionmaking and the Disaggregation of Sovereignty: International Regulatory Policy, Expert Communities, and the Multinational Pharmaceutical Industry*, 72 TUL. L. REV. 1597, 1647–48 (1998) (exploring the incentives for drug companies to reduce the time required to bring new compounds to market due to market erosion).

179. For example, an applicant must file a patent application within one year of disclosing the invention in a printed publication. 35 U.S.C. § 102(b) (2000). Likewise, if the invention is used in public, sold, or subject to an offer for sale in the United States, the applicant must file within one year of the event. *Id.* A fundamental purpose of the § 102(b) "statutory bar" is to encourage prompt filing. *See* Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) ("Section 102(b) . . . is primarily concerned with the policy that encourages an inventor to enter the patent system promptly . . . ."); *see also* ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 117–18 (2004) (explaining the three-fold policy rationale for § 102(b)). Section 102(g) also functions to "penalize[ ] the unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of [the] invention' with the public after the invention has been completed." Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n, 54 F.3d 756, 761 (Fed. Cir. 1995) (quoting Paulik v. Rizkalla, 760 F.2d at 1280 (Rich, J., concurring)). Mark Lemley explains that "[b]y waiting too long to file a patent application or inventing without giving the world the benefit of the invention, inventors lose not only their own rights to file for a patent but also the ability to prevent a second inventor who *does* give the world the benefit of the invention from obtaining her own patent." Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 BERKELEY TECH. L.J. 1085, 1102 (2003).

180. This potential delay is in tension with the idea that "[e]arly public disclosure is a linchpin of the patent system." W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983).

> if the patentee tried to enforce the patent. Such a rule would soon render patents useless.[181]

The real issue underlying both concerns is the problem of generic claiming. It is true that the current framework allows a patentee to obtain a broad claim with a minimal amount of disclosure, which means that he only needs to undertake a minimal amount of experimentation before entering the patent system.[182]

There are several responses to these concerns. First, under the proposed framework, an applicant can still claim an invention generically, meaning that in every case he need not provide a working example for every species encompassed by a generic claim.[183] The amount of disclosure required will depend on the size of the genus and the characteristics of the individual species:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus . . . consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.[184]

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181. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 845 (1990). Judge Arthur J. Gajarsa holds a similar view:

> Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.

Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005); *see also* SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) ("The law does not require the impossible [in that] it does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention."); Lever Bros. Co. v. Procter & Gamble Mfg. Co., 139 F.2d 633, 638 (4th Cir. 1943) (explaining that "it is both impracticable and unreasonable to require [the applicant] to set out an extended list of precise combinations and formulae with specific designation of the exact characteristics [obtained]").

182. *See supra* Parts II.A and II.B.

183. *See In re* Grimme, 274 F.2d 949, 952 (C.C.P.A. 1960) ("It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it."). But "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed." *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).

184. *In re* Shokal, 242 F.2d 771, 773 (1957) (emphasis added) (citation omitted).

This illustrates that the proposal affords flexibility in the number of working examples required.[185]

Second and conversely, generic claims can thwart innovation. The Supreme Court recognized this long ago in an infringement suit involving licenses to use Thomas Edison's lamp:

> [T]o hold that one who had discovered that a certain fibrous or textile material answered the required purpose, should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, *and operate rather to discourage than to promote invention.*[186]

In this vein, I contend that the proposed framework does not thwart innovation. Rather, by using the inventor's actual experimental details to limit claim scope, the new framework will promote invention by allowing other scientists who are trying to elucidate how to make and use the claimed invention while the purported inventor does not know how to do so.[187]

B. The Narrow Teaching Function of a Patent

Patents are difficult to understand.[188] Although esoteric language and formalism certainly contribute,[189] I believe that the current framework's minimal

185. Indeed, there are instances where "[c]hemists knowing the properties of one member of a series would in general know what to expect in adjacent members" because chemically related species often behave similarly. Brenner v. Manson, 383 U.S. 519, 522 n.3 (1966) (quoting *In re* Henze, 181 F.2d 196, 200–01 (C.C.P.A. 1950) (applying this rule to homologous compounds, which is a family of chemical compounds which vary from member to member by a methylene group)). There is also a belief that there are instances where a limited disclosure may be preferable. *See In re* Cavallito, 282 F.2d 363, 367 (C.C.P.A. 1960) ("If a claim covers compounds which are closely related, a comparatively limited disclosure may be sufficient to support it" because a limited disclosure "may be of greater value in determining the patentable characteristics of the claimed compounds than a more extensive disclosure would be."). That said, there are also cases where a single working example is insufficient to enable a small genus. *See supra* note 154 and accompanying text; *see also* Herbert H. Goodman, *The Invalidation of Generic Claims by Inclusion of a Small Number of Inoperative Species*, 40 J. PAT. OFF. SOC'Y 745 (1958) (outlining several problems which arise in drafting chemical claims involving inductive reasoning from limited examples).

186. Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 476 (1895) (emphasis added).

187. *See supra* note 96 and accompanying text (discussing the chilling effect).

188. *See, e.g.*, Allison & Lemley, *supra* note 166, at 134–44 (exploring how the increasing complexity of patents may be due in part to the changes in the nature of technologies being patented); Note, *supra* note 176, at 2022 (explaining that patents "are notoriously hard to interpret" (quoting Matthew D. Powers & Steven C. Carlson, *The Evolution and Impact of the Doctrine of Willful Patent Infringement*, 51 SYRACUSE L. REV. 53, 102–03 (2001))).

189. *See, e.g.*, Daniel C. Munson, *The Patent-Trade Secret Decision: An Industrial Perspective*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 689, 713–14 (1996) (observing that chemical patents tend to be

enablement threshold stymies a patent's potential to provide substantive scientific information. Below I address concerns that patents do and should have only a narrow teaching function.[190]

The first such concern relates to the intended audience for which the patent document is written. Although the public is the ultimate beneficiary of the disclosure,[191] Judge Newman has explained that patents are written to enable a PHOSITA, and not the general public, to practice the invention.[192] Her view is that the written description should not contain known scientific information because it would greatly enlarge its size, increase the cost of patent prosecution, and "obfuscate rather than highlight the contribution to which the patent is directed."[193] It is probably true that the PTO, jurists, and members of the patent bar would not embrace thicker patent documents.[194]

"shrouded" in chemical nomenclature, which makes them hard to comprehend); *see also* Kelly Casey Mullally, *Patent Hermeneutics: Form and Substance in Claim Construction*, 59 FLA. L. REV. 333, 379 (2007) (explaining that the inventor's difficulty in describing the invention carries forward to the subsequent reader). Sometimes a patentee purposely drafts an instrument which is hard to understand. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1029 & n.52 (1989) (suggesting that some patentees deliberately suppress crucial information, and that many published patents are of little use to others as a result of suppression).

190. *See* Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987) ("The written description must communicate that which is needed to enable the [person having ordinary skill in the art] to make and use the claimed invention.").

191. The teaching and claim scope functions of the enablement requirement are necessary "in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue a patent." Grant v. Raymond, 31 U.S. (6 Pet.) 218, 219 (1832).

192. *See, e.g.*, Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1119 (Fed. Cir. 2002) (explaining that patent documents are meant to be "a concise statement for persons in the field"); 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").

193. *Ajinomoto*, 228 F.3d at 1347. "[Although] an applicant for a patent [must] give to the public a complete and adequate disclosure in return for the patent grant, the certainty required of the disclosure is not greater than that which is reasonable. . . . [I]t cannot be forgotten that the disclosure is not addressed to the public generally, but to those skilled in the art." *In re* Storrs, 245 F.2d 474, 478 (C.C.P.A. 1957); *see also* A.B. Dick Co. v. Barnett, 288 F. 799, 801 (2d Cir. 1923) ("[T]he specification of a patent is not addressed to people who are ignorant about the matter . . . .").

194. Judge Giles S. Rich expresses the opinion that "[n]ot every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. United States specifications have often been criticized as too cluttered with details to give an easy understanding of what the invention really is." *In re* Gay, 309 F.2d 769, 774 (C.C.P.A. 1962); *accord* N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed. Cir. 1990) ("It is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification."). Also, the PTO charges additional filing fees for patent specifications which exceed a threshold page count or claim count. *See* 35 U.S.C. § 41(a)(1)(B) (2000).

