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To Infinity and beyond: The Problem of Open-Ended Product Claim Language in the Unpredictable Arts,

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TO INFINITY AND BEYOND: THE PROBLEM OF OPEN-ENDED PRODUCT CLAIM LANGUAGE IN THE UNPREDICTABLE ARTS

I. INTRODUCTION

Imagine that Mary has invented a new process for making carbon fibers. Not only is her process cheaper and more efficient than previously known processes, but it also produces fibers of superior tensile strength. In fact, Mary's fibers exhibit much higher tensile strength than any fibers made before, with her most successful experiments yielding a tensile strength of X. The highest tensile strength previously achieved was Y—some value less than X.

Excited about her breakthrough and aware of its commercial implications, Mary immediately calls her patent attorney, Kris, and asks him to draft a patent application. As competent counsel, Kris recognizes that Mary can potentially claim both the process and the resulting fiber. He begins drafting right away, and two days later the specifications and claims are complete. The first three claims cover Mary's new process. Claim 4 reads, "A carbon fiber having a tensile strength of X or more." Kris carefully selects this open-ended¹ language to maximize the scope of Mary's patent protection.² Though Kris knows that Mary has not yet achieved tensile strengths greater than X, Mary told him that she suspects her new method could obtain higher tensile strengths. Kris wants to make sure the patent also covers those superior fibers. Besides, Kris has seen similar claim language in other chemistry-related patents.³ Satisfied by his effort, Kris sends the application to the Patent and Trademark Office (PTO).

1. In this Comment, an "open-ended" claim is one written such that it has no boundary on one end. For example, the literal language of Mary's hypothetical Claim 4 captures any fiber with a tensile strength between X (marking a lower boundary) and infinity (marking the *absence* of an upper boundary). Where the open-ended language refers to a property of a claimed material, as here, patentees frequently use phrases such as "at least X," "X or more," "more than X," or "greater than X."

2. Kris also knows that this claim will not read on the prior art because the highest tensile strength previously achieved was Y—some value less than X.

3. See, e.g., U.S. Patent No. 7,247,372 col.22 ll.30–34 (filed Apr. 4, 2003) (claiming a "polyethylene filament having a tensile strength of 15 cN/dtex *or more* and a tensile modulus of 500 cN/dtex *or more*, wherein an index value of a Circular knit comprising the filament is 3.0 *or more* as determined by using a coup tester" (emphasis added)); U.S. Patent No. 7,214,428 col.22 ll.55–62 (filed Apr. 9, 2003) (claiming a "coated nanocrystal comprising: a core comprising a first semiconductor material, a shell layer deposited on the core comprising a second semiconductor material, a coating material deposited on said shell layer comprised of an imidazole-based composition wherein said coated nanocrystal has a quantum yield of *greater than* 30% when excited with light" (emphasis added)); U.S. Patent No. 5,281,477 col.10 ll.41–45 (filed Apr. 9, 1991) (claiming a "carbon fiber of a high tenacity and a high modulus of elasticity which has a fiber diameter of 1–6 microns, a strand tenacity of 503 kg/mm² *or more*, a strand modulus of elasticity of 28 ton/mm² *or more* and a density of 1.773 g/cm³ *or more*" (emphasis added)); U.S. Patent No. 5,087,710 col.9 l.64 to–col.10 l.5 (filed Jan. 4, 1990) (claiming a "homogeneous rhenium metathesis catalyst, comprising a rhenium (VII) atom centrally linked to an alkylidene ligand, an alkylidyne ligand, and two other ligands of which at least one ligand is an electron withdrawing ligand in which its corresponding free ligand in protinated form has a pKa below about 9; wherein the catalyst has significant metathesis activity that can effect the metathesis of an ordinary or functionalized olefin at room temperature at a rate of *at least* one turnover per hour" (emphasis added)).

About a year later, the examination process begins when junior examiner Alfonso finally takes a look at Mary's application. Alfonso is smart. He earned a Bachelor of Science in chemistry from a prestigious state university, graduating with honors. He then worked for a start-up company for three years as a chemist before moving to the PTO, where he has been for seven months.⁴ Alfonso is also pressed for time. Typically, he has only eight hours to devote to each application⁵ over the course of 2.6 years—the average time an application spends in prosecution.⁶ Scanning Mary's specification and claims, Alfonso immediately notices the open-ended language in Claim 4. He asks himself if Mary really has made such an amazing breakthrough in carbon fiber synthesis that her new process can achieve fibers having unlimited tensile strength.⁷ Skeptical, Alfonso consults the *Manual of Patent Examining Procedure* (MPEP) and finds section 2164.08, titled "Enablement Commensurate in Scope with the Claims."⁸ Regarding scope of enablement, section 2164.08 suggests a two-part inquiry: the examiner must (1) "determine how broad the claim is with respect to the disclosure" and (2) determine if a person having ordinary skill in the art is able to practice the full scope of the invention without undue experimentation.⁹ Hoping for additional guidance, Alfonso carefully reads section 2164.08 several more times but remains uncertain about whether the MPEP requires or even presents a special framework for evaluating open-ended product claims. Should he allow Claim 4, and how should he decide?

This Comment explains why the MPEP guideline offers little help to an examiner faced with Alfonso's predicament and suggests that a change to the guideline may be in order. In short, the difficulty arises from two sources. First, claim construction principles demand that open-ended terms in product claims be given their plain meaning in virtually all cases.¹⁰ As a result, the scope of "open-ended product claims" will typically be quite broad. In this Comment, open-ended product claims are those like Mary's hypothetical Claim 4, in which (1) the open-ended language refers to one or more properties of a claimed product, (2) the novelty and value of the product substantially depend upon the magnitudes of the relevant properties, and (3) the underlying art is "unpredictable." This Comment

4. A person with Alfonso's qualifications would likely be hired at the GS-9 grade level. See USAJOBS, Patent Examiner (Chemistry), Qualifications Required, <http://jobsearch.usajobs.opm.gov/getjob.asp?JobID=62664828&TabNum=3&rc=2> (last visited Dec. 7, 2007). The lowest examiner grade level is GS-5. See *id.* The GS-5 level requires candidates to meet relatively minimal "basic qualifications." See *id.* To be a patent examiner, a candidate must "[h]ave at least a bachelor's degree in physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics." *Id.* Alternatively, a candidate without even a bachelor's degree could be hired if he possessed an appropriate "combination of education and experience" in chemistry. See *id.*

5. John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 135 n.128 (2002) ("[Eight hours] is an average across all industries, and thus there may be substantial variation in the hours spent from one industry to another.").

6. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006, at 120 tbl.1 (2006), available at <http://uspto.gov/web/offices/com/annual/2006/2006annualreport.pdf>.

7. Alfonso realizes that Claim 4 does not read on the prior art.

8. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.08 (8th ed., 6th rev. 2007) [hereinafter MPEP].

9. *Id.*

10. See discussion *infra* Part III.

assumes that patents including one or more open-ended product claims also include at least one corresponding process claim, where the new process is what has enabled achievement of the superior product.¹¹

Second, available scope of enablement tests, including the one found in section 2164.08, essentially do nothing more than restate the basic enablement inquiry.¹² This basic inquiry is highly fact-specific and leaves a great deal of discretion in the hands of a factfinder.¹³ While such a result might be acceptable for most types of claims, this Comment contends that where open-ended product claims are concerned, the patent examiner ought to take a different approach.¹⁴ The exceptional breadth of open-ended product claims weakens the patent system's presumption that patent examiners are competent to judge whether broad claims are truly enabled.¹⁵ Moreover, prudent policy suggests in this context that the PTO err on the side of allowing narrower claims rather than broader ones.¹⁶ Therefore, as an alternative to the current MPEP approach for open-ended product claims, this Comment suggests that patent examiners should presumptively reject open-ended product claims in the unpredictable arts, allowing only those claims that are limited by the highest values actually achieved by the patentee and disclosed in the specification.

This Comment's proposed approach is preferable to the current MPEP guideline for at least two reasons. First, in the particular context of open-ended product claims in the unpredictable arts, the patent examiner is not well-equipped to undertake such a difficult and fact-specific inquiry; not even the inventor will know for certain what her method can in fact achieve through subsequent experimentation.¹⁷ Given that the examiner will have very little time to devote to the application, this concern is especially relevant.¹⁸ Second, erring on the side of

11. This Comment assumes that products with relevant properties of higher magnitudes are "superior" products.

12. See discussion *infra* Part IV.A.

13. See Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. (forthcoming Autumn 2008) (manuscript at 30 n.143), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1103968 ("[W]hether a given disclosure . . . 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." (quoting *In re Metcalfe*, 410 F.2d 1378, 1382 (C.C.P.A. 1969)) (internal quotation marks omitted)); discussion *infra* Part IV.A (examining current tests for enablement).

14. At least one other commentator has suggested that broad claims in the unpredictable arts pose unique difficulties. Professor Sean B. Seymore has contended that "the current patent examination framework allows a patentee [in an unpredictable art] to obtain a broad claim encompassing millions of compounds enabled by a trivial amount of supporting disclosure." Seymore, *supra* note 13 (manuscript at 4). Suggesting that allowance of such claims "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," Professor Seymore "propose[s] a new approach to the prima facie case of nonenablement for patent applications in the unpredictable arts." *Id.* (manuscript at 5). Despite the highly fact-specific nature of the enablement inquiry, Professor Seymore argues that the patent examiner is "uniquely poised to derail nonenabled inventions," *id.* (manuscript at 30–31), and should serve as "the gatekeeper of the patent system," *id.* (manuscript at 30).

15. See discussion *infra* Part IV.B.1.

16. See discussion *infra* Part IV.B.2.

17. See discussion *infra* Part IV.B.1.

18. See Allison & Lemley, *supra* note 5, at 135 n.128. Further, this Comment argues that giving examiners additional time and resources would not solve the problems presented by open-ended product claims. See discussion *infra* Part IV.B.1.

allowing narrower claims—compared to allowing broader claims—better encourages innovation over time.¹⁹

Further, this Comment's suggested approach does not punish an inventor whose new process really does enable the full range of possible products—the inventor's *process* claims will protect her process, even though her *product* claims, no longer open-ended, will not. For example, imagine that Mary's new process really does enable scientists to produce carbon fibers having tensile strengths of virtually infinite magnitude. An examiner following this Comment's suggested approach would reject Mary's Claim 4, which claims a "carbon fiber having a tensile strength of X or more," but would allow a claim omitting the words "or more." However, such a rejection would not mean that Mary's competitors could read Mary's patent and based on its teaching, brazenly make, use, and sell carbon fibers having a tensile strength greater than X. Mary's competitors could not do so because Mary's patent would still grant her a monopoly in her new fiber-making process, which she also claims. Therefore, this Comment's suggested approach does not rob inventors of the fruits of their labor in those instances (perhaps rare) when the open-ended product claims truly are enabled. The accompanying process claims will protect those extraordinary inventors. Rather, this Comment's suggested approach will prevent all inventors from receiving unearned windfalls.

