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Citation: 6 Nw. J. Tech. & Intell. Prop. 278 2007-2008

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This work was originally published in
6 Nw. J. Tech. & Intell. Prop. 278 2007-2008

The Enablement Pendulum Swings Back

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I. INTRODUCTION

Perhaps in response to criticisms that the U.S. patent system hinders innovation and economic growth by affording too much legal protection to patent owners, courts have begun to chip away at patent rights. For example, over its last three terms the Supreme Court has decided cases that limit the availability of injunctive relief for patent owners,¹ allow licensees to challenge the validity of a licensed patent without breaching or terminating the license agreement,² and make it easier to defeat a patent for obviousness.³ Since this amount of patent law activity is atypical for the Supreme Court,⁴ several commentators and members of the patent bar contend that the Court is unhappy with the U.S. Court of Appeals for the Federal Circuit's "stewardship" of the patent system⁵ and is, among other things, inviting the court to rethink its historical "pro-patent" stance.⁶

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¹ See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (rejecting the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances" and holding that the traditional four-factor framework for injunctive relief applies "with equal force" for patent disputes).

² See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (holding that a licensee is not required, insofar as Article III is concerned, to break or terminate a license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed).

³ See *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) (discussed *infra* Part III.A).

⁴ The last wave of patent activity occurred in 1965, when the Supreme Court granted certiorari in four patent cases.

⁵ See Rebecca S. Eisenberg, Commentary, *The Supreme Court & the Federal Circuit: Visitation & Custody of Patent Law*, 106 MICH. L. REV. FIRST IMPRESSIONS 28 (2007), available at <http://www.michiganlawreview.org/firstimpressions/vol106/eisenberg.pdf> (explaining that the increased propensity of the Supreme Court to grant certiorari in patent cases "suggests that it is concerned about how good a job the Federal Circuit is doing").

⁶ The Federal Circuit's "pro-patent" reputation has generated a vigorous academic debate. See, e.g., William M. Landes & Richard A. Posner, *An Empirical Analysis of the Patent Court*, 71 U. CHI. L. REV. 111, 128 (2004) (concluding that the "pro-patent leanings" of the Federal Circuit "has had a significant effect on patent activity"); Mark D. Janis, *Reforming Patent Validity Litigation: The "Dubious Preponderance"*, 19 BERKELEY TECH. L.J. 923, 928 (2004) ("The perception that the Federal Circuit enhanced the effect of the presumption of validity coincides with the generally received wisdom that the Federal Circuit adopted a pro-patent bias early in its tenure."); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 251 (1998) (concluding that findings of patent validity have been significantly higher since the establishment of the Federal Circuit). But see Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 3 (2004) ("Despite the Federal Circuit's pro-patent holder reputation[,] claims of patent infringement are no more likely to succeed since the Federal Circuit's advent."); Paul M. Janicke &

And the Federal Circuit appears to have accepted the invitation. Within the past year, for example, the Federal Circuit has issued opinions that limit the availability of treble damages for willful infringement⁷ and trim the scope of patentable subject matter.⁸

The breadth and extent of these decisions illustrate that courts can employ various levers to modulate patent rights. One set of levers, the patentability levers, control the substantive requirements that must be met in order for an invention to be patented.⁹ Nonobviousness, a popular lever which the Supreme Court recently pulled in *KSR v. Teleflex*,¹⁰ is often viewed as the most significant barrier to patentability.¹¹ But the Federal Circuit has started to pull *another* patentability lever, enablement, that has received considerably less attention from the media, legal academics, and the patent bar. In short, the enablement requirement ensures that the patent discloses the claimed invention in sufficient detail so that a “person having ordinary skill in the art” (“PHOSITA”) can make and use it without undue experimentation.¹²

This Article examines the Federal Circuit’s new enablement standard and explores its potential impact on patentees. Part II sets the stage for the discussion by briefly exploring the contours of the enablement requirement. It then describes the two strands of enablement jurisprudence which have emerged over the past half-century and the limits of this dichotomy. Part III begins by exploring how *KSR*’s lesson about the importance of the PHOSITA in patent law may partially explain the Federal Circuit’s

LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 39 (2006) (concluding that their findings do not support the view that the Federal Circuit has pro-patent leanings).

⁷ See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) (holding that proof of willful infringement permitting enhanced damages requires “at least a showing of objective recklessness” and abandoning the “affirmative duty of due care” requiring a potential infringer to seek the opinion of counsel).

⁸ See *In re Comiskey*, 499 F.3d 1365, 1379 (Fed. Cir. 2007) (holding that a claim directed toward “[a] method for mandatory arbitration resolution” is unpatentable); *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (holding that a transitory, propagating signal is unpatentable because it is not a “process, machine, manufacture, or composition of matter”).

⁹ The conditions for patentability are found in Title 35 of the U.S. Code. First, the claimed invention must be useful (§ 101), novel (§ 102), and nonobvious (§ 103), and the claims must be directed to patentable subject matter (§ 101). In addition, § 112 paragraph 1 requires that the patent specification describe, enable, and set forth the best mode of carrying out the invention, and § 112 paragraph 2 requires that the claims set forth the subject matter that the applicant regards as his invention and that the claims particularly point out and distinctly define the invention.

¹⁰ 127 S.Ct. 1727, 1739 (2007) (rejecting the Federal Circuit’s rigid approach of the teaching-suggestion-motivation test because it is inconsistent with the “expansive and flexible” approach to the nonobviousness question set forth in prior Supreme Court precedent). Several commentators view *KSR* as the most important patent case in recent history. See, e.g., John F. Duffy, *KSR v. Teleflex: Predictable Reform of Patent Substance and Procedure in the Judiciary*, 106 MICH. L. REV. FIRST IMPRESSIONS 34 (2007), available at <http://www.michiganlawreview.org/firstimpressions/vol106/duffy.pdf> (arguing that *KSR* has immense significance “not merely because it rejected the standard of [nonobviousness] that had been applied in the lower courts for decades, but also because it highlights many separate trends that are reshaping the patent system”); Harold C. Wegner, *Chemical & Biotechnology Obviousness in a State of Flux*, 26 BIOTECH. L. REP. 437, 456 (2007) (noting that *KSR* is regarded as the most important patent case at the Supreme Court in over 40 years).

¹¹ See, e.g., John K. Flanagan, *Gene Therapy & Patents*, 80 J. PAT. & TRADEMARK OFF. SOC’Y 739, 750 (1998) (explaining that nonobviousness is often the most difficult patentability hurdle to overcome, particularly if the level of skill in the art is high). Not surprisingly, obviousness is the most common basis for patent invalidation. See Gregory Mandel, *Patently Non-obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR v. Teleflex*, 9 YALE J.L. & TECH. 1, 7 n.16 (2007) (collecting empirical sources).

¹² See *infra* Part II.A.

adoption of the “full scope” enablement standard. It then briefly discusses several recent cases where the court applies the new standard. Finally, Part IV discusses the implications of full scope enablement by providing lessons for patentees and presenting thoughts on the future of claim drafting.

II. THE PENDULUM SWINGS OUT: THE RISE OF “SINGLE-EMBODIMENT” ENABLEMENT

A. *The Enablement Puzzle*

A bedrock principle of patent law is that an applicant must sufficiently disclose the invention in exchange for the right to exclude.¹³ The essential facet of this disclosure obligation is enablement,¹⁴ which compels a patent applicant to “enable” a PHOSITA to make and use the full scope of the claimed invention without undue experimentation.¹⁵ Enablement, therefore, places an outer limit on the scope of the claims.¹⁶

Curiously enough, it is well-settled in U.S. patent law that an applicant need not physically reduce an invention to practice before obtaining a patent.¹⁷ Working examples

¹³ 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 ¶¶ 1–2 (2007) (emphasis added). The authorities often refer to 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.”). See also *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974) (explaining that adequate and full disclosure ensures that the public will benefit from the exclusory right). Interestingly, the disclosure requirement can be traced back at least five centuries to the Venetian Patent Statute of 1474, which 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. PATENT 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).

¹⁴ See *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005) (describing enablement as the essential part of the patent bargain).

¹⁵ The words “undue experimentation” do not appear in the text of the statute. See 35 U.S.C. § 112. The purpose of this judicially-created element is to determine if “undue experimentation” is required to practice the invention as of the filing date of the patent application. 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); *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’”).

¹⁶ The scope of the claims must “be less than or equal to the scope of 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 written description plus what is known by a PHOSITA without undue experimentation. *Id.*

¹⁷ According to the Supreme Court:

are certainly ideal, but not required. In the courts' view, prophetic examples or broad terminology are sufficient to satisfy enablement.¹⁸ But the issue is whether the PHOSITA, armed with the written description¹⁹ and knowledge in the art, can practice the *full scope* of the claimed invention without undue experimentation. In other words, one must ask if the PHOSITA can rely on the level of skill in the art to fill in the information gaps omitted from the disclosure.²⁰ And as discussed below, recent Federal Circuit enablement opinions make clear that a disclosure that merely “provides a starting point from which one of skill in the art can perform further research” in order to practice the claimed invention does not fulfill the requirement.²¹

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 (1999). *See also* *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (“Conception is the touchstone of inventorship, the completion of the mental part of invention.”), *cert. denied*, 515 U.S. 1130 (1995).

¹⁸ *See In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971) (“[§ 112 paragraph 1] requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.”). Indeed, an inventor can “constructively” reduce an invention to practice, which is unique to patent law. As Judge Newman has described, “[t]he 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” because “[u]nlike 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.” *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.”).

¹⁹ The “written description” is the part of the patent application (or issued patent) which completely describes the invention. Technically speaking, “specification” refers to the written description and the claims. *See* 35 U.S.C. § 112 (2007) (“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. 2002).

²⁰ *See, e.g., 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.”) (internal citation and quotation marks omitted).

²¹ *Nat'l Recovery*, 166 F.3d at 1198. It is certainly true that the written description “need not teach, and preferably omits, what is well known in the art.” *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954 (1987). But according to Judge Lourie, this oft-cited statement “is merely a rule of supplementation, not a substitute for a basic enabling disclosure.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997). Most importantly, Judge Lourie warns that a patentee cannot rely on the PHOSITA's knowledge to fill in gaps which pertain to the novel aspects of an invention:

[T]he omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Id.

B. An Imperfect Dichotomy

1. Two Strands of Enablement Jurisprudence

As inventions have evolved from agricultural-mechanical to predominately chemical in nature, courts have responded by developing two strands of enablement jurisprudence. One strand focuses on inventions in chemistry and the experimental sciences, which courts have deemed the “unpredictable” arts.²² PHOSITAs in these fields often cannot predict if a reaction protocol that works for one embodiment will work for others.²³ Thus, the applicant typically must enable multiple embodiments with a specific and detailed teaching because there is a danger that embodiments not so described either cannot be made or may require unduly extensive experimentation.²⁴

The second strand focuses on inventions in applied technologies like electrical and mechanical engineering, which are regarded as the “predictable” arts because they are rooted in well-defined, predictable factors.²⁵ In electrical engineering, for example, a PHOSITA can typically predict what will happen when circuits are combined.²⁶ Similarly, a PHOSITA in mechanical engineering can use thermodynamics to predict how much power a new engine will produce.²⁷ Historically, this predictability led the courts to adopt the view that a single embodiment was often sufficient to enable a broad claim in the applied sciences.²⁸

²² See, e.g., *Schering Corp. v. Gilbert*, 153 F.2d 428, 433 (2d Cir. 1946) (observing that the field of organic chemistry “is essentially an experimental science [where] results are often uncertain, unpredictable, and unexpected”).

²³ 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.

Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 458 (1994). 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.

²⁴ See *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (“Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, 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). A “specific and useful teaching” is particularly important in newer technologies. See *Genentech*, 108 F.3d at 1367–68 (“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.”).

²⁵ See *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving a “predictable” factor such as a mechanical or electrical element is less than that required for the unpredictable arts).

²⁶ See, e.g., JOHN D. CUTNELL & KENNETH W. JOHNSON, *PHYSICS* 577–619 (6th ed. 2004) (explaining electrical circuits).

²⁷ See *id.* at 416–449 (explaining the laws of thermodynamics).

²⁸ See *In re Vickers*, 141 F.2d 522, 525 (C.C.P.A. 1944) (explaining that an inventor “is generally allowed [broad] claims, when the art permits, which cover more than the specific embodiment shown.”). See also *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent

The facts in *Cedarapids, Inc. v. Nordberg, Inc.* illustrate this point.²⁹ The broad claim in the patent claimed a method for increasing the efficiency and output of a rock crusher by simultaneously changing two variables that affect crusher performance.³⁰ The written description disclosed values that pertained to a seven-foot rock crusher. The district court held that the broad claim lacked enablement because the written description did not specify values for crushers of other sizes, and that a PHOSITA must perform undue experimentation to apply the process to other sizes of rock crushers.³¹ The Federal Circuit reversed. According to the court, rock crusher technology is not in the same category as the chemical arts “where a slight variation in a method can yield an unpredictable result or may not work at all.”³²

Indeed, until recently, courts upheld a broad claim directed to inventions in predictable technologies even if it encompassed other embodiments that were inadequately disclosed.³³ The underlying assumption was that the PHOSITA could rely on the teachings of the single embodiment and the knowledge in the art to fill in missing pieces from the written description.³⁴ Stated another way, the PHOSITA could extrapolate the teachings of the single embodiment across the breadth of the claimed invention with a reasonable expectation of success.³⁵

2. Limits of the Predictable-Unpredictable Dichotomy

Although the predictable-unpredictable distinction can serve as a helpful starting point for the enablement inquiry, the dichotomy has its drawbacks. First, classifying an invention as one or the other oversimplifies the inquiry and ignores that an engineering-type invention can, for example, have unpredictable features. As Judge Giles Rich argued nearly forty years ago, “[W]e would prefer to see denominated a dichotomy between predictable and unpredictable factors *in any art* rather than between ‘mechanical cases’ and ‘chemical cases.’”³⁶

Second, the assumption that the “predictable art” PHOSITA could always fill in gaps omitted from the disclosure often resulted in a PHOSITA with no identity. As long

need only disclose a single embodiment to satisfy enablement), *cert. denied*, 484 U.S. 954 (1987).

²⁹ No. 95-1529, 1997 WL 452801 (Fed. Cir. Aug. 11, 1997).

³⁰ *Id.* at *1.

³¹ *Id.* at *2.

³² *Id.*

³³ See cases cited *supra* notes 28–29.

³⁴ *In re Cook*, 439 F.2d 730, 735 (C.C.P.A. 1971) (explaining that patent claims can and do read on 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”).

³⁵ It should be noted, however, that *some* experimentation is allowed. See, e.g., *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (“[T]he question of undue experimentation is a matter of degree. The fact that some experimentation [including a considerable amount of routine experimentation] is necessary does not preclude enablement; what is required is that the amount of experimentation ‘must not be unduly extensive.’”).

³⁶ *Cook*, 439 F.2d at 734 (emphasis in original); accord *In re Bowen*, 492 F.2d 859, 861–62 (C.C.P.A. 1974) (Rich, J.) (“To the extent that there may be a difference in the resolution of the question whether enablement is accomplished when the Patent Office has not shown the inability of one skilled in the art to use the invention as broadly as it is claimed and appellant has not shown that materials other than those he discloses will operate in the claimed process, we do not think it hinges on whether the case is denominated ‘chemical’ or ‘mechanical.’”).

as a single embodiment was provided, a reviewing court rarely felt the need to scrutinize or peer into the level of skill in the art. So, as Professors Burk and Lemley point out, in the predictable fields the enablement requirement “[was] easily satisfied and therefore play[ed] virtually no role in limiting the scope of claims.”³⁷

III. THE PENDULUM SWINGS BACK: THE EMERGENCE OF “FULL SCOPE” ENABLEMENT

A. KSR’s Invigorated PHOSITA

As discussed above, the heart of the enablement inquiry turns on what the PHOSITA knows and whether the PHOSITA can fill in gaps omitted from the disclosure.³⁸ 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]³⁹ views the prior art and the claimed invention.”⁴⁰ Thus, the importance of this hypothetical construct cannot be overstated.⁴¹

Unlike inventors and patentees, whom the patent law presumes to have extraordinary skill in the art,⁴² the authorities view the PHOSITA as simply a user of the technology. In the enablement context,⁴³ Judge Rich described the PHOSITA not as an

³⁷ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1654 (2003).

³⁸ See *supra* note 20 and accompanying text.

³⁹ An applicant whose claims have been twice rejected by the Examiner may appeal to the Board of Patent Appeals & Interferences (“Board”). 35 U.S.C. § 134(a) (2008). The Board reviews adverse decisions of Examiners and determines priority of invention among contesting parties. See 35 U.S.C. § 7(b)(2008). The Board can affirm a rejection or reverse and remand to the examining corps. 37 C.F.R. § 1.197 (2008) (promulgating Patent Office rules for the Board). An applicant dissatisfied with a Board decision can appeal to the Federal Circuit. 35 U.S.C. § 141 (2008).

⁴⁰ *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1128 (2002).

⁴¹ The PHOSITA is akin to the reasonably prudent person in tort law. 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”), *cert. denied*, 481 U.S. 1052 (1987). For an in-depth analysis of the PHOSITA, see generally John O. Tresansky, *PHOSITA — The Ubiquitous and Enigmatic Person in Patent Law*, 73 J. PAT. & TRADEMARK OFF. SOC’Y 37 (1991); Joseph P. Meara, Note, *Just Who is the Person Having Ordinary Skill in the Art? Patent Law’s Mysterious Personage*, 77 WASH. L. REV. 267 (2002). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology and the educational level of active workers in the field. See *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983) (listing six factors relevant to a determination of ordinary skill), *cert. denied*, 464 U.S. 1043 (1984). The level of ordinary skill in the art is a question of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

⁴² Judge Rich described a PHOSITA as one “who thinks along the line of conventional wisdom in the art” and “is not one who undertakes to innovate, whether by patient, and often expensive, systematic research[,] or by extraordinary insights” *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). By contrast “[i]nventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something—call it what you will—which sets them apart from the workers of ordinary skill” *Id.*; *accord* *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1580 (Fed. Cir. 1993) (Lourie, J.) (explaining that “inventors generally have extraordinary skill”), *cert. denied*, 511 U.S. 1069 (1994). See also 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.” (citation omitted)); Dan L. Burk, *Feminism and Dualism in Intellectual Property*, 15 AM. U. J. GENDER SOC. POL’Y & L. 183, 189–190 (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.” (citation omitted)).

⁴³ There is also a nonobviousness PHOSITA. See 35 U.S.C. § 103(a). Unlike the enablement

innovator, but rather as a “plodder.”⁴⁴ If the PHOSITA has any problem-solving ability, it is “in tapping the prior art to fill in gaps left by the inventor’s disclosure.”⁴⁵ Curiously enough, until quite recently Judge Rich’s view of the PHOSITA as an unimaginative and uncreative person persisted in patent law even as inventions became more technologically complex.

A unanimous Supreme Court in *KSR Int’l Co. v. Teleflex Inc.* breathed new life into the PHOSITA. In resolving a nonobviousness issue, the Court had to consider what would lead a PHOSITA to combine teachings of the prior art to arrive at the claimed invention.⁴⁶ The Federal Circuit and its predecessor court⁴⁷ resolved the question with the “teaching, suggestion, or motivation” (hereinafter “TSM”) test, which deemed a patent claim obvious if some motivation or suggestion to combine the prior art teachings could be found in the prior art, the nature of the problem, or the knowledge of a PHOSITA.⁴⁸

The Court held that the Federal Circuit’s rigid application of the TSM test was inconsistent with the “expansive and flexible” approach to the nonobviousness question set forth in precedent.⁴⁹ A critical flaw with the Federal Circuit’s application of the TSM test was the assumption that a PHOSITA lacked the creative ability to combine the teachings of the prior art:

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 and nonobviousness PHOSITA, see Burk & Lemley, *supra* note 42, at 1185–1202 and Tresansky, *supra* note 41, at 52–54.

⁴⁴ 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 Prof. 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).”).

⁴⁵ Burk & Lemley, *supra* note 42, at 1190.

⁴⁶ See *Takeda Chemical Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356–57 (Fed. Cir. 2007) (recognizing that the Supreme Court in *KSR* “acknowledged 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*, 127 S.Ct. at 1731)), *cert. denied*, 128 S.Ct. 1739 (2008).

⁴⁷ The Federal Courts Improvement Act abolished the U.S. Court of Customs and Patent Appeals (“C.C.P.A.”) on September 30, 1982. 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.”).

⁴⁸ 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.”).

⁴⁹ 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 Court of Appeals applied its TSM test here.” (citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851))).

[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 . . .

⁵⁰

Thus, one lesson from *KSR* is that the PHOSITA is not a plodder, but rather a creative individual.⁵¹

B. A New Enablement Standard?

Not surprisingly, the Federal Circuit's post-*KSR* opinions devote more attention to the PHOSITA.⁵² Perhaps the most conspicuous result of the court's new PHOSITA-centered approach is the emergence of "full scope" enablement as a lever to invalidate patents. The following discussion examines three recent Federal Circuit cases applying the full scope enablement standard. It contends that these cases vitiate the belief that a single embodiment is sufficient to enable a PHOSITA in predictable technologies.⁵³

1. *Liebel-Flarsheim*: Explanation

In *Liebel-Flarsheim Co. v. Medrad, Inc.*,⁵⁴ the Federal Circuit held that the written description must enable the full scope of the broadest claim, even if one or more embodiments are specifically enabled. The invention in *Liebel-Flarsheim* was directed toward a high-pressure medical injection system. When Liebel originally applied for the patent, the application explicitly recited an injector with a pressure jacket.⁵⁵ After learning that Medrad had a competing injector without a pressure jacket, Liebel deleted

⁵⁰ *KSR*, 127 S.Ct. at 1742 (emphasis added).

⁵¹ For additional perspectives on the post-*KSR* PHOSITA, see Joseph Scott Miller, *Remixing Obviousness*, 16 TEXAS INTELL. PROP. L.J. (forthcoming 2008).

⁵² See, e.g., *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1257 (Fed. Cir. 2007) (determining that the district court erred in its nonobviousness analysis by finding that in the case of a claim directed to a method of treating an ear infection with an antibiotic, the PHOSITA was a general practitioner who prescribes the drug rather than a person trained in the art of drug formulation and in ear treatments), *cert. denied*, 128 S.Ct. 1259 (2008). See also *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) (explaining that the nonobviousness analysis "is not the result of a rigid formula disassociated from the consideration of the facts of a case," but requires a consideration of "the common sense of those skilled in the art").

⁵³ One could argue that a Federal Circuit case a few years earlier signaled the demise of single-embodiment enablement in the predictable arts. See *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that where the claims covered a Type 1 or a Type 2 aluminum coating, yet the specification only described a Type 2 coating, the claims were nonenabled because a PHOSITA could not fill in the gaps without undue experimentation), *cert. denied*, 543 U.S. 925 (2004).

⁵⁴ (*Liebel II*), 481 F.3d 1371 (Fed. Cir. 2007).

⁵⁵ See *id.* at 1374 (explaining the prosecution history).

all references to the pressure jacket in order to bring Medrad's injector within the scope of its claims. In a subsequent infringement suit, the Federal Circuit affirmed the district court's conclusion that Liebel's broad claim covered Medrad's jacketless injector.⁵⁶

Yet, for at least two reasons, the Federal Circuit affirmed the district court's determination that Liebel's broad claim was invalid for a lack of enablement. First, although Liebel provided an enabling disclosure for an injector with a pressure jacket, nowhere did the written description describe a jacketless injector.⁵⁷ The court rejected Liebel's argument that "if an invention pertains to an art where the results are predictable, e.g., in the mechanical arts, then disclosure of a single embodiment can enable a broad claim [and thus the enablement requirement is satisfied and the inquiry should end there]."⁵⁸ According to Judge Lourie, the disclosure of a jacketed system "does not permit [a PHOSITA] to make and use the invention as broadly as it was claimed, including without a pressure jacket."⁵⁹ Indeed, there must be "reasonable enablement of the scope of the range,"⁶⁰ which means that the written description can only leave gaps that can be filled by the PHOSITA's knowledge and routine experimentation.⁶¹

Second, and relatedly, Liebel's written description included statements that disparaged a jacketless injector, calling it "expensive" and "impractical."⁶² As the Federal Circuit has previously held, "where the [written description] teaches against a purported aspect of an invention, such a teaching 'is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.'"⁶³

2. *Automotive Technologies*: Confirmation

Any doubts about the Federal Circuit's commitment to full scope enablement were put to rest in its subsequent opinion in *Automotive Technologies International, Inc. v. BMW of North America, Inc.*⁶⁴ The invention related to automotive side impact crash sensors. After adopting the district court's construction of the broad claim to cover both mechanical and electronic sensors, the Federal Circuit affirmed the summary judgment of invalidity because the written description only provided a detailed and enabling

⁵⁶ *Id.* at 1375. In the first appeal to the court, the Federal Circuit reversed the district court's claim construction and determined that the asserted claims did not require a pressure jacket. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 915 (Fed. Cir. 2004) (reversing summary judgment of noninfringement and remanding to consider proper claim construction in light of the Federal Circuit's interpretation), *cert. denied*, 543 U.S. 925 (2004).

⁵⁷ *Liebel II*, 481 F.3d at 1378–1380.

⁵⁸ *Id.* at 1379. *Cf.* *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement), *cert. denied*, 484 U.S. 954 (1987). To support its argument, Liebel also relied on *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991) ("The enablement requirement is met if the description enables any mode of making and using the claimed invention.").

⁵⁹ *Liebel II*, 481 F.3d at 1380.

⁶⁰ *Id.*

⁶¹ *Cf.* *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (explaining that the written description 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").

⁶² *See* U.S. Patent No. 5,456,669 col. 1 ll.26–28 (filed Nov. 30, 1993).

⁶³ *Liebel II*, 481 F.3d at 1379 (quoting *AK Steel*, 344 F.3d at 1244).

⁶⁴ 501 F.3d 1274 (Fed. Cir. 2007).

disclosure for a mechanical sensor. As in *Liebel-Flarsheim*,⁶⁵ Judge Lourie rejected the patentee's argument that the enablement of one mode of practicing the invention was sufficient to enable the broad claim.⁶⁶

Two aspects of the claimed invention appeared to disturb the panel. First, with respect to the written description, "although two full columns and five figures [in the patent] detail[ed] mechanical side impact sensors, only one short paragraph and one figure related to an electronic sensor."⁶⁷ Moreover, the lone paragraph was simply an overview of electronic sensors and the figure only provided a "conceptual view," which the inventor admitted "[was] not meant to represent any specific design."⁶⁸

Second, the written description stated that "[s]ide impact sensing is a *new* field," which signaled that a PHOSITA could not readily fill in the gaps omitted from the disclosure without undue experimentation.⁶⁹ This newness, the fact that there were no electronic sensors in existence at the time of filing, and the gaps in the disclosure led the court to conclude that mechanical and electronic side impact sensors are "distinctly different."⁷⁰ Accordingly, the court found that the written description provided "only a starting point, a direction for further research" for using electronic sensors.⁷¹

3. *Sitrick*: Reiteration

The Federal Circuit's recent opinion in *Sitrick v. Dreamworks, LLC* completes the full scope enablement trilogy and reiterates that claims broad enough to encompass significant nonenabled subject matter will be found nonenabled.⁷² The invention related to integrating a user's audio signal or video image into a preexisting video game or movie. *Sitrick*, a sole inventor, alleged that the defendants infringed his patents because their products allowed users to combine their own voices with pre-existing video images stored on movie DVDs. Although the district court construed the claims to encompass both movies and video games, it granted summary judgment of invalidity for nonenablement because the teachings of the patents only related to video games.⁷³

The Federal Circuit affirmed the grant of summary judgment for the defendants because the patentee failed to enable the full scope of the claimed invention.⁷⁴ Writing for the panel, Judge Moore asserted that "[if] the claims were broad enough to cover movies and video games, the patents must enable both embodiments."⁷⁵ The court agreed with the defendants' experts that the technological differences between video games and movies would not allow a PHOSITA to apply the teachings to movies without

⁶⁵ See *supra* Part III.B(1).

⁶⁶ *Automotive Techs.*, 501 F.3d at 1285.

⁶⁷ *Id.* at 1282.

⁶⁸ *Id.* at 1283.

⁶⁹ *Id.* at 1284.

⁷⁰ *Id.* at 1285.

⁷¹ Cf. *In re Gardner*, 427 F.2d 786, 789 (C.C.P.A. 1970) (determining that 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).

⁷² 516 F.3d 993 (Fed. Cir. 2008).

⁷³ *Id.* at 1002.

⁷⁴ *Id.*

⁷⁵ *Id.* at 1000.

undue experimentation.⁷⁶ The message here appears to be that broadly construed claims supported by a narrow disclosure run the risk of invalidation.⁷⁷

IV. IMPLICATIONS

A. *Lessons for Patentees*

This Article demonstrates that the Federal Circuit has reshaped the law of enablement in light of the *KSR* decision. It posits that the court's recent insistence on full scope enablement suggests at least three possible lessons for patentees with inventions in the "predictable" arts to consider during prosecution and litigation.

First, and perhaps most importantly, if a claim covers a range of embodiments, the disclosure should contain sufficient written description to adequately enable the scope of the range.⁷⁸ In other words, if a claim reads on "distinctly different" embodiments of the invention, the written description must sufficiently enable each of the "distinctly different" embodiments.⁷⁹ This lesson, however, is hardly radical as it has long been the rule in the unpredictable arts.⁸⁰ So while the written description need not disclose every embodiment encompassed by the claims,⁸¹ there is a danger that embodiments not

⁷⁶ *Id.*

⁷⁷ *See, e.g., Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999) (explaining that the scope of the claims must "be less than or equal to the scope of enablement"); *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) ("[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed." (internal citation and quotation marks omitted)).

⁷⁸ *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378 (Fed. Cir. 2007) (agreeing with the defendant that the disclosure must teach the full range of embodiments in order for the claims to be enabled). But patentees must be mindful of the disclosure-dedication rule. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) ("[W]hen a patent drafter discloses but declines to claim subject matter[,] this action dedicates that unclaimed subject matter to the public."); *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004) (holding that if a PHOSITA can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public). When the rule is applied, it bars a finding of infringement when an accused infringer practices disclosed but unclaimed subject matter. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106 (Fed. Cir. 1996), *cert. denied*, 520 U.S. 1115 (1997). Thus the rule "requires an inventor who discloses specific matter to claim it, and to submit the broader claim for examination." *PSC*, 355 F.3d at 1360.

⁷⁹ An inference of "distinctly different" embodiments might arise when the applicant provides substantial written description for one embodiment and relatively little written description for another. *See supra* notes 67–68 and accompanying text.

⁸⁰ *See, e.g., In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993) (affirming the Board's rejection because the single working example did not enable the broad scope of the claims); *In re Colianni*, 561 F.2d 220, 225 n.2 (C.C.P.A. 1977) (Miller, J., concurring) ("[T]he lack of a working example is nonetheless a factor to be considered, especially in a case involving an unpredictable and undeveloped art.") (internal quotation marks omitted). However, enablement is not a numbers game, inasmuch as the sufficiency of the disclosure depends not only on the number of examples but also on the nature of the claimed subject matter and the disclosure as a whole. *See In re Borkowski*, 422 F.2d 904, 910 (C.C.P.A. 1970) ("there is no magical relation between the number of representative examples and the breadth of the claims" with respect to enablement); *In re Cavallito*, 282 F.2d 363, 367 (C.C.P.A. 1960) (holding that a specification with 19 examples adequately enabled a broad claim covering hundreds of thousands of compounds because "[t]he sufficiency of a disclosure depends not on the number but rather on the nature of the claimed compounds *per se* and the nature of the supporting disclosures").

⁸¹ *See, e.g., AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill

described either cannot be made or may require unduly extensive experimentation.⁸² Patentees might also consider adopting a patenting strategy where they prosecute a group of smaller, discrete applications rather than a single, omnibus application.

Second, a broadly construed claim coupled with a narrow disclosure creates a high risk of invalidation.⁸³ Indeed, a bedrock principle of patent law is that the sufficiency of the disclosure under § 112 para. 1 is judged as of the filing date of the application.⁸⁴ This also means that an applicant who broadens a claim during prosecution must ensure that the embodiments encompassed by the amended claim are fully enabled by the disclosure as originally filed.⁸⁵ Indeed, the disclosure requirements of § 112 para. 1 can be used to police claim amendments and to hold the patentee to the scope of the original filing.⁸⁶

Third, if there are statements in the written description that disparage an embodiment, indicate that an embodiment is impractical, or teach away from an embodiment, this may suggest that a significant amount of experimentation would be required to practice that embodiment.⁸⁷ These disparaging statements can constitute a disavowal of claim scope,⁸⁸ or possibly suggest that the disparaged embodiment was

gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments . . .”), *cert. denied*, 543 U.S. 925 (2004).

⁸² See *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (“Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation.”).

⁸³ This indeed was the result in *Liebel-Flarsheim Co. v. Medrad, Inc.*, as Judge Lourie described:

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, [Liebel] then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, “beware of what one asks for,” might be applicable here.

481 F.3d 1371, 1380 (Fed. Cir. 2007). See also *supra* notes 75–77 and accompanying text.

⁸⁴ *In re Glass*, 492 F.2d 1228 (C.C.P.A. 1974) (Rich, J.) (explaining the rule). See also *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (Lourie, J.) (explaining that in both 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”) (emphasis in original).

⁸⁵ See *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004) (explaining that “it is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor’s products, as long as the disclosure supports the broadened claims,” but “[i]f the disclosure does not support the broadened claims, the applicant will not be accorded priority based on the original disclosure, and the claims may be invalidated”) (citations omitted), *cert. denied*, 543 U.S. 925 (2004). See also *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479–80 (Fed. Cir. 1998) (holding that a claim broadened during prosecution was invalid because the original disclosure limits the permissible breadth of later-drafted claims).

⁸⁶ It is clear that both the enablement and “written description” requirements of § 112 paragraph 1 can be used for this purpose. See *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319–1320 (Fed. Cir. 2003) (tracing the emergence of the “written description” requirement of § 112 paragraph 1, which ensures that newly claimed subject matter was described in the patent application as originally filed), *cert. denied*, 540 U.S. 982 (2003). Stated another way, an amended claim can fail under § 112 paragraph 1 because the originally filed disclosure (1) fails to teach a PHOSITA how to make and use the full breadth of the newly claimed subject matter (a lack of enablement); or (2) suggests that the applicant did not have possession of the newly claimed subject matter at the time of filing, meaning that it was not a part of his original creation (a lack of written description). 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).”), *cert. denied*, 543 U.S. 1015 (2004).

⁸⁷ See *supra* note 63 and accompanying text.

⁸⁸ See *SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (“One purpose for examining the specification is to determine if the patentee has limited the scope of the

nonenabled at the time of filing.⁸⁹ At a minimum, the lesson here is that patent applicants should carefully choose language when drafting the written description, particularly when characterizing their inventions or the state of the art.⁹⁰

B. Revisiting the Generic Claim

The Federal Circuit's shift toward full scope enablement fuels the debate over generic claiming.⁹¹ A generic claim, which often covers countless embodiments,⁹² affords the broadest possible scope under the patent laws.⁹³ Indeed, it is the generic claim which allows a patentee to dominate an entire field of technology.⁹⁴ While several commentators argue that broad protection is necessary to stimulate invention and promote early disclosure,⁹⁵ another commentator warns that generic claims can give rise to undue patent scope, which "can have a chilling effect on other [investigators] who are

claims."); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) ("The public is entitled to take the patentee at his word [with respect to what] the invention is . . ."). *See also* *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1355 (Fed. Cir. 2006) (affirming district court's narrow construction of the term "host interface" in a claim directed to a PDA device to require a "direct parallel bus interface" and not encompass a serial interface, where the written description only described an embodiment using a direct parallel bus interface, and in the written description the inventor had disparaged serial interfaces).

⁸⁹ *See supra* Part III.B(1).

⁹⁰ For example, instead of stating "the invention *is*," some drafters state "*one* aspect of the invention relates to" or "in *an* embodiment" and avoid terms like "superior." *See generally* STEPHEN A. BECKER, PATENT APPLICATIONS HANDBOOK § 1:36 (2007) (providing suggestions for drafting patent applications). Quite often the temptation to disparage or characterize arises when the applicant tries to distinguish the invention over the prior art. But, by doing so, "an applicant is indicating what the claims do not cover, [and] is by implication surrendering such protection." *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997).

⁹¹ Generic claims employ broad terminology to cover embodiments that share a common attribute. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 806.04(d) (8th ed., rev. 5, 2006) (defining a generic claim).

⁹² *See, e.g.*, U.S. Patent No. 4,801,613 (filed June 17, 1987) (issued Jan. 31, 1989). 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 8 smaller generic substructures. *See id.* col.19 1.21-41. Accordingly, this claim covers 10,235,904 formulations of a peptide. *See also* U.S. Patent No. 4,838,925 (filed Sep. 25, 1987) (issued Jun. 13, 1989) (including a broad generic claim which covers billions of compounds).

⁹³ *See, e.g.*, Lucille J. Brown, *The Markush Challenge*, 31 J. CHEM. INF. COMPUT. SCI. 2-3 (1991) (discussing the widespread use of generic structures in chemical patents and the broad protection they convey).

⁹⁴ But the scope of enablement provides a check on a broad generic claim:

It is apparent that . . . an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on hit teachings. . . . It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. § 112.

In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

⁹⁵ *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 845-852 (1990) (advancing an argument for broad claims; particularly for pioneering inventions); Edlyn S. Simmons, *Prior Art Searching in the Preparation of Pharmaceutical Patent Applications*, DRUG DISCOVERY TODAY, Feb. 1998, at 52 (explaining the importance of drafting broad generic claims which includes hypothetical compounds in order to prevent competitors from developing them).

trying to elucidate how to make and use the claimed invention while the inventor does not know how to do so.”⁹⁶

While it certainly remains the case that a patentee need not disclose *every* embodiment encompassed by a generic claim at the time of filing,⁹⁷ clearly the quantum of exemplification required to enable a broad genus has increased, given that the Federal Circuit is now policing these claims more aggressively.⁹⁸ The end result might be a shift toward narrower claiming. Specifically, applicants should draft claims more precisely, meaning that there should be a closer correspondence between the disclosed embodiments and claim breadth. Indeed, applicants should be less inclined to draft claims reading on millions or billions of embodiments because it is unlikely that an inventor can provide enough exemplification to support claims of that breadth. Although a full discussion of this issue is beyond the scope of this Article, elucidating the precise amount of enablement required to support a generic claim is an open question for the court, other legal actors, and policymakers to resolve.⁹⁹

V. CONCLUSION

It appears that the Federal Circuit’s adoption of the full scope enablement standard mitigates the historical dichotomy between the predictable and unpredictable arts and moves the court toward a unitary adjudicatory framework. At a minimum, the court’s new enablement standard vitiates old doctrines and raises new questions about the adequacy of disclosure and the proper scope of claims. Indeed, it may be that full scope enablement is moving the patent system away from a disclosure standard based on speculation and uncertainty and toward one based on true testing and experimentation.¹⁰⁰

⁹⁶ Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. (forthcoming 2008) (citing Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006)).

⁹⁷ See *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (Rich, J.) (explaining the principle). Professor Merges elaborates:

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 actually created at the time the application is filed. But imitators would soon find some minor variation over the disclosed embodiments . . . [which would give them] a nonenablement defense if the patentee tried to enforce the patent. Such a rule would soon render patents worthless.

Merges & Nelson, *supra* note 95, at 845.

⁹⁸ See *supra* Part III.B. It also appears that the standard has been raised in the unpredictable arts. In *Pharm. Res., Inc. v. Roxane Labs., Inc.*, the court affirmed 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 claim to “a surfactant,” which was construed to cover any and all surfactants. 253 Fed.Appx. 26, 27-31 (Fed. Cir. 2007) (Moore, J.) (nonprecedential).

⁹⁹ The debate over generic claiming also points to a broader question of whether the purpose of the patent system is to promote innovation or disclosure. Compare *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc) (Newman, J.) (arguing that the obligation to disclose the workings of the invention should not diminish the patent-supported incentive to innovate because “the obligation to disclose is not the principal reason for a patent system The reason . . . is to encourage innovation and its fruits . . .”) with Seymore, *supra* note 96 (arguing that generic claims can thwart innovation and proposing that the inventor’s actual experimental details should be used to limit claim scope).

¹⁰⁰ See Seymore, *supra* note 96 (advocating an enablement standard based on an actual reduction to practice; i.e., “true testing and experimentation”).