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Ending the Invalidity Shell Game: Stabilizing the Application of the Written Description Requirement in Patent Litigation

Aaron B. Rabinowitz*

I. INTRODUCTION

With the recent battles fought over whether particular inventions are patent-eligible,[1] one might be forgiven for overlooking the other requirements for patentability. The written description requirement mandates that the specification of the patent application shall "contain a written description of the invention,"[2] which

> [A]llows the United States Patent and Trademark Office ("PTO") to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.[3]

While issued patents are presumed valid and can only be invalidated upon a showing of clear and convincing evidence,[4]

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1. *E.g.*, *In re* Bilski, 130 S. Ct. 3218 (June 28, 2010) (assessing patentability of methods of hedging investment risk); Ass'n for Molecular Pathology v. USPTO, 09-CV-4515, 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. Apr. 2, 2010) (assessing patentability of breast cancer genes).

2. 35 U.S.C. § 112 (2006); *see also* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345–51 (Fed. Cir. 2010) (*en banc*) (affirming that 35 U.S.C. § 112 contains a written description requirement separate from the enablement and best mode requirements).

3. *Ariad*, 598 F.3d at 1345.

4. *E.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367,

nearly half of all litigated patents are nonetheless adjudged invalid.[5] An analysis of federal court patent decisions issued in the last ten years reveals that those (typically accused infringers) who challenge issued patents on the ground of insufficient written description succeed more than forty percent of the time in their challenges.[6]

The fact that the federal courts so frequently overturn granted patents that (1) have been thoroughly vetted by the PTO and (2) can only be invalidated by a showing of clear and convincing evidence[7] underscores that there is a disconnect between the way in which the PTO evaluates—and approves—patent applications and the way in which those approved patents are treated in litigation.[8]

This has created what can be termed a "shell game" for patentees that assert their patents in litigation. Having confidence in their PTO-approved patent claims, patentees bet on the strengths of those patents by initiating litigation against infringers, only to discover in litigation that their patents are invalid based on written descriptions that the PTO concluded were sufficient.

The causes of this problem are likely at least twofold. First, the law of written description is ever-evolving, and there is still internal debate within the Federal Circuit regarding the scope

1375 (Fed. Cir. 1986); *see also* 35 U.S.C. § 282 (2006) (establishing a presumption of patent validity).

5. Alan Devlin, *Revisiting the Presumption of Patent Validity*, 37 SW. U. L. REV. 323, 326 n.10 (2008) (citing Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 76 (2005)). While patents may be invalidated for any number of reasons (*e.g.*, lack of novelty, obviousness, failure to disclose best mode), this paper focuses on the issue of patents invalidated for failure to comply with the written description requirement of 35 U.S.C. § 112.

6. This analysis is based on summary patent litigation statistics for 2000–2009, *available at* www.patstats.org. *See infra* section IV.

7. *E.g.*, *Hybritech*, 802 F.2d at 1375; *see also* 35 U.S.C. § 282 (establishing a presumption of patent validity).

8. This 40% figure is also in tension with suggestions that the written description doctrine has not had much of an impact on patent litigation. *E.g.*, 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, 80 (2007); *see also* Dennis F. Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution*, 104 NW. U. L. REV. COLLOQUY 382, 383 (2010) (observing that written description requirement plays little role in patent prosecution before the PTO).

and purpose of the requirement.[9] Second, courts may encounter difficulty in applying the presumption of validity in the litigation context because the PTO need not necessarily explain how a given patent claim satisfied the written description requirement.[10] While the disconnect between the PTO and the courts may have more than one cause, the fact that courts frequently agree with patent challengers suggests that courts are implicitly applying an incorrect evidentiary standard.

This disconnect is a matter of importance to both patentees and to the public. First, the frequency with which courts apply the written description requirement to overturn patents stands as a clear disincentive for firms to invest in patentable research that may benefit the public. Second, the frequent invalidation of patents on some grounds (i.e., written description) that was necessarily evaluated by the PTO[11] suggests that the PTO's evaluation of patent applications is flawed.

This paper examines this disconnect and proposes a solution to harmonize the application of the written description requirement at the PTO and in the courts. This solution empowers patent applicants and the PTO to more consistently produce patents that possess claims that satisfy the written description requirement and are more likely to be upheld in litigation.