Part II of this Comment describes basic enablement principles. Part III argues that claim construction principles in both litigation and prosecution contexts demand that open-ended terms in product claims be given their plain meaning in virtually all cases. Part IV reviews several currently accepted tests for determining the scope of enablement, particularly as they relate to open-ended claims, and concludes that all the tests leave enormous discretion in the hands of courts and examiners. Part IV thus proposes that patent examiners should presumptively reject open-ended product claims, allowing only those claims that are limited by the highest values actually achieved by the patentee and disclosed in the specification. Part V concludes by summarizing the arguments of this Comment.

19. See Seymore, *supra* note 13 (manuscript at 5) ("[U]ndue 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."); discussion *infra* Part IV.B.2 (discussing the policy concerns that arise from the allowance of open-ended product claims).

II. ENABLEMENT PRINCIPLES²⁰

Patents have often been described as monopolies granted by the government in exchange for the patentee's disclosure of her invention.²¹ In other words, an inventor tells the world how to accomplish some new thing, and the government gives the inventor the right to prevent others from doing that new thing for a set amount of time.²² But the government will not give away such broad rights in exchange for any new thing. Rather, the invention must satisfy the so-called requirements of patentability: "(1) patentable subject matter, (2) novelty, (3) utility, (4) nonobviousness, and (5) enablement."²³ Among these, "enablement" particularly emphasizes the nature of the patent grant as a bargain with society. The basic principles of enablement are well known. To begin, an inventor must disclose enough of her invention to enable a person having ordinary skill in the art to practice it.²⁴ The first paragraph of 35 U.S.C. § 112 provides,

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.²⁵

20. The reader may notice that this discussion employs both "patentability" and "infringement" language. In the enablement analysis, the two contexts are nearly identical, and the following principles apply equally during prosecution and after issue. *See* 35 U.S.C. § 282 (2000) (listing "failure to comply with any requirement of [§] 112" as a defense "in any action involving the validity or infringement of a patent"). In fact, under a § 112 enablement analysis, the only difference between unissued and issued claims is the presumed validity of the latter. *See* *Magnaflux Corp. v. Coe*, 139 F.2d 531, 532 (D.C. Cir. 1943) ("In a suit to obtain a patent the presumption of administrative and judicial correctness runs against the rejected claims, while in an infringement suit the presumption of administrative correctness runs in favor of the issued patent."); *Drexelbrook Controls, Inc. v. Magnetrol Int'l, Inc.*, 720 F. Supp. 397, 400 (D. Del. 1989) ("A patent is presumed valid, and each claim of a patent is presumed valid independent of the validity of the other claims." (citing 35 U.S.C. § 282)), *aff'd*, 904 F.2d 45 (Fed. Cir. 1990).

21. *See, e.g.,* *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("[Patents are] grant[s] of a statutory monopoly . . . [and] are not given as favors, . . . but are meant to encourage invention by rewarding the inventor . . ." (citations omitted)); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("[A] patent is an exception to the general rule against monopolies . . ."); *Zachos v. Sherwin-Williams Co.*, 166 F.2d 79, 81 (5th Cir. 1948) ("A patent is a monopoly granted by the public and is of public interest . . ."), *aff'd on reh'g*, 177 F.2d 762 (5th Cir. 1949); *Am. Foundry & Mfg. Co. v. Josam Mfg. Co.*, 79 F.2d 116, 117 (8th Cir. 1935) ("A patent is a governmental grant of monopoly for the making, selling, and use of a novelty (disclosed therein) as claimed by the patent.").

22. The Supreme Court emphasized the nature of the bargain in the following way: "[I]mmediate disclosure is not the objective of, but is *extracted from*, the patentee. It is the price paid for the exclusivity secured." *Eldred v. Ashcroft*, 537 U.S. 186, 216 (2003).

23. ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 128 (rev. 4th ed. 2007).

24. 35 U.S.C. § 112 (2000).

25. *Id.*

Further, “to be enabling, the specification of [a] patent must teach those skilled in the art how to make and use the *full scope* of the claimed invention without undue experimentation.”²⁶ In other words, the scope of enablement provided must be “commensurate with the scope of protection sought by the claims”;²⁷ stated differently, “the 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.”²⁸ Importantly, enablement “must be judged as of [the application] filing date.”²⁹ In addition, whether a claim is enabled depends in part on the predictability of the art: “Patents concerning chemical reactions . . . generally involve unpredictable factors and thus enable a narrower range of claims [than patents concerning more predictable arts].”³⁰

Courts and the PTO have distinguished “scope” enablement from “general” enablement.³¹ When the specification does not enable any subject matter within the scope of the claim, a general enablement rejection is appropriate.³² General enablement rejections frequently arise when “there is reason to doubt the objective truth of the statements [in the specification] which must be relied on for enabling support.”³³ For example, such a rejection was appropriate where an inventor claimed a “method of dwarfing sugar beets by cold shock” under conditions the examiner believed would immediately freeze the plants “beyond revival.”³⁴

26. *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)) (internal quotation marks omitted).

27. *In re Moore*, 439 F.2d 1232, 1236 (C.C.P.A. 1971).

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

29. *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977) (quoting *In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974)) (internal quotation marks omitted).

30. *Hormone Research Found., Inc. v. Genentech, Inc.*, 708 F. Supp. 1096, 1107–08 (N.D. Cal. 1988) (citing *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970)), *aff’d in part, vacated in part, and remanded*, 904 F.2d 1558 (Fed. Cir. 1990); *see also* *United States v. Teletronics, Inc.*, 857 F.2d 778, 786 (Fed. Cir. 1988) (“[C]hemical reactions [were] recognized by our predecessor court as having a high degree of unpredictability and therefore requiring an increased enablement disclosure.”); *Fisher*, 427 F.2d at 839 (“In cases involving unpredictable factors, such as most chemical reactions . . . , the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.”).

31. *See In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999); MPEP, *supra* note 8, at § 706.03(c), ¶ 7.31.02–.03. Though the MPEP does not have the force of law, it is entitled to judicial notice so far as it is an official interpretation of statutes and regulations with which it is not in conflict. *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)).

32. *Cortright*, 165 F.3d at 1356.

33. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (quoting *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971)) (internal quotation marks omitted).

34. *In re Pottier*, 376 F.2d 328, 329–30 (C.C.P.A. 1967). The rejection in *Pottier* was nominally a lack-of-utility rejection under 35 U.S.C. § 101. *Id.* at 329. However, later courts have made clear that “[i]f the written description fails to illuminate a credible utility,” rejections under both § 112 (enablement) and § 101 (utility) are appropriate. *Cortright*, 165 F.3d at 1356. The *Cortright* court noted, “This dual rejection occurs because ‘[t]he how to use prong of [§] 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.’” *Id.* (quoting *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993)) (alteration in original); *see also* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 4.04 n.2 (2007) (listing authorities for the proposition that the enablement requirement of § 112 inherently includes the utility requirement of § 101).

A claim can also be rejected for lack of “scope” enablement, or “undue breadth,” when the claim includes material to which the specification is not enabling in addition to material to which the specification is enabling.³⁵ Scope of enablement rejections under § 112 “orbit about the more fundamental question: To what scope of protection is this applicant’s particular contribution to the art entitled?”³⁶ For example, an applicant whose invention increased hair growth by a factor of three—some “filling-in” and additional “fuzz” on the scalp of the user—could not legitimately claim to “cure baldness” but could claim to “restore hair growth.”³⁷

The Federal Circuit’s predecessor court addressed the appropriate scope of protection for broad or open-ended claims in the seminal opinion of *In re Fisher*.³⁸ There, inventor Joseph Fisher’s patent application claimed an adrenocorticotrophic hormone (ACTH) preparation “containing at least 1 International Unit of ACTH per milligram,” where the number of International Units of ACTH per milligram (IU/mg) was a measure of the preparation’s potency for treating arthritis and other pathologies in humans.³⁹ Previous ACTH preparations could not effectively treat humans, in part because their potencies were too low, reaching only about 0.5 IU/mg.⁴⁰ In contrast, the Fisher specification disclosed preparations having 1.11 to 2.30 IU/mg.⁴¹ It is unclear why Fisher chose not to include an upper limit in his ACTH claim. Perhaps he believed his method could indeed produce preparations of greater potencies than those he obtained in his experiments to date;⁴² or perhaps he simply wished to claim for himself all future ACTH preparations suitable for human patients. Regardless, Fisher’s choice meant the court had to decide “whether an inventor who is the first to achieve a potency of greater than 1.0 . . . should be allowed to dominate *all* such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill.”⁴³

To guide its analysis, the court enunciated two principles. First, “an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings.”⁴⁴ Second, however, “[i]t is equally apparent . . . that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with . . . 35 U.S.C. § 112.”⁴⁵ Two facts led the *Fisher* court to conclude that the specification did not enable the inventor’s open-ended claim: the invention related

35. See *Cortright*, 165 F.3d at 1356; MPEP, *supra* note 8, at § 706.03(c), ¶ 7.31.03.

36. *In re Hogan*, 559 F.2d 595, 605–06 (C.C.P.A. 1977).

37. *Cortright*, 165 F.3d at 1357–59.

38. 427 F.2d 833 (C.C.P.A. 1970).

39. *Id.* at 834–35. One IU/mg was considered equal to a potency of 1.0. *Id.* at 839.

40. *Id.* at 834.

41. *Id.* at 839.

42. In a separate, related patent, Fisher listed fourteen numbered examples of ACTH preparations and indicated that other experiments had been carried out also. See *Process for Preparing Adrenal Gland Stimulating Substance*, U.S. Patent No. 3,192,115 col. 4–11 (filed Jan. 30, 1957) (issued June 29, 1965).

43. *Fisher*, 427 F.2d at 839.

44. *Id.*

45. *Id.*

to an unpredictable art,⁴⁶ and there was no “inherent upper limit” to the theoretically possible potencies of compositions like those claimed.⁴⁷

Ultimately, *Fisher* established several important principles and one test. The principles include the following: (1) “[o]pen-ended claims are not inherently improper”;⁴⁸ (2) the scope of claims must bear a “reasonable correlation” to the scope of the specification;⁴⁹ and (3) enablement is a “sliding scale”: the more unpredictable the art, the more explicit and detailed the specification must be.⁵⁰ *Fisher*’s sole test was more precisely articulated by the Federal Circuit over twenty years later in *Scripps*: open-ended claims “may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.”⁵¹ Notably, if a fear had existed that allowance of a broad claim “might lead to enforcement efforts against . . . later developers,” after *Fisher* that fear “is both irrelevant and unwarranted.”⁵²

Based on the foregoing, *Fisher* and its progeny undeniably establish that open-ended claims can be appropriate, depending on whether or not they are enabled. But such a conclusion merely begs the question as to how an applicant, patent examiner, court, or market competitor can know whether an open-ended claim is in fact enabled. Open-ended claims present a more difficult problem for practitioners than bounded claims do because the former’s language extends into infinity.⁵³ No matter how detailed the specification, it cannot disclose an infinite number of embodiments. In other words, the unbounded claim language will always literally include more than the specification explicitly discloses.⁵⁴ For example, consider

46. See *id.* The court characterized the field of the invention as “physiological activity.” *Id.* Though this narrow classification may not constitute an entire “art” as some now conceive the term, see, e.g., MPEP, *supra* note 8, at § 2164.03 (using the term *art* implicitly to refer to larger fields such as chemistry, mechanical engineering, and electrical engineering), such differences in nomenclature are irrelevant. Rather, it is important that the *Fisher* court recognized the unpredictable nature of the science underlying the invention, grouping “physiological activity” with “most chemical reactions” in the “unpredictable” category. *Fisher*, 427 F.3d at 839.

47. *Id.* at 839–40.

48. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed. Cir. 1991). The *Scripps* court continued, “[A]s for all claims[, the] appropriateness [of open-ended claims] depends on the particular facts of the invention, the disclosure, and the prior art.” *Id.*

49. Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 8 (2007).

50. Robert Unikel & Douglas Eveleigh, *Protecting Inventors, Not Fortune Tellers: The Available Patent Protection for After-Developed Technologies*, 34 AIPLA Q.J. 81, 103 (2006).

51. *Scripps*, 927 F.2d at 1572.

52. *In re Hogan*, 559 F.2d 595, 607 (C.C.P.A. 1977).

53. While this proposition is generally true, not all open-ended claims necessarily extend into infinity. Some are instead bounded by an inherent upper limit, such as 100%. See, e.g., U.S. Patent No. 7,132,559 col.50 ll.20–21 (filed Feb. 25, 2002) (claiming a chemical compound having an enantiomeric excess of “greater than or equal to about 95%,” where the maximum value for enantiomeric excess is 100%). Such claims, however, face the same enablement difficulties as truly infinite claims when the specification does not disclose an example or embodiment reaching the upper limit, such as 100%, which it rarely does.

54. The problem may be especially acute where the language concerns a material’s properties, as in this Comment’s opening hypothetical. See Nikolas J. Uhler, Note, *Throwing a Wrench in the System: Size-Dependent Properties, Inherency, and Nanotech Patent Applications*, 16 FED. CIR. B.J. 327, 338 (2007) (arguing that patentees’ reliance on properties to protect their nanotechnology inventions places a heavy burden on patent examiners). Uhler, a former patent examiner, observes the

U.S. Patent No. 5,087,710, which claims a “homogeneous rhenium metathesis catalyst . . . ; wherein the catalyst has significant metathesis activity that can effect the metathesis of an ordinary or functionalized olefin at room temperature *at a rate of at least one turnover per hour*.”⁵⁵ The specification provides three examples of olefin metathesis reactions, with only one example of the three disclosing a catalyst activity—“at least 200.”⁵⁶ This claim language captures catalysts with an activity of 200, just as it captures catalysts with an activity of 1, 100, 1000, 1 million, or 1 billion. Therefore, it can readily be seen that even if the specification listed three hundred examples instead of three, and even if those three hundred examples all disclosed different activities, ranging from 1 to 1 million, the claim language would *still* literally include more than the specification explicitly discloses. This results from the fact that the claim language literally captures an infinite number of catalysts with a potentially infinite activity, including a catalyst with an activity of 1,000,001. Two dispositive issues thus emerge for any particular open-ended claim: how broadly should it be construed and how does one test whether a broad claim has been enabled? Parts III and IV will address these issues in turn.

III. OPEN-ENDED CLAIM INTERPRETATION

The MPEP provides relatively clear claim interpretation guidelines to examiners like Alfonso.⁵⁷ Before addressing the MPEP guidelines, however, this Part will survey the ways open-ended product claims could be interpreted during litigation. Litigation is addressed first because this Comment’s ultimate suggestion that examiners not allow open-ended product claims is based in part on avoiding harms that are likely to occur if such claims appear in issued patents.⁵⁸ However, it should be distinctly recognized that claim interpretation occurs in two different contexts: prosecution and litigation. The prudent patentee will draft her claims with an eye toward potential litigation—where an accused or potential infringer can challenge the patent’s validity.⁵⁹ While patentees understandably want to draft their claims as broadly as possible, overreaching can result in invalidity of the claims

following:

[P]roperty limitations are difficult to search for and locate in the prior art. Even if a property is well known, the chance that the prior art will disclose that property in a context that is useful to the examiner (i.e., relevant and applicable to the pending claims) is relatively small.

Id. at 339–40 (internal footnote omitted). An examiner considering an open-ended claim in Patent A will recognize not only that he may not find relevant prior art during prosecution, but also that the *next examiner* who considers a later application disclosing an improvement to the properties in Patent A will likely not find Patent A’s broad claim. Such a failure will be particularly troublesome because Patent A may capture, but will not disclose, the properties of the later application.

55. U.S. Patent No. 5,087,710 col.9 1.64–col.10 1.5 (filed Jan. 4, 1990) (emphasis added). Catalytic olefin, or alkene, metathesis occurs when a catalyst facilitates first the breaking of two carbon-carbon double bonds and then the reformation of the two bonds, except with the bonding partners switched. See ROBERT H. CRABTREE, *THE ORGANOMETALLIC CHEMISTRY OF THE TRANSITION METALS* § 11.4 (3d ed. 2001).

56. ’710 Patent, at col.9 ll.5–55.

57. See MPEP, *supra* note 8, at §§ 2111, 2111.01.

58. See discussion *infra* Part IV.B.2.

59. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 53 (3d ed. 2002).

entirely. Thus, it is in the best interest of patentees to draft claims as broadly as possible without overreaching.⁶⁰ Therefore, in addition to identifying the current PTO claim interpretation standard, this Part seeks to accomplish two goals regarding open-ended product claims: (1) help patentees choose appropriate language—accurate, fair, and likely to survive judicial scrutiny—during prosecution; and (2) help predict how open-ended product claims in issued patents might be interpreted in litigation. This Part should be read with both contexts in mind.

A. Litigation

In an issued patent, open-ended product claim language could conceivably be interpreted in three ways. First, the open-ended language can be given its plain meaning. Second, the language can be interpreted in accordance with a definition the patentee set forth in the specification, taking on a particular and perhaps even idiosyncratic meaning. Finally, the language can be given whatever meaning is necessary to make the claim valid, which will usually result in a meaning narrower than the plain meaning. This Part suggests that the first interpretation is most common, the second interpretation presents pitfalls to the unwary patentee, and the third interpretation should be universally rejected.

A fundamental principle of claim interpretation is that “claim construction analysis must begin and remain centered on the claim language itself.”⁶¹ This cardinal rule recognizes that “[c]laim construction . . . is not . . . policy-driven” but instead is “a contextual interpretation of language.”⁶² Thus, it is implicitly assumed that the patentee has chosen her words carefully.⁶³ As a result, courts do not have the option of enlarging or restricting the scope of the claims as written.⁶⁴ Instead, Courts must take the claims as they find them, shunning “a construction that flies in the face of the express language of the claim.”⁶⁵

A patentee may, however, act “as his own lexicographer,” defining a term as he chooses in his patent specification.⁶⁶ If a patentee does not act as his own lexicographer, the ordinary meaning of the term to one skilled in the art at the time of invention controls.⁶⁷ In turn, the ordinary meaning of a term to one skilled in the art is based primarily on the patent specification, because that person is “deemed to read the claim term . . . in the context of the entire patent, including the specification.”⁶⁸ If, however, the meaning of a term is no different in the context of the invention than in everyday, lay usage, there is no need for “elaborate

60. MERGES, MENELL & LEMLEY, *supra* note 23, at 308 (“The trick in drafting patent claims . . . is to make them as broad as the prior art and other patent doctrines will allow.”).

61. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

62. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339 (Fed. Cir. 2005).

63. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1358 (Fed. Cir. 1999).

64. *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967).

65. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001).

66. *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998).

67. *Id.*

68. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

interpretation”⁶⁹ and the “widely accepted meaning of commonly understood words” applies.⁷⁰ When more than one plain meaning exists, courts should adopt the narrower meaning when “the narrower one is clearly supported by the intrinsic evidence while the broader one raises questions of enablement under § 112.”⁷¹ This rule arises from the patent applicant’s burden to “distinctly” and “particularly” identify the metes and bounds of her invention.⁷² If the patentee fails to use language that unambiguously stakes out a broader claim, she will be limited to the narrower interpretation of the language.⁷³ However, because terms like “or more” or “at least” have only one plain meaning, this rule is not relevant to their interpretation.

When a patentee uses phrases like “or more” or “at least” to claim a material having a property included in an open-ended range bounded on the low end by a specific number, she is likely using the words according to their widely accepted, everyday meanings. For example, consider United States Patent 5,281,477, which is paradigmatic of the type of language this Comment is concerned with. Claim 1 of the ’477 Patent reads as follows:

A carbon fiber of a high tenacity and a high modulus of elasticity which has a fiber diameter of 1–6 microns, a strand tenacity of 503 kg/mm² *or more*, a strand modulus of elasticity of 28 ton/mm² *or more* and a density of 1.773 g/cm³ *or more*.⁷⁴

The ’477 Patent’s specification does not define the term “or more”; thus, its ordinary meaning to one skilled in the art controls.⁷⁵ There is no reason to think that the term “or more” means something different to one skilled in the art of carbon fiber synthesis than it does to any other person, because the “*words themselves*” must have special meaning to a person skilled in the art,⁷⁶ rather than the *words in*

69. *Id.* at 1314 (quoting *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)) (internal quotation marks omitted).

70. *Id.*

71. *Digital Biometrics*, 149 F.3d at 1344.

72. *Id.* (quoting 35 U.S.C. § 112 (1994)) (internal quotation marks omitted).

73. For example, in *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*, the patentee claimed a stringed sports racket having a “pattern of splay” in which “[the offset] distance *di varies between* minimum distances for the first and last string ends in [the] sequence and a maximum distance for a string end between [the] first and last string ends in [the] sequence.” 73 F.3d 1573, 1578 (Fed. Cir. 1996) (alteration in original) (emphasis added) (internal quotation marks omitted). The court concluded that the plain meaning and prosecution history equally supported two different interpretations of the key phrase “varies between.” *See id.* at 1579–80. In addition, the specification did not define the term. *Id.* at 1579. The accused infringer favored an interpretation that required the offset distance to take on three or more values—a greater limitation, which would result in a narrower claim—whereas the patentee argued that only two or more values were needed—a lesser limitation, which would result in a broader claim. *Id.* at 1580–81. To decide between the two otherwise equal interpretations, the court chose the interpretation that would result in a narrower claim, grounding its decision in the “notice” function of the second paragraph of § 112. *See id.* at 1581.

74. U.S. Patent No. 5,281,477 col.10 ll.41–45 (filed Apr. 9, 1991) (emphasis added).

75. *See supra* text accompanying notes 66–70.

76. *ChefAm., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1375 (Fed. Cir. 2004) (emphasis added). It is not enough for a person skilled in the art to realize that the words, taken literally, would result in something other than the patentee envisioned. *Id.* (holding that a baker’s interpretation of claim words were irrelevant insofar as he interpreted the claim words in an unusual way “not because the words

context of the claim. In similar contexts, courts have assigned the usual “dictionary definition” to such language.⁷⁷ Most likely, a court would similarly construe the words “or more” in Claim 1 of the ‘477 Patent. For example, “a strand tenacity of 503 kg/mm² or more” probably means exactly what it says: a strand tenacity of at least 503 kg/mm².⁷⁸

A patentee who wishes to avoid a “plain meaning claim construction,”⁷⁹ therefore, might wish to act as her own lexicographer with respect to open-ended terms. Such a patentee may do so either explicitly or implicitly;⁸⁰ but in any case he must do so “with reasonable clarity, deliberateness, and precision”⁸¹ and must “‘set out his uncommon definition in some manner within the patent disclosure’ so as to give one of ordinary skill in the art notice of the change” in meaning.⁸² It is unclear, however, what a patentee would gain by redefining open-ended product claim terms. While special definitions can give the patentee control and certainty in claim interpretation, why a patentee would not choose different words to achieve the same purpose without idiosyncratically redefining common, everyday terms

[had] special meaning to him, but because [he knew] that raising the temperature of a dough product itself to such high temperatures would result in an unusable product” (internal quotation marks omitted)).

77. See, e.g., *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1581 (Fed. Cir. 1995) (holding that “at least” means “as the minimum”); *Minn. Mining & Mfg. Co. v. Beutone Specialties Co.*, 117 F. Supp. 2d 72, 88 (D. Mass. 1999) (noting that the term “at least” establishes a limitation of “no less than”); *Hybritech Inc. v. Abbott Labs.*, 4 U.S.P.Q.2d 1001, 1013 (C.D. Cal. 1987) (enjoining use of antibodies having a certain affinity “or higher” where the claims cover antibodies having “at least” a certain affinity), *aff’d*, 849 F.2d 1446 (Fed. Cir. 1988); *Nat’l Research Dev. Corp. v. Great Lakes Carbon Corp.*, 410 F. Supp. 1108, 1119 (D. Del. 1975) (equating “at least” to “the minimum value”). For an example of an alternative construction of such language, see *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563 (Fed. Cir. 1997). In *J.T. Eaton*, the court construed the phrase “a plastic flow temperature above 120° F” to mean that “the adhesive must resist flow when exposed for 24 hours to 120° F in both horizontal and vertical orientations.” *Id.* at 1570 (emphasis added). However, the patentee suggested this unusual definition during prosecution not because “above 120° F” required explication but because “plastic flow temperature” had no accepted meaning in the art. *Id.* at 1566, 1568. The use of “or more” in the ‘477 Patent is not analogous. In the ‘477 Patent, the metrics associated with the open-ended numerical ranges—strand tenacity, modulus of elasticity, and density—all have well-defined meanings in the carbon fiber industry.

78. To some, such a construction of the term “or more” might seem frustrating or circular because it merely uses a synonym—“at least”—in place of “or more.” However, any apparent circularity merely emphasizes the crux of this Comment’s conclusion about open-ended terms such as “or more”: They are common English terms that, barring a patentee’s internal lexicography, can only mean one thing. No matter how much such terms are shaken, stirred, or examined with squinty eyes, they have only one plain meaning.

79. This Comment uses the term “plain meaning claim construction” to refer to a claim construction in which open-ended terms are given their plain meaning in ordinary, everyday use.

80. MPEP, *supra* note 8, at § 2111.01(IV). Explicit lexicography occurs when the patentee states specifically what she means when she uses certain words. E.g., U.S. Patent No. 7,308,496 col.4 ll.21–26 (filed June 7, 2002) (“As used throughout this application, the word ‘may’ is used in a permissive sense (i.e., meaning having the potential to), rather than the mandatory sense (i.e., meaning must). Similarly, the words ‘include,’ ‘including,’ and ‘includes’ mean including, but not limited to.”). Implicit lexicography occurs when the use of the term in context implies a different meaning than the plain meaning. MPEP, *supra* note 8, at § 2111.01(IV); see, e.g., *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (construing the term “solder reflow temperature” to mean “peak reflow temperature, rather than the liquidus temperature,” because the only embodiment of the invention in the specification would fall outside the scope of the claim if the alternative definition were chosen).

81. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

82. *Id.* (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992)).

such as “or more” to take on counterintuitive meanings is difficult to see. For example, if a patentee wished to claim a material having a property of “about” a certain magnitude, he could simply use that word instead of redefining “at least” to mean “about.”⁸³

A more difficult situation arises when a patentee uses open-ended terms as if they carried something other than their plain meaning, without explicitly redefining them. Consider, for instance, United States Patent 7,214,428. Dependent Claims 2, 3, 4, and 5 claim the “functionalized fluorescent nanocrystal probe of claim 1, wherein said fluorescent nanocrystal emits light with a quantum yield of greater than about” 10%, 30%, 50%, and 70%, respectively.⁸⁴ If the term “greater than” is given its ordinary meaning, Claims 3, 4, and 5 are redundant as written, for the sake of capturing the fluorescent probes of potential infringers.⁸⁵ Does such use create an implicit lexicography such that Claim 2 covers quantum yields of 10% to 29% and Claim 3 covers quantum yields of 30% to 49%, or are all the claims to be construed broadly? While resolution of this issue is outside the scope of this Comment, the careful patentee should consider this question before drafting such a series of claims.

Having addressed the situations in which open-ended claim language is given its plain meaning and in which the patentee acts as his own lexicographer, this Part now turns to the third possibility—that the language could be given whatever meaning is necessary to make the claim valid. Though courts “construe claims, if possible, so as to sustain their validity, it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.”⁸⁶ In addition, the Federal Circuit has disclaimed a broad application of the “maxim that claims should be construed to preserve their validity” and has refused to “endorse[] a regime in which validity analysis is a regular component of claim construction.”⁸⁷ Rather, the court has “limited the maxim to cases in which ‘the court concludes, after applying all the available tools of claim construction, that the claim is still

83. For a discussion of the potential consequences and problems of imprecise claim terms, see Peter G. Dilworth, *About “About” and Other Imprecise Claim Terms*, 78 J. PAT. & TRADEMARK OFF. SOC’Y 423 (1996), which argues that imprecise terms expand the literal scope of claims, cloud their exact boundaries, and jeopardize the priority or validity of a patent.

84. U.S. Patent No. 7,214,428 col.21 ll.36–47 (filed Apr. 9, 2003).

85. Note that this series of claims does not refer to different kinds or categories of nanocrystals. The quantum yield of colloidal semiconductor nanocrystals (also called “quantum dots”) is frequently used as a metric of quality for a given type or category of nanocrystals, not as a way to distinguish between types or categories of nanocrystals. See John P. Zimmer, *Quantum Dot-Based Nanomaterials for Biological Imaging* 23–25 (June 26, 2006) (unpublished Ph.D. dissertation, Massachusetts Institute of Technology) (on file with Hayden Library, Massachusetts Institute of Technology).

86. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) (citations omitted). However, Stephanie Ann Yonker has noted,

The scope of claim terms is limited where the specification makes clear that the invention does not include a particular feature, even if the language of the claim might be considered broad enough to encompass the feature in question. Accordingly, claims are not properly construed to have a meaning or scope that would lead to their invalidity for failure to satisfy the requirements of patentability, i.e. written description or enablement.

Stephanie Ann Yonker, *Post-Phillips Claim Construction: Questions Unresolved*, 47 IDEA 301, 305 (2007) (citations omitted) (internal quotation marks omitted).

87. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc).

ambiguous.”⁸⁸ Open-ended product claims will rarely or never satisfy this residual ambiguity test because terms like “or more” or “at least” have only one plain meaning.⁸⁹

A court’s refusal to narrowly construe an open-ended product claim comports well with the claim interpretation principles outlined above, especially those that emphasize the importance of careful language choice. Indeed, as a policy matter, the onus to draft claims of appropriate—reasonably fair and accurate—scope should rest on the patentee. Based on the foregoing, only a foolish claim drafter would rely on a court’s post facto reigning in of an open-ended product claim.

B. Prosecution: MPEP Guidelines

Part III.A has argued that open-ended terms in product claims in an issued patent may very well be interpreted according to their plain meaning. Interestingly, in the context of open-ended terms in product claims, a similar result is mandated by the MPEP during prosecution. Section 2111 of the MPEP requires examiners to give claims “their broadest reasonable interpretation” in light of the specification as read by a person having ordinary skill in the art.⁹⁰ As a policy matter, the *broadest* reasonable interpretation is chosen to prevent a claim from being construed too broadly after the patent issues.⁹¹ In other words, if the examiner construes the claim as broadly as he reasonably can and ultimately allows the claim, then there is no fear that a court or market competitor will read the claim in the issued patent as covering more ground than the inventor and examiner intended for the claim to cover. This is because the inventor and examiner chose the broadest possible reasonable reading in the first place.

Claim construction under section 2111 of the MPEP requires that the words of a claim be given their plain meaning, unless that plain meaning conflicts with the specification (e.g., the specification defines the words specially, in accordance with the patentee’s acting as his own lexicographer).⁹² Just like in the litigation context, the plain meaning is what a person having ordinary skill in the art would think the plain meaning is.⁹³ Further, the MPEP prohibits the importation of limitations from the specification into the claim terms.⁹⁴ As a result, “[o]rdinary, simple English words whose meaning is clear and unquestionable . . . are construed to mean

88. *Id.* (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004)).

89. *See supra* notes 76–78 and accompanying text.

90. MPEP, *supra* note 8, at § 2111. The Federal Circuit has recognized this standard for patent prosecution many times. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (“During examination, ‘claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.’” (alterations in original) (quoting *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990))).

91. MPEP, *supra* note 8, at § 2111 (citing *In re Prater*, 415 F.2d 1393, 1404–05 (C.C.P.A. 1969)).

92. *Id.* at § 2111.01(I) (citing *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372 (Fed. Cir. 2004); *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989)).

93. *Id.* at § 2111.01(III) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

94. *Id.* at § 2111.01(II) (quoting *Superguide Corp. v. DirecTV Enter., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004)).

exactly what they say.”⁹⁵ As an example, section 2111 cites the result in *Chef America, Inc. v. Lamb-Weston, Inc.*, where the phrase “heating the resulting batter-coated dough to a temperature in the range of about 400°F to 850°F” was construed to require heating the dough itself, as opposed to the air inside the oven, to that temperature.⁹⁶

As discussed in Part III.A above, open-ended terms like “or more” or “at least” have only one plain meaning—their ordinary meaning in everyday English. Therefore, when these words appear in claims like Claim 1 of the ’477 Patent⁹⁷ or Mary’s hypothetical Claim 4,⁹⁸ they will impart a very broad scope to the claim as a whole, and an examiner may not read the claim to encompass only the highest value disclosed in the specification.⁹⁹

Based on the foregoing, an examiner like Alfonso confronted with an open-ended claim like Mary’s Claim 4 will interpret the claim broadly, according to the everyday meaning of the open-ended terms. The next task for the examiner is to determine whether the claim so construed is enabled. Part IV of this Comment addresses the enablement inquiry in the PTO.

IV. THE PTO ENABLEMENT INQUIRY

Section 2164.08 of the MPEP, titled “Enablement Commensurate in Scope with the Claims,” addresses scope of enablement.¹⁰⁰ Section 2164.08 requires that when a “reasonable interpretation of the claim is broader than the description in the specification, [the examiner must] make sure the full scope of the claim is enabled.”¹⁰¹ Part II of this Comment argued that open-ended product claims will fall into this category.¹⁰² To carry out its mandate, section 2164.08 suggests a two-part inquiry: the examiner must (1) “determine how broad the claim is with respect to the disclosure” and (2) determine if a person having ordinary skill in the art is able to practice the full scope of the invention without undue experimentation.¹⁰³ The second prong of this inquiry essentially restates the basic enablement standard.¹⁰⁴ Therefore, section 2164.08 articulates an uncontroversial proposition: examiners

95. *Id.* at § 2111.01(I) (citing *Chef Am.*, 358 F.3d at 1371–72).

96. *Id.* at § 2111.01(I) (citing *Chef Am.*, 358 F.3d at 1372). To adopt the alternative view that the phrase should be construed to refer to heating the air inside the oven, rather than the dough, it was not enough that a person skilled in the art might realize that the words, taken literally, would result in something other than the patentee envisioned. *Chef Am.*, 358 F.3d at 1375. The *Chef America* court ultimately held that a baker’s interpretation of claim words was irrelevant insofar as he interpreted the claim words in an unusual way “not because the words ha[d] special meaning to him, but because [he knew] that raising the temperature of a dough product itself to such high temperatures would result in an unusable product.” *Id.* (internal quotation marks omitted).

97. U.S. Patent No. 5,281,477 col.10 ll.41–45 (filed Apr. 9, 1991).

98. See discussion *supra* Part I.

99. See *supra* text accompanying note 94. For example, if a patentee claimed “nanocrystals having a quantum yield of 30% or more” but disclosed no embodiment having a quantum yield greater than 45%, the examiner could not interpret the claim as written to cover nanocrystals with a quantum yield of 45% but not those with a quantum yield of 90%.

100. MPEP, *supra* note 8, at § 2164.08.

101. *Id.*

102. See *supra* notes 53–56 and accompanying text.

103. MPEP, *supra* note 8, at § 2164.08.

104. See discussion *supra* Part II.

should first understand what exactly the patentee is claiming and then decide if the specification enables the claimed matter. This inquiry is one of the fundamental tasks of the PTO, and the patent system inherently presumes that examiners are competent to undertake it.¹⁰⁵

In the case of open-ended product claims, however, this Part argues that the presumption is wrong. Specifically, the presumption fails for two reasons: (1) scope of enablement tests are highly fact-dependent and leave an enormous amount of discretion in the hands of the examiner or the court; and (2) even the inventor will not know for certain what subsequent experimentation will show her method can in fact achieve. The second reason is especially important. The examiner, like the inventor and any other person skilled in the art, will likely not have enough information on which to make anything better than an educated guess about what the new method can achieve.¹⁰⁶ Given that the examiner will have very little time to devote to the application,¹⁰⁷ this concern is especially relevant to the validity of the above presumption.

Part IV.A outlines the tests for scope of enablement and concludes that they all do little more than restate the basic inquiry, which results in highly fact-dependent outcomes, which in turn leaves great discretion in the hands of an examiner or court. Part IV.B argues that, in the case of open-ended product claims, which are likely to be construed very broadly,¹⁰⁸ patent examiners are ill-equipped to undertake such a fact-dependent inquiry. In addition, the policy concerns that normally require examiners to undertake such fact-specific inquiries actually militate against the inquiry in the case of open-ended products claims. As an alternative to the current MPEP approach for open-ended product claims,¹⁰⁹ Part IV.B suggests that patent examiners should presumptively reject open-ended product claims, instead allowing claims that are limited by the highest values disclosed in the specification.

A. Tests for Enablement

Despite the ubiquitous citation of the undue experimentation standard, no universally applicable scope of enablement test exists. Instead, “the factual diversity of cases involving disclosure issues leads to generalized standards that must be applied to a wide array of specific technologies. As a result, [factfinders] have a large amount of discretion in applying the [disparate enablement] doctrines.”¹¹⁰ Or, put another way, the undue experimentation analysis need not

105. See Ann Bartow, *Separating Marketing Innovation from Actual Invention: A Proposal for a New, Improved, Lighter, and Better-Tasting Form of Patent Protection*, 4 J. SMALL & EMERGING BUS. L. 1, 18 (2000).

106. Arguably, it is better for the patent system as a whole if the examiner, rather than a competitor during litigation, is the one to bear the burden of winnowing out overly broad claims. See Seymore, *supra* note 13 (manuscript at 31 & n.147) (“[T]he public need not bear the cost and burden of litigation to determine if the disclosure adequately enables the claimed invention.”).

107. See *supra* text accompanying notes 5–6.

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

109. See MPEP, *supra* note 8, at § 2164.08.

110. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 852 (1990).

always be explicitly carried out,¹¹¹ though it frequently is.¹¹² Instead, other tests can be used to answer the same fundamental question. This Part addresses three of the tests, including the formal undue experimentation test.

In brief, for an open-ended claim to be enabled, one of three tests must be met: (1) the *Wands* test, requiring the application of the so-called *Wands* factors to ensure that undue experimentation is not needed to practice the full scope of the claimed invention (the formal undue experimentation standard);¹¹³ (2) the *Scripps* test, requiring that the specified lower limit is close to an inherent upper limit that a person skilled in the art could obtain based on the specification's teaching;¹¹⁴ or (3) the subset test, requiring that the specification describes and exemplifies a subset of a larger claimed class, which subset enables the larger class.¹¹⁵ However, none of these principles provide much guidance to patentees, examiners, courts, or market competitors, as this Part will show. Except for certain fact patterns, the above tests do little more than restate the original enablement question, which is one reason why factfinders indeed "have a large amount of discretion."¹¹⁶

1. The Wands Test

As noted in Part II, the scope of enablement includes both what "is disclosed in the specification [and] what would be known to one of ordinary skill in the art without undue experimentation."¹¹⁷ "While determining whether [a] required amount of experimentation is 'undue' is an inherently imprecise undertaking,"¹¹⁸ the Federal Circuit has enumerated eight "illustrative" factors (the "*Wands* factors") to consider.¹¹⁹ The *Wands* factors include the following:

- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

111. An explicit application of the undue experimentation analysis is one in which the so-called *Wands* factors are specifically listed and applied. See discussion *infra* Part IV.A.1.

112. See discussion *infra* Part IV.A.1.

113. See discussion *infra* Part IV.A.1.

114. See discussion *infra* Part IV.A.2.

115. See discussion *infra* Part IV.A.3.

116. Merges & Nelson, *supra* note 110, at 852.

117. *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999); see also *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))). Despite the doctrine's entrenchment in patent law, imputing the fruits of future experimentation to a patentee's present disclosure is a common law creation. The Supreme Court first articulated the idea in *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916). See generally Mark H. Hopkins, Comment, *Has the Reasonable Experimentation Doctrine Become Unreasonable?: Rethinking the Reasonable Experimentation Doctrine in Light of Automated Experimental Techniques*, 2 J. MARSHALL REV. INTELL. PROP. L. 116, 122–24 (2002) (tracing the common law evolution of the doctrine).

118. *Northpoint Tech., Ltd. v. MDS Am., Inc.*, 413 F.3d 1301, 1310 (Fed. Cir. 2005).

119. *Wands*, 858 F.2d at 737. Though called the *Wands* factors, the Court of Customs and Patent Appeals and the PTO Board of Appeals and Patent Interferences first articulated these factors in *In re Colianni*, 561 F.2d 220, 224 (C.C.P.A. 1977), and *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Bd. Pat. App. & Int. 1986), respectively.

predictability or unpredictability of the art, and (8) the breadth of the claims.¹²⁰

Not all of these factors weigh heavily in the typical *Wands* analysis.¹²¹ For example, the state of the prior art has rarely been identified as a key factor.¹²² For purposes of open-ended product claims in the unpredictable arts, this Comment suggests that the most important factors are probably the breadth of the claims, the quantity of experimentation necessary, the relative skill of those in the art, and the unpredictability of the art. The breadth of the claims refers to claim construction.¹²³ As noted above in Part III, open-ended claims will typically be construed very broadly,¹²⁴ which favors a finding of undue experimentation.¹²⁵ The touchstone for the amount of experimentation is not the *amount* so much as the *type*: as long as the required experimentation is *routine*, the amount can be *considerable* without a finding of undue experimentation.¹²⁶ In addition, the higher the relative skill of those in the art, the greater the amount of experimentation that may be permissible without a finding of undue experimentation.¹²⁷ Conversely, chemistry's unpredictability requires a higher showing of enablement to obtain the same scope of claim protection *vis a vis* predictable arts.¹²⁸

Despite its frequent employment, commentators have criticized the *Wands* test as unhelpful. One commentator noted, "While the scope of enablement theoretically varies inversely with the degree of unpredictability, the *Wands* test failed to enumerate specific criteria for determining adequate disclosure in the unpredictable arts. This inadequacy resulted in the granting of overbroad patents in unpredictable fields, like [chemistry]."¹²⁹ Another scholar attacked the *Wands* test as ambiguous, and its factors as duplicative and confusingly interdependent.¹³⁰

These critiques should come as no surprise. The *Wands* factors are multitudinous, broadly worded,¹³¹ and partially dependent on hindsight analysis.¹³²

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

121. See Hopkins, *supra* note 117, at 125.

122. *Id.*

123. *Id.*

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

125. See, e.g., Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1156 (Fed. Cir. 1997) (holding that the patentee's broadly construed claim of a device that behaved as a transistor "at all times" was not enabled because the invented device behaved as a transistor under only *some* operating conditions).

126. *Ex parte* Jackson, 217 U.S.P.Q. 804, 807 (Bd. Pat. App. & Int. 1982).

127. Hopkins, *supra* note 117, at 126.

128. Hormone Research Found. v. Genentech Inc., 708 F. Supp. 1096, 1107–08 (N.D. Cal. 1988) ("Patents concerning chemical reactions . . . generally involve unpredictable factors and thus enable a narrower range of claims [than patents concerning more predictable arts].") (citing *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970)), *aff'd in part, vacated in part, and remanded*, 904 F.2d 1558 (Fed. Cir. 1990).

129. Corrin Nicole Drakulich, Note, University of Rochester v. G.D. Searle & Co.: *In Search of a Written Description Standard*, 21 BERKELEY TECH. L.J. 11, 17 (2006).

130. See Hopkins, *supra* note 117, at 130.

131. For example, the "nature" of the invention, the "state" of the prior art, and the "relative skill" of practitioners can each be articulated in many different ways, depending on the whim of the person conducting the analysis.

132. How can one know a priori the "quantity of experimentation necessary" to practice the full scope of the claimed invention? The only accurate way to determine this quantity is to ask afterwards how much experimentation competitors in fact needed.

As a result, patentees, examiners, and market competitors on the front end are left to guess how a court will conduct the analysis later. In other words, confronted with the “undue experimentation” standard and the malleable *Wands* factors, an interested party is left with little guidance—but great discretion—as he asks the original enablement question about an open-ended product claim: Given that this patent claims more than it literally discloses, how do I decide whether the narrower disclosure enables the broader claims? Or, to what protection is the patentee entitled?¹³³

2. *The Scripps Test*

Like the undue experimentation standard, the second test was also introduced in Part II. The *Fisher* court suggested that one reason the inventor’s open-ended claim was not enabled was because there was no “inherent upper limit” to the theoretically possible potencies of ACTH compositions like those claimed.¹³⁴ The court cited three cases involving claims of pure or uncontaminated substances.¹³⁵ Those cases disclosed “pure” aspirin,¹³⁶ an L-lactone “substantially free from” the presence of the undesired D-lactone,¹³⁷ and a substance “practically free from” certain impurities.¹³⁸ Compared to the 100% maximum inherent in all purities, the *Fisher* court stated that these disclosed purities left a “possible range of further purification [that] was either small or nonexistent.”¹³⁹ By contrast, the invention in *Fisher* was not bounded by an inherent upper limit analogous to 100% purity, removing it from the rules of those cases.¹⁴⁰

The Federal Circuit rearticulated this test twenty-one years later in *Scripps Clinic & Research Foundation v. Genentech, Inc.*¹⁴¹: “Open-ended claims . . . may be supported if [1] there is an inherent, albeit not precisely known, upper limit and [2] the specification enables one of skill in the art to approach that limit.”¹⁴² In *Scripps*, the patentees claimed a process for purifying human Factor VIII:C—a naturally occurring protein important for blood clotting.¹⁴³ They also claimed human VIII:C preparations “substantially free” of a certain impurity.¹⁴⁴ The

133. It is important to remember that the scope of enablement inquiry is ultimately about fairness not only to the patentee, but also to the rest of society, including her competitors. Judicial enablement doctrines should be evaluated with this principle in mind.

134. See *In re Fisher*, 427 F.2d 833, 839–40 (C.C.P.A. 1970).

135. See *id.* (citing *Parke-Davis & Co. v. H.K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912); *In re Williams*, 171 F.2d 319 (C.C.P.A. 1948); *Farbenfabriken of Elberfeld Co. v. Kuehmsted*, 171 F. 887 (N.D. Ill. 1909), *aff’d*, 179 F. 701 (7th Cir. 1910)).

136. See *Farbenfabriken*, 171 F. at 888.

137. See *Williams*, 171 F.2d at 319.

138. See *Parke-Davis*, 196 F. at 497.

139. *Fisher*, 427 F.2d at 839.

140. *Id.* at 839–40.

141. 927 F.2d 1565 (Fed. Cir. 1991).

142. *Id.* at 1572. This Comment refers to this test as the “*Scripps* test,” rather than the “*Fisher* test” or some other moniker, for two reasons. First, the author likes the way the *Scripps* court phrased the test. Second, the Federal Circuit recently cited *Scripps*, not *Fisher*, for this principle. See *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376–77 (Fed. Cir. 2007). However, as noted the *Scripps* court rearticulated a principle first set forth in *Fisher*.

143. *Scripps*, 927 F.2d at 1568.

144. *Id.* at 1570.

inventors in *Scripps* tried to distinguish their product claims from those in *Fisher* by saying, essentially, that the *Scripps* claims were not open-ended.¹⁴⁵ The court did not address this issue, however, remanding on other grounds.¹⁴⁶

Applying the *Scripps* test, the Federal Circuit in *Andersen Corp. v. Fiber Composites, LLC*¹⁴⁷ recently upheld a jury's determination that a patentee's claims were enabled, where the open-ended claims required a wood-polymer composite fiber having a "Young's modulus rating of greater than 500,000."¹⁴⁸ The novelty of the invention in *Andersen* lay in the fiber's physical properties.¹⁴⁹ Importantly, the specification disclosed a Young's modulus rating well above the specified lower limit: "greater than 500,000" claimed and up to 1.2 million disclosed.¹⁵⁰ Further, the Federal Circuit cited an expert's testimony regarding the range of possible values for the Young's modulus of such a fiber as that claimed:

[A] person of skill in the art would recognize that the upper limit of the Young's modulus of the [fiber] would lie somewhere between the Young's modulus of the wood fiber and that of the polymer used in the composition, and that a person of skill in the art would be fully enabled to practice the invention based on the specification's disclosure.¹⁵¹

The result in *Andersen*¹⁵² suggests that the *Scripps* test requires that the inherent upper limit be known to some degree of precision.

Even where the first element of the *Scripps* test is satisfied, the specification must be scrutinized for actual enablement. Six days before it decided *Scripps*, the Federal Circuit held an open-ended claim invalid for lack of enablement in *Amgen, Inc. v. Chugai Pharmaceutical Co.*¹⁵³ In *Amgen*, the patent in suit claimed a purified protein having a "specific activity of at least 160,000 IU per absorbance unit at 280 nanometers."¹⁵⁴ The district court upheld the claim but the Federal Circuit reversed.¹⁵⁵ Even though there was an inherent upper limit corresponding to a protein of 100% purity, the Federal Circuit reversed because the patentee's procedure for measuring the specific activity did "not establish . . . a workable method for actually obtaining the pure material that it claimed."¹⁵⁶ The accused

145. *See id.* at 1572.

146. *See id.* at 1574.

147. 474 F.3d 1361.

148. *Id.* at 1376.

149. *Id.* at 1372.

150. *Id.* at 1376.

151. *Id.* at 1377.

152. Though the court deemed the open-ended claim in *Andersen* to be enabled, the presumption of validity favored such a result because the patent had already issued. *See Andersen*, 474 F.3d at 1376 ("Fiber's arguments fall short of satisfying the heavy burden required to overturn the jury's verdict."). Generally, a factfinder could weigh the presumption of validity for issued claims more or less heavily.

153. *See* 927 F.2d 1200, 1216 (Fed. Cir. 1991).

154. *Id.* at 1203.

155. *Id.* at 1203, 1216.

156. *Id.* at 1216.

infringer won its argument that specific activities within the open-ended range (e.g., 190,000 IU/AU) should not be protected.¹⁵⁷

The shortcoming of the *Scripps* test is simply that it is a positive test: it defines one situation in which an open-ended claim may be enabled. It says nothing definitive about whether an open-ended claim that does not involve a relatively near inherent upper limit could be enabled. For that matter, it says nothing about how close to the highest disclosed value the inherent upper limit need be to trigger the second part of the *Scripps* inquiry.¹⁵⁸ In addition, when that second inquiry does occur, an interested party is left in essentially the same position he was in before coming to the *Scripps* test for guidance: he must look at what is disclosed, look at the theoretical upper limit which was not disclosed, and decide whether enablement of the former convinces him that the latter has been enabled too.

3. *The Subset Test*

Where a patent claims a broad class but the specification describes and exemplifies only a subset of the larger claimed class, the patent's broad claims are invalid unless achievement of the subset enables the larger class as well. This test is especially pertinent where the invention concerns an unpredictable art like chemistry. This proposition can be gleaned from *In re Fisher*,¹⁵⁹ *In re Vaeck*,¹⁶⁰ and *Harris Corp. v. IXYS Corp.*¹⁶¹

In *Fisher*, the court rejected a claim of a polypeptide having "at least 24 amino acids" where "the specification [did] not enable one skilled in the art to make or obtain [polypeptides] with other than 39 amino acids."¹⁶² Similarly, the Federal Circuit in *Vaeck* upheld a rejection for lack of enablement of a claim that claimed all types of cyanobacteria, where cyanobacteria were incompletely understood and included "150 different genera," and where only one strain of cyanobacteria was disclosed.¹⁶³ Likewise, the Federal Circuit in *Harris* held that the patentee "predicted—rather than invented" a device that behaved as a transistor "at all times," because the invented device behaved as a transistor under *some* operating conditions;¹⁶⁴ in other words, the patentee invented a device that behaved as a transistor at *almost* all times. In all three of these cases, the patentee disclosed and exemplified one portion of a larger class, but claimed the entire class. And in each case the court concluded that the disclosure of the subset did not enable the larger class.

To see how this proposition relates to open-ended product claims, consider once again the '477 Patent.¹⁶⁵ Like the patents at issue in *Fisher* and *Vaeck*, the

157. *Amgen Inc. v. Chugai Pharm. Co.*, 13 U.S.P.Q.2d 1737, 1795 (D. Mass. 1989), *aff'd in part, rev'd in part, vacated in part*, 927 F.2d at 1216.

158. Perhaps as other courts cite *Scripps* and apply its test, it will become clearer how close—as a percentage perhaps—the inherent upper limit need be.

159. 427 F.2d 833 (C.C.P.A. 1970).

160. 947 F.2d 488 (Fed. Cir. 1991).

161. 114 F.3d 1149 (Fed. Cir. 1997).

162. 427 F.2d at 836.

163. 947 F.2d at 489, 495.

164. 114 F.3d at 1156.

165. U.S. Patent No. 5,281,477 col.10 ll.41–45 (filed Apr. 9, 1991).

'477 Patent claims a broad class of materials in an unpredictable art.¹⁶⁶ Also like the *Fisher* and *Vaack* patents, the '477 specification probably enables only a subset of the broad class.¹⁶⁷ Teaching how to obtain the subset of carbon fibers having, for example, a strand tenacity of approximately 565 kg/mm²—probably roughly what the '477 Patent actually enables—or less is not the same as teaching how to make carbon fibers having a strand tenacity of 700 kg/mm². Put another way, the specification simply does not teach one skilled in the art how to do all that the patent claims. Therefore, the '477 Patent's achievement of the subclass does not also enable the larger class. Accordingly, under *Fisher*, *Vaack*, and *Harris*, the '477 Patent's claims are probably not enabled.

Like the *Scripps* test, the subset test does little more than restate the basic enablement inquiry. The subset test essentially asks if the disclosure, enabling for a subset of the claimed materials, truly enables all the other claimed materials that are not apparently enabled on the face of the specification—for which there is no proof of enablement. In addition, the subset test applies more squarely to broad claims like those in *Vaack* than it does to open-ended product claims like Mary's hypothetical Claim 4 or Claim 1 of the '477 Patent. Thus, the outcomes of cases like *Vaack* offer little guidance for the analysis of typical open-ended product claims.¹⁶⁸

Before concluding this Part, this Comment must briefly address another line of cases. Some patentees, improperly relying on a series of post-*Fisher* cases, errantly judge the enablement of a claim based on technology in existence at a time other than the time of filing.¹⁶⁹ After *Fisher*, the Federal Circuit's predecessor court vacated a rejection of broad polymer claims under § 112 on the grounds that a later state of the art cannot be used to invalidate a claim as not enabled when filed.¹⁷⁰ The patentee in *In re Hogan* claimed a solid polymer of propylene having certain properties.¹⁷¹ Because the claim did not specify the polymer's crystallinity, it captured both the crystalline and amorphous forms, though the specification taught only how to obtain the crystalline form.¹⁷² At the time of filing, however, no one

166. See *id.* For these purposes, consider the universe of all possible carbon fibers as the "larger class" and any set of carbon fibers not containing all possible carbon fibers as the "subset" of the larger class. While such a definition of classes is unlike that usually seen in cases invoking this enablement test, see, e.g., *Vaack*, 947 F.2d at 490, 495 (involving different genera of cyanobacteria), the idea is the same.

167. This conclusion is, of course, a legal one and, moreover, is uncertain for all the reasons outlined in this Part. Nevertheless, the conclusion is as certain as any could be in this uncertain field due to the '477 Patent's particularly weak specification. Though expert testimony would be needed to establish the issue, it is likely that the highest values achievable by the '477 Patent's teaching in 1991 are far below those achievable by other methods today. Accordingly, today's improved carbon fibers are not enabled by the '477 Patent, yet are part of the very broad class of fibers that the patent claims.

168. See *supra* text accompanying notes 12–16.

169. See *Plant Genetic Sys., N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335, 1339–42 (Fed. Cir. 2003) (analyzing this line of cases superbly).

170. See *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977). Among *Hogan*'s progeny are the following: *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1249, 1251 (Fed. Cir. 1989); and *Hormone Research Foundation, Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568–69 (Fed. Cir. 1990).

171. 559 F.2d at 597–98.

172. See *id.* at 601.

knew that the amorphous form could be obtained at all.¹⁷³ That the *Hogan* specification did not enable the full scope of the claim only became apparent years later, after the state of the art had changed.¹⁷⁴ The Court of Customs and Patent Appeals held simply that the later state of the art could not be used to “‘reach back’ and preclude or invalidate a patent on the underlying invention.”¹⁷⁵ In other words, the state of the art at the time of filing, not a later state of the art, must indicate that the full scope of the claims is enabled.¹⁷⁶

Because the enablement rejection in *Hogan* was based on a “post-filing date state of the art,”¹⁷⁷ courts will usually “not [be required to] consider the effect of *Hogan* and its progeny on *Fisher*’s analysis of when an inventor should be allowed to ‘dominate the future patentable inventions of others.’”¹⁷⁸ The Federal Circuit later stated, “We do not read *Hogan* as allowing an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it.”¹⁷⁹ Therefore, a later development cannot save a nonenabled claim. That is, a claim like Mary’s Claim 4, if not enabled at the time of filing, is not made valid by a subsequent breakthrough in Mary’s laboratory or elsewhere.

In sum, this Part suggests that the three standard tests for scope of enablement—the *Wands* test, the *Scripps* test, and the subset test—do not provide much additional guidance for the analysis of open-ended claims. Rather, they all essentially restate the basic enablement inquiry in a way that may not be very helpful for an examiner like Alfonso. However, on its own, this observation signifies little. After all, the task of the PTO is to engage in highly fact-specific investigations for the sake of judging whether the statutory requirements of patentability, including enablement, have been satisfied by a particular applicant. While the unhelpfulness of available tests might make this task more difficult in the case of open-ended product claims, the job can theoretically still be done. Thus, the critical question becomes why the patent system should make an exception to its normal operating assumptions and procedures in the case of open-ended product claims. In other words, might the system be better served if the ordinary presumption of examiner competency to filter out unworthy claims were suspended in this limited context? Or, put another way, should the PTO promulgate a new guideline categorically barring open-ended product claims? Part IV.B answers this question in the affirmative.

173. *Id.* at 605.

174. *See id.* at 606.

175. *Id.*

176. The Federal Circuit commented on this issue in 2003 by stating, In both *Hogan* and *Hormone Research*, which relied on *Hogan*, compounds having better qualities did not seem to be in existence on the date when the patent applications were filed, but the claims (albeit with a narrower scope) might be nevertheless enabled in view of the state of the art then existing.

Plant Genetic Sys., N.V. v. Dekalb Genetics Corp., 315 F.3d 1335, 1341 (Fed. Cir. 2003).

177. *In re Vaeck*, 947 F.2d 488, 495 n.22 (Fed. Cir. 1991) (citing *Hogan*, 559 F.2d at 605–07).

178. *Vaeck*, 947 F.2d at 495 n.22 (quoting *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970)).

179. *Plant Genetic Sys.*, 315 F.3d at 1340.

B. *An Alternative Approach*

It is important to remember that open-ended product claims are very broad claims, in some cases stretching literally into infinity.¹⁸⁰ Due largely to this exceptional breadth, this Part argues that patent examiners are ill-equipped to undertake such a fact-dependent inquiry as is required to determine enablement of such claims. In addition, the policy concerns that normally require examiners to undertake such fact-specific inquiries in fact militate against the inquiry in the case of open-ended products claims. As an alternative to the current MPEP approach for open-ended product claims,¹⁸¹ this Part suggests that patent examiners should presumptively reject open-ended product claims, allowing only those claims that are limited by the highest values actually achieved by the patentee and disclosed in the specification. Patentees may not like this suggested alternative approach because they would no longer have the option of seeking the very broad right to exclude granted by open-ended product claims. Nevertheless, as Part IV.B.2 argues, the patent system as a whole would be better served by adoption of this Comment's suggested approach.

1. *Examiner Competency*

While it is true that the "patent system is premised on the belief that Patent Examiners will do a competent job of winnowing out subpatentable inventions most of the time,"¹⁸² this Comment suggests that the breadth of open-ended product claims weakens this presumption, at least in this limited context. The problem is two-fold. First, open-ended product claims extend into the future in a way that most other claims do not. Second, even the inventor, who is presumably among the world's leading authorities on her invention, cannot be certain at the time of filing whether her new process will allow her or others to realize products having properties far superior to the best she has been able to produce to date.

Imagine, for example, that an inventor has achieved a major breakthrough in semiconductor nanocrystal synthesis, developing a method for producing gallium arsenide nanocrystals with a quantum yield of up to 30%. Assume the previous best was 5%. The inventor seeks to patent not only the new method, but also the nanocrystals themselves—made by her method or any other method. She drafts an open-ended product claim to cover any gallium arsenide nanocrystals having a quantum yield of at least 25%. This claim, if allowed, would bar others from making gallium arsenide nanocrystals having a quantum yield of 90%, even if they made them some other way.¹⁸³ Moreover, it might take other chemists a decade or

180. See discussion *supra* Part III.

181. See MPEP, *supra* note 8, at § 2164.08.

182. Bartow, *supra* note 105, at 18.

183. A stymied competitor could of course challenge the validity of the claim in litigation. However, it is arguably better for the patent system as a whole if the examiner is the one to bear the burden of winnowing out overly broad claims, rather than a competitor during litigation. See Seymore, *supra* note 13 (manuscript at 31 & n.147) ("[T]he public need not bear the cost and burden of litigation to determine if the disclosure adequately enables the claimed invention."). In addition, the mere existence of the issued patent, which is presumed valid during litigation, see *supra* note 20, could chill a competitor's efforts, see discussion *infra* Part IV.B.2.

more to figure out how to reach 90%. Not only that, but it might also take the patentee herself many years of experimentation based on her new method to reach a quantum yield of 90%—if her method is capable of producing such nanocrystals at all. Alternatively, it might take the patentee only a few months to reach 90%. Or, *no one* may *ever* achieve a quantum yield of 90% by *any* method. The problem is that neither the patentee nor her competitors nor a patent examiner can possibly know *a priori* which contingency will in fact occur.

Despite the murkiness of gallium arsenide nanocrystal research's future, the hypothesized open-ended product claim would extend deeply into it. This scenario, easily imagined for many open-ended product claims in the unpredictable arts, suggests that no patent examiner, regardless of his level of training, experience, or intelligence, is competent to make a presumptively valid judgment. Rather, he could make a guess. The patent system ought not to be premised on guesses.¹⁸⁴

2. Policy Concerns

The patent system's mission is spelled out in the same constitutional provision that authorizes Congress to legislate in the area: the so-called Intellectual Property Clause gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹⁸⁵ Because the patent system's purpose is to promote progress, it is always appropriate to ask whether a given statute, common law rule, or administrative guideline does in fact encourage innovation. If it does not, then legislative, judicial, or administrative change might be in order.

Granting an overbroad patent means overcompensating an inventor for her contribution to the progress of science and the useful arts.¹⁸⁶ Not only does an

184. This Comment argues that examiners are not generally competent to accurately judge the enablement of open-ended product claims, yet current law assumes that they are. See Bartow, *supra* note 105, at 18. To gauge the severity of the resulting problem, it would be useful to collect statistics on how many open-ended product claims get through the PTO and end up in issued patents; how many get rejected during prosecution; and how many of the allowed claims have been shown to be not enabled, either directly through subsequent litigation or indirectly through the issuance of later patents that literally infringe the first patent. However, this latter, indirect measure may be difficult to interpret. Later-infringing patents could also be issued because the original patent was not found or considered during prosecution. Therefore, it might be more revealing to limit this metric to only those later-infringing patents that reference the original. Such a search is beyond the scope of this Comment, however, and would address only the *severity*, not the *existence*, of the problem of open-ended product claims in the unpredictable arts. Patents like those cited in note 3 *supra* show that the problem exists.

185. U.S. CONST. art. I, § 8, cl. 8.

186. Many scholars have debated whether stronger patent protection or weaker patent protection better encourages innovation. See, e.g., Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 253 (1994) (“[O]verly broad patent protection can inhibit future innovation.”); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977) (“The patent system achieves [efficiency] by awarding exclusive and publicly recorded ownership of [a particular opportunity to develop a known technological possibility] shortly after its discovery.”); Merges & Nelson, *supra* note 110 (analyzing the economic effects of patent scope). More precisely, the debate centers on ascertaining the “economically optimal balance between innovation today and innovation tomorrow.” Dam, *supra*, at 253. For a more recent discussion of various scholars’ attempts to articulate the ideal scope of patent protection from an economic point of view, see Sami J. Valkonen & Lawrence J. White, *An Economic Model for the Incentive/Access Paradigm of Copyright*

overbroad patent enrich its owner unjustly, but it also blocks further progress in the field. In fact, according to a seminal study, “increases in [patent] scope have greater preclusive effect than increases in [patent] length.”¹⁸⁷

Due to their exceptional breadth—potentially extending into infinity—this Comment argues that open-ended product claims are inherently overbroad. Therefore, the presumed validity of issued claims, which is based on the assumption that examiners are competent,¹⁸⁸ militates *against* allowing open-ended product claims. Notwithstanding the presumption of validity, patents may issue that are invalid.¹⁸⁹ To overcome the presumption during litigation, a patent’s invalidity must be proven by clear and convincing evidence.¹⁹⁰ This barrier, already formidable, can be “prohibitively” high due to judges’ reluctance to “second-guess” examiners—whose technical expertise far surpasses that of the bench.¹⁹¹ As a result, the harm of erroneously allowing an open-ended product claim is particularly high. Not only does its exceptional breadth generate exceptional preclusive effect on competitors, but the technical difficulty of judging its enablement also reduces the likelihood that an error in its allowance will be corrected in litigation.¹⁹² Indeed, competitors (or accused infringers) may very well choose to license the technology (or otherwise settle with the patentee) rather than engage in expensive, time-consuming, and uncertain litigation.

In sum, open-ended product claims in issued patents may retard innovation in two ways. First, their exceptional breadth may exert an exceptionally preclusive effect on the innovation of competitors. This preclusive effect is felt whether allowing the claims is erroneous or not—whether or not the specification “really” enables them. Second, the technical difficulty of judging the enablement of open-ended product claims may make mounting a successful challenge against an issued claim extremely difficult. This Comment argues that, as a policy matter, the foregoing harms outweigh the primary benefit of allowing open-ended claims—namely encouraging early disclosure by the first inventor by maximizing her monopoly.

In light of both the gravity of the harm and the reduced competency of examiners to accurately gauge the enablement of open-ended product claims,¹⁹³ this Comment recommends a cautious approach. As an alternative to the current MPEP

Propertization: An Argument in Support of the Orphan Works Act, 29 HASTINGS COMM. & ENT. L.J. 359, 378–82 (2007) (“[Previous] articles and models . . . do not present a cohesive framework sufficiently simple for the legal community or the legislature to use as a practical analytical tool for the evaluation of policy decisions.”). This Comment does not attempt to summarize the debate. Rather, it will be taken as a starting premise that overly broad claims discourage total innovation over time, including innovation “today” and “tomorrow.”

187. Merges & Nelson, *supra* note 110, at 869 n.128 (citing Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON. 106 (1990)).

188. See Bartow, *supra* note 105, at 18.

189. One court noted that the presumption of validity “does not automatically foreclose thought and analysis.” *Ashcroft v. Paper Mate Mfg. Co.*, 434 F.2d 910, 914 (9th Cir. 1970).

190. *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999).

191. Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of “Lock-Out” Programs*, 68 S. CAL. L. REV. 1091, 1176 (1995).

192. See *id.*

193. See Cohen, *supra* note 191, at 1176 (“[T]he presumption of validity is justified only if the examiner’s qualifications warrant it.”).

guidelines for open-ended product claims,¹⁹⁴ patent examiners should presumptively reject open-ended product claims and allow only those claims that are limited by the highest values actually achieved by the patentee and disclosed in the specification. For example, consider again the gallium arsenide nanocrystal inventor from Part IV.B.1. The examiner should reject her “at least 25%” claim, but could allow a claim limited to quantum yields “between 5% and 30%,” or perhaps “up to 30%.”

Though section 2164.08 contains language from *In re Goffe*¹⁹⁵ seemingly counseling against such an approach,¹⁹⁶ that case is distinguishable, and the approach this Comment recommends does not undermine the policy concern *Goffe* raises. In *Goffe*, the examiner rejected numerous process claims on scope of enablement grounds.¹⁹⁷ The claims called for an “agglomerable” material generically, and the specification did not “adequately instruct one skilled in the art how to determine the scope of materials which may be capable of producing the desired effect (agglomerate) under the conditions of the claimed method.”¹⁹⁸ Reversing the decision of the PTO Board of Appeals to uphold the rejection, the Federal Circuit’s predecessor court stated the following:

For all practical purposes, the board would limit [the applicant] to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for “preferred” materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.¹⁹⁹

Despite this strong language, *Goffe* is distinguishable because the broad term in *Goffe* (“agglomerable”) concerned a required characteristic of a functional material used in a claimed process. In contrast, the “open-ended-ness” of open-ended terms in product claims is not necessary for a claimed process to work. In addition, the incentivization policy cited in *Goffe* is not offended by disallowing open-ended product claims, because the inventor is adequately protected by her remaining process claims.²⁰⁰ In other words, this Comment’s suggested approach does not punish an inventor whose new process really does enable the full range of possible products, because such an inventor’s process claims will protect her process, and

194. See MPEP, *supra* note 8, at § 2164.08.

195. 542 F.2d 564 (C.C.P.A. 1976).

196. See MPEP, *supra* note 8, at § 2164.08.

197. 542 F.2d at 565.

198. *Id.*

199. *Id.* at 567.

200. This Comment has assumed throughout that open-ended product claims will always be accompanied by process claims. See *supra* text accompanying note 11.

thus her economic interest, even though her product claims, no longer allowed to be open-ended, will not.

V. CONCLUSION

In sum, this Comment argues that the PTO should consider changing its approach to open-ended product claims. Claim construction principles in both litigation and prosecution contexts demand that open-ended terms in product claims be given their plain meaning in virtually all cases. As a result, the scope of open-ended product claims will typically be quite broad. This exceptional breadth weakens the presumption that patent examiners are competent to judge whether open-ended product claims are truly enabled. Moreover, prudent policy, for the sake of the patent system as a whole, suggests that in this context the PTO err on the side of allowing narrower claims rather than broader ones. Therefore, as an alternative to the current MPEP approach for open-ended product claims, this Comment suggests that patent examiners should presumptively reject open-ended product claims, instead allowing claims that are limited by the highest values actually achieved by the patentee and disclosed in the specification.

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