The second concern, advanced by Timothy Holbrook, is that structural flaws in the patent system itself inhibit the ability of a patent to perform a teaching function.[195] For example, he contends that the Federal Circuit's evisceration of the common law experimental-use exception means that "[o]ne can read the patent but cannot make or use the invention for purposes of exploring its function or the manner in which it works" without risking infringement.[196] Holbrook also describes how the teachings in the disclosure are often untimely due to delays in publication.[197] Holbrook concludes that even if persons in several fields consult the patent for technical information, the disclosure plays a limited teaching role, particularly if the patentee publishes the information in another medium.[198]

I have several responses to these concerns. First, I agree with Judge Pauline Newman that the patent's disclosure is directed at a limited audience. Although the written description should not become a scientific treatise, in many ways a scientific publication and the written description share similar goals, namely to disclose something novel,[199] to teach fellow artisans how to replicate the invention or discovery,[200] and to spur further innovation in the field.[201]

Second, one long-term consequence of my proposal is that the written description will eventually resemble the experimental section of a scientific publication.[202] This is the first step toward the broader goal to bridge the disconnect between patent law and the experimental sciences. So while the proposed framework cannot and is not intended to fix every problem with patent law's disclosure function, it would mitigate these problems by transforming

195. Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 139–46 (2006).

196. *Id.* at 139–40.

197. *Id.* at 143.

198. *Id.* at 146 (describing how patents can provide a "feedback loop to encourage teachings via pre-patent disclosures and publications").

199. Rebecca Eisenberg argues that both the scientific community and the patent system favor full disclosure. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 217 (1987).

200. *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922 n.5 (Fed. Cir. 2004) ("[T]he role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement).").

201. *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that a patent's addition of knowledge is so important to the public good "that the Federal Government is willing to pay the high price of . . . years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art"); Charles E. Smith, *Requirements for Patenting Chemical Intermediates: Do They Accomplish the Statutory Goals?*, 29 ST. LOUIS U. L.J. 191, 192 n.7 (1984) ("The very purpose of this disclosure to the public is to catalyze other inventors into activity and make possible additional advances in the art." (citing *Ex parte* Hull, 191 U.S.P.Q. 157, 159 (Bd. App. 1975))).

202. In the experimental sciences, peer-reviewed journal publications have an experimental section which includes working examples and other experimental details.

the written description into an instructional tool. Specifically, including working examples combined with some discussion of what is already known serves a teaching role because together they provide context[203] and allow the PHOSITA to more precisely and to more quickly replicate the invention or discovery.[204]

CONCLUSION

The enablement requirement ensures that the public will obtain some benefit in return for the patent holder's right to exclude. One hoped-for benefit is that the teachings of patent disclosures will induce other inventors to innovate. When a patent issues with nonenabled claims, it prevents other scientists who are trying to elucidate how to make and use the claimed invention while the inventor does not know how to do so. By requiring working examples and actual experimental results as proof of enablement, this proposal mitigates this problem and resolves a striking incongruity between the patent laws and the norms of scientific research. It guarantees that the PHOSITA, armed with the written description, can make and use the claimed invention without excessive time or labor. But this proposal is only the beginning of an effort to harmonize the patent laws with science. As the number of annual patent applications emerging from the biotech, nanotech, and pharmaceutical

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203. This proposal points to another disconnect between law and science. In the realm of scientific publishing, the author-scientist must demonstrate an understanding of the underlying science (which is policed through peer review). By contrast, patent law is insensitive to the inventor's comprehension of the underlying science. *See 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.").

204. This proposal would be a marked departure from a well-settled principle. *See* Loom Co. v. Higgins, 105 U.S. 580, 586 (1881) ("He may begin at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old."). I contend that a PHOSITA should not have to engage in laborious experimentation. In *In re Gardner*, 427 F.2d 786 (C.C.P.A. 1970), a case in which the court affirmed the Board's rejection of claims related to an alleged antidepressant activity in pharmaceutical compounds due to nonenablement, Judge Giles S. Rich rejected the appellants' argument that the PHOSITA must figure out how to use the invention:

> In other words, [the appellants argue that] those skilled in the art, by investigations along the above lines, and by a great amount of work, can eventually find out how to use appellants' invention. But our view is that the law requires that the disclosure in the application shall inform them how to use, not how to find out how to use for themselves. The above argument is self-defeating. It demonstrates the inadequacy of the disclosure by saying, in effect: We have detected and disclosed the presence of activity; if you wish to practice our invention, go and find out how to use it.

Id. at 789.

industries continue to rise, this increase will spur more debate about the patent system's ability to adapt to new sciences and emerging technologies.