To frame the issues surrounding the current state of the law on written description, Part II of this paper reviews the evolution of the written description requirement from its origins as a device to prevent applicants from adding improper "new matter" to their patent claims to its current incarnation as a device used to invalidate patent claims that lack sufficient support in the specification. A statistical review of federal court decisions issued from 2000–2009 that apply the written

9. LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing *en banc*); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing *en banc*); *id.* at 1325 (Linn, J., dissenting from denial of rehearing *en banc*); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc); *see also* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1361–67 (Fed. Cir. 2010) (Rader, J., dissenting).

10. Because written descriptions are presumed to be adequate, examiners need only comment on the written description when they believe it is deficient. *See* Manual of Patent Examining Procedure ("MPEP") § 2163.04, *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm.

11. 37 C.F.R. § 1.104 (2006); MPEP § 2163(II)(A)(2).

description requirement is provided in Part IV of this paper, which demonstrates the prevalence of written description issues in patent litigation.

Part V of this paper proposes a way to harmonize the PTO's written description analysis of patent applications with the way in which the federal courts assess the written description of granted patents, namely by having patent applicants affirmatively identify during prosecution the written description support for their claims. Part V of this paper also discusses the likely benefits of this solution and some of the solution's likely criticisms. Finally, Part VI of this paper provides additional commentary and observations on the state of written description law.

II. THE DEVELOPMENT OF THE WRITTEN DESCRIPTION REQUIREMENT

The written description doctrine carries the same weight in patentability determinations as any of the other three requirements for patentability.[12] But because the contours of the written description have changed over time, compliance with the requirement presents a puzzle for patent applicants and the courts alike.

The written description requirement originated as a device to prevent patent applicants from adding new inventions to an already-existing disclosure.[13] In more recent decisions, however, the Federal Circuit has changed course and applied the written description requirement as a tool to protect against inadequate disclosure. In this new incarnation, the written description is applied to claims, including originally-filed claims, to assess whether the patent specification adequately discloses or supports the subject matter recited in the claims.[14]

12. 35 U.S.C. §§ 101–03, 112 (2006).

13. *See Univ. of Rochester*, 375 F.3d at 1307 (Rader, J., dissenting) (collecting cases).

14. *E.g.*, LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1347 (Fed. Cir. 2005) (concluding that originally-filed claims lacked written description support).

A. HISTORY OF THE WRITTEN DESCRIPTION REQUIREMENT

As the Federal Circuit recently reiterated:

> [T]he purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time.[15]

At the outset of modern patent law, the doctrine was used to police priority.[16] During the early development of the patent law, 35 U.S.C. § 132 was used to enforce the prohibition against adding material to patent claims that was not present in the originally-filed application: "[n]o amendment shall introduce new matter into the disclosure of the invention."[17] The Federal Circuit then adapted 35 U.S.C. § 112 to police priority in *In re Ruschig*.[18]

In *Ruschig*, the applicant added a new claim to the application about a year after the application was filed.[19] The court then determined whether the new claim was supported by the disclosure in the applicant's original application.[20] Instead of using § 132 to police this priority question, however, the *Ruschig* court applied § 112 to analyze priority and "calved" a new written description doctrine out of the enablement requirement of § 112.[21]

In *In re Wertheim*,[22] the court again addressed a priority issue. Applying the written description doctrine, the court reiterated that "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."[23] In later cases, the U.S. Court of Customs

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15. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353–54 (Fed. Cir. 2010) (internal citations omitted) (quoting Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920 (Fed. Cir. 2004)); Holman, *supra* note 8, at 4–6.

16. *See* Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 976–89 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing *en banc*).

17. 35 U.S.C. § 132 (2006).

18. *In re* Ruschig, 379 F.2d 990 (C.C.P.A. 1967).

19. *Id.* at 991.

20. *Id.* at 992–96.

21. *Enzo Biochem*, 323 F.3d at 978 (Rader, J., dissenting from denial of rehearing *en banc*).

22. *In re* Wertheim, 541 F.2d 257 (C.C.P.A. 1976).

23. *Id.* at 262.

and Patent Appeals and then the Federal Circuit continued to apply the written description requirement only for purposes of policing priority.[24]

B. *REGENTS OF THE UNIVERSITY OF CALIFORNIA V. ELI LILLY, INCORPORATED*—CREATING A "FREE-STANDING DISCLOSURE REQUIREMENT"

In *Regents of the University of California v. Eli Lilly, Incorporated*,[25] however, the Federal Circuit applied the written description requirement not to police priority, but instead as a "new free-standing disclosure requirement."[26]

In *Lilly*, the claims at issue recited recombinant plasmids and microorganisms that produce human insulin, which is protein involved in the regulation of sugar metabolism.[27] One of the claims at issue recited "a nucleotide sequence having the structure of the reverse transcript [i.e., cDNA] of an mRNA of a [human], which mRNA encodes insulin."[28] The specification, however, provided "only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains."[29] The court concluded that, whether or not that disclosure was enabling, the general disclosure regarding rat insulin "[did] not provide a written description of the cDNA encoding human insulin . . . ."[30] Judge Lourie explained that the cDNA described in the specification was:

> [N]ot itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there

24. *See In re* Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983) ("The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language."); *see also Enzo Biochem*, 323 F.3d at 978–80 (Rader, J., dissenting from denial of rehearing *en banc*).

25. Regents of the Univ. of Cal. v. Eli Lilly, Inc., 119 F.3d 1559 (Fed. Cir. 1997).

26. *Enzo Biochem*, 323 F.3d at 980 (Rader, J., dissenting from denial of rehearing *en banc*).

27. *Eli Lilly*, 119 F.3d at 1562.

28. *Id.* at 1567 (second alteration in original).

29. *Id.*

30. *Id.*

> is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent . . . .[31]

Because the specification lacked such sequence information, the Federal Circuit held the claim invalid.[32] The *Lilly* patentee's other claims generically recited cDNA encoding vertebrate insulin (claims 1 and 2), cDNA encoding mammalian insulin (claim 4), and cDNA encoding vertebrate insulin (claims 6 and 7).[33] The patentee argued that the disclosure of a species (the rat insulin-encoding cDNA) within the scope of those generic claims satisfied the written description requirement.[34] The court, however, disagreed:

> [A] description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials.[35]

This result was notable for at least two reasons. First, the Federal Circuit had applied the written description requirement—historically used to prevent applicants from later-claiming matter not included in the original application[36]—to the patentee's originally-filed claims.[37] Second, the biotechnology community was also concerned about the "stringent disclosure requirements" the decision had imposed on biotechnology inventions.[38]

The free-standing disclosure requirement developed in *Lilly* and its subsequent application by the Federal Circuit in *Enzo Biochem, Inc. v. Gen-Probe Inc.*,[39] *University of Rochester*

31. *Id.*
32. *Id.*
33. U.S. Patent No. 4,652,525 col.20 l.64 (filed June 28, 1983).
34. *Eli Lilly*, 119 F.3d at 1567.
35. *Id.* (alteration in original) (quoting Fiers v. Revel, 984 F.2d. 1164, 1171 (Fed. Cir. 1993)).
36. *See supra* Part II.A.
37. Holman, *supra* note 8, at 14.
38. *Id.*
39. Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo I*), 285 F.3d 1013 (Fed. Cir. 2002) (applying *Lilly* and concluding that a deposit of DNA material did not satisfy the written description requirement for claim directed to a DNA sequence, when the application did not contain a written recitation of the

v. G. D. Searle, Inc.,[40] and *LizardTech, Inc. v. Earth Resource Mapping, Inc.*[41] generated significant tension among the Federal Circuit's judges. Each of those cases applied the *Lilly* approach to written description to invalidate claims for lack of sufficient disclosure in the patent specification.[42] In each of these three cases, the patentee petitioned for rehearing *en banc*, and rehearing was denied in all three cases over vigorous dissents from Judges Gajarsa, Linn, and Rader.[43] The *Lilly* approach to written description quickly expanded beyond the complex biotechnology invention at issue in that case. The "free-standing" disclosure requirement has since been applied outside of biotechnology to fields such as medical devices,[44] computer graphics,[45] and beverage cans.[46]

sequence). After Enzo petitioned for panel rehearing, the *Enzo I* panel vacated its original decision and remanded for analysis of whether a patentee could comply with the written description requirement if the deposits "indicate that the patentee has invented species sufficient to constitute the genera." Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo II*), 323 F.3d 956, 967–70 (Fed. Cir. 2002).

40. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004).

41. LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336 (Fed. Cir. 2005).

42. Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009), *aff'd en banc* 598 F.3d 1366 (Fed. Cir. 2010) (Linn, J., concurring); LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing *en banc*); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing *en banc*); *id.* at 1325 (Linn, J., dissenting from denial of rehearing *en banc*); MOBA, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); *id.* at 1327 (Bryson, J., concurring); *Enzo Biochem*, 323 F.3d at 976 (Rader, J., dissenting from denial of rehearing en banc); *id.* at 987 (Linn, J., dissenting from denial of rehearing *en banc*).

43. *LizardTech*, 433 F.3d at 1376 (Rader, J., dissenting from denial of rehearing *en banc*); *Univ. of Rochester*, 375 F.3d at 1307 (Rader, J., dissenting from denial of rehearing *en banc*); *id.* at 1325 (Linn, J., dissenting from denial of rehearing *en banc*); *Enzo Biochem*, 323 F.3d at 976 (Rader, J., dissenting from denial of rehearing *en banc*).

44. ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F. 3d 1368 (Fed. Cir. 2009).

45. *LizardTech*, 424 F.3d 1336.

46. Crown Packaging Tech. v. Rexam Beverage Can Co., 531 F. Supp. 2d 629 (D. Del. 2008).

C. *ARIAD PHARMACEUTICALS*[47]—REAFFIRMING LILLY

While the Federal Circuit seemed to retract the Lilly doctrine in *Enzo II*,[48] the court ultimately affirmed in *Ariad* that the written description requirement could be used to police priority and——as in *Lilly*——could also be used to invalidate claims for lack of supporting disclosure in the specification.[49]

The patent claims at issue in *Ariad* concerned the use of reducing the activity of the NF-kB transcription factor present in cells to regulate the expression of genes (e.g., genes that code for cytokines, which can harm the body if present in excess amounts).[50] The patent specification recited the goal of reducing NF-kB activity and reducing the binding between NF-kB and NF-kB binding sites in cells.[51] The specification "hypothesize[d] three types of molecules with the potential to reduce [NF-kB] activity in cells: decoy, dominantly interfering, and specific inhibitor molecules."[52] A panel decision invalidated Ariad's claims on the ground that the specification did not actually describe the molecules that reduced the binding between the NF-kB molecules and the NF-kB binding sites.[53]

On Ariad's petition for rehearing, the *en banc* Federal Circuit granted the petition to determine whether 35 U.S.C. § 112 contained a "written description requirement separate from the enablement requirement and, if so, the scope and purpose of that requirement."[54]

Before turning to the merits of the case,[55] Judge Lourie noted that while the written description requirement had historically been used to police priority:

> Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of § 112 supports such a restriction; the statute does not say '[t]he specification shall contain a written description of the invention *for purposes of determining priority*.' And although the issue arises

47. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

48. *See supra* note 39 and accompanying text.

49. *Ariad*, 598 F.3d at 1349.

50. *Id.* at 1340.

51. *Id.* at 1341.

52. *Id.*

53. Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009), *aff'd en banc* 598 F.3d 1366 (Fed. Cir. 2010).

54. *Ariad*, 598 F.3d at 1340.

55. The *Ariad en banc* court ultimately determined that the written description requirement exists separately from the enablement requirement, an issue which is outside the scope of this paper.

> primarily in cases involving priority, Congress has not so limited the statute, and neither will we.[56]

Judge Lourie also took the opportunity to address the long-standing test for written description, namely that the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."[57] Put another way, the accepted test was whether "the disclosure of the application relied upon 'reasonably conveys to [those skilled in the art] that the inventor had possession at that time of the later claimed subject matter.'"[58]

Acknowledging that "[t]he term 'possession,' however, has never been very enlightening,"[59] Judge Lourie then concluded that:

> [W]hatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.[60]

The *en banc* court then adopted, in full, the reasoning of the earlier panel decision and affirmed the invalidity of Ariad's claims for failure to comply with the written description requirement.[61]

Judges Rader and Linn dissented from the *Ariad en banc* opinion.[62] The dissenting judges first criticized the majority's reaffirmation of the "fabrication," begun in *Lilly*, that written description was not limited to policing new matters and was instead a free-standing requirement.[63] The dissenting judges also rightly criticized the *Ariad-Lilly* application of written description as "in tension" with the Federal Circuit's approach to claim construction.[64]

In claim construction, claims are read "in view of the

56. *Ariad*, 598 F.3d at 1349.

57. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

58. *Id.* (quoting Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

59. *Ariad*, 598 F.3d at 1351.

60. *Id.*

61. *Id.* at 1354.

62. *Id.* at 1361–67 (Rader, J., dissenting).

63. *Id.* at 1363–64.

64. *Id.* at 1364.

specification" to determine their meaning and scope.[65] In Judge Rader's view, "If this court followed its own rule [from claim construction] and ensured that claims do not enlarge what the inventor has described, then the claims would never have a scope that exceeds the disclosure in the rest of the specification."[66] Given that under principles of claim construction, claims could never be construed to encompass any more than what is disclosed in the specification, courts would never find that a claim "lacks support" in the patent application.[67] Judge Rader observed that "this court's new written description doctrine only has meaning if this court ignores its own claim construction rules."[68] The dissent concluded by arguing that "[a]s it stands, the court's inadequate description of its written description requirement acts as a wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection."[69]

Thus, while the *Ariad en banc* decision clarified that the written description requirement could be used as a free-standing disclosure requirement, the decision nonetheless left somewhat open the precise standard under which patent claims should be evaluated. Rather than providing bright-line guidance, the decision stated only that the written description inquiry required an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art," leaving the analysis of an individual patent up to the specific facts of that case.

III. THE PRESUMPTION OF VALIDITY AND WRITTEN DESCRIPTION

Aside from the turbulence in the law of written description, the presumption of validity that attaches to all granted patents is a second layer of complexity courts confront when analyzing patent claims for compliance with written description. Issued

65. *Id.* at 1364–65 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005)).

66. *Id.* at 1365.

67. *Id.*

68. *Id.*

69. *Id.* at 1366; *see also* LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1379 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing *en banc*) (characterizing Federal Circuit's approach to written description issues as "[b]ring your specifications to the Federal Circuit and we will tell you if they contain sufficient descriptions.").

patents are presumed valid—a challenger cannot overturn a patent without showing that the patent is invalid by clear and convincing evidence.[70] Taken literally, the presumption means that courts must give deference to the PTO in all cases, even where the court itself may disagree with the PTO's ultimate conclusion on patentability:

> A patent is presumed valid and invalidity must be shown by clear and convincing evidence. . . . It is quite possible that [a] patent should have never been granted, but once it was granted, attacking its validity is a very difficult task indeed. . . . [T]he law is the law.[71]

The presumption of validity and the attendant clear and convincing evidentiary standard are squarely in play when a challenger in litigation bases its invalidity theory on prior art that was already reviewed by the PTO: "[w]hen no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job . . . ."[72] Hence, "[w]hen an attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent."[73]

This same analysis should also apply in the written description context to require courts to give proper deference to the PTO's conclusions on written description. The PTO is obligated by rule to review the specification during prosecution to determine the claim's compliance with the written description requirement.[74] Given that the written description

70. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986).

71. Aventis Pharma Deutschland GmbH v. Lupin Ltd., 2006 U.S. Dist. LEXIS 48246, at *144, *150 (E.D. Va. July 17, 2006).

72. Am. Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Some have questioned whether the same standards should apply in court when the PTO did not review the evidence that a challenger is using to support a theory of invalidity. In a recent petition to rehear a case *en banc*, Microsoft urged the court to overrule its precedents that require clear and convincing evidence of invalidity when the PTO did not consider the art at issue. Lucent v. Gateway, Inc., Federal Circuit Appeal Nos. 2008-1485, -1487, -1495, Appellants' Petition for Rehearing *En Banc* at 8–14 (filed Oct. 13, 2009) (on file with author); *see also* Doug Lichtman & Mark Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 49–50 (2007).

73. *Am. Hoist*, 725 F.2d at 1360.

74. 37 C.F.R. § 1.104(a) (2010); *see also* MPEP § 2163(II)(A)(2) ("[T]he examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how

analysis encompasses only the claims and the specification,[75] a written description-based challenge asserted in litigation could be considered as going "over the same ground travelled by the PTO . . . ."[76]

Part of the challenge facing the courts, however, is that while the PTO must review all patent claims for compliance with the written description requirement,[77] the PTO does not as a matter of course make findings regarding written description.[78] This presents a practical problem for reviewing courts: when a challenger raises an issue that was considered by the PTO during prosecution, the challenger's burden is to show that the PTO's reasoning on that issue was incorrect and overcome the deference the court must give to the PTO's reasoning.[79] But it is difficult to see how a court can properly defer to the PTO's reasoning when the PTO concludes that the claims satisfy written description requirements but do not supply express reasoning to educate the court (and the public) regarding precisely how the patent claims and specification satisfy the requirement.[80]

Where the PTO does not make any findings or "[w]hen new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with

applicant provides support for the various features of the claimed invention.").

75. Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009), *aff'd en banc* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (noting that the written description analysis addresses only the claims and the "four corners" of the specification).

76. *Am. Hoist*, 725 F.2d at 1360.

77. 37 C.F.R. § 1.104(a) (2010); *see also* MPEP § 2163(II)(A)(2).

78. *See, e.g.*, PIN/NIP v. Platte Chem. Co., 304 F.3d 1225, 1243 (Fed. Cir. 2002) ("[A] patent issued by the PTO is presumed to be valid."); Brooktree Corp. v. Advanced Micro Devices, 977 F.2d 1555, 1575 (Fed. Cir. 1992) ("[T]he fact that the Patent Office allows . . . an amendment without objection thereto as new matter (within the meaning of Title 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness" (citation omitted)).

79. *Am. Hoist*, 725 F.2d at 1360.

80. *See* PIN/NIP, Inc. v. Platte Chem., 304 F.3d 1225 (Fed. Cir. 2002) (highlighting the problems that can result from the lack of express reasoning from the PTO. Specifically, the PTO allowed the patentee's claims on the first office action, but in subsequent litigation the Federal Circuit reversed a jury verdict that one of the allowed claims complied with the written description requirement. Thus, the patentee may have been penalized in litigation for claims that—in the PTO's judgment—comply with written description because there will be no PTO findings a court can review and defer to). *Cf. Am. Hoist*, 725 F.2d at 1360 (observing that court is normally required to defer to PTO's reasoning and expertise).

having to disagree with the PTO or with deferring to its judgment or with taking its expertise into account."[81] This may mean that courts likely have trouble appreciating that the written description of a granted patent can only be overturned by clear and convincing evidence even in the absence of any express findings by the PTO, which may explain why written description challenges so frequently go the way of the challenger.[82]

Thus, in any given case, a court must contend with (1) the uncertainty in the ever-evolving law surrounding written description and (2) the challenge of properly considering the presumption of validity when the court may or may not have express findings from the PTO to which the court can defer. Given the layers of complexity surrounding written description, it is no surprise that the courts have encountered significant challenges in properly applying the requirement in litigation, as described in the next section of this paper.

IV. WRITTEN DESCRIPTION—PLAYING A LEADING ROLE IN LITIGATION

A. STATISTICAL ANALYSIS OF WRITTEN DESCRIPTION OUTCOMES IN LITIGATION

Some commentators have suggested that the written description requirement does not ultimately play much of a role in patent validity.[83] During *en banc* oral arguments in *Ariad*, Chief Judge Michel stated that:

> I can't remember ever seeing a patent office rejection that was based only on the failure of written description. I'm not saying there aren't any, but the flow of cases that come through this court at three or four hundred a year, it's exceedingly rare that the patent office hangs its case on written description. I can't remember a single case.[84]

A follow-up study revealed that Judge Michel's comment was correct.[85]

81. *Am. Hoist*, 725 F.2d at 1360.

82. *See Infra* Part IV.

83. Holman, *supra* note 8, at 80; *see also* Crouch, *supra* note 8, at 396 (observing that written description requirement plays little role in patent prosecution before the PTO).

84. Recording of Oral Argument at 23:58–24:18, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (2010), *available at* http://oralarguments.cafc.uscourts.gov.

85. As detailed in the follow-up study, not one of 2,858 Board of Patent

In contrast to its limited effect in prosecution, written description has played a critical role in patent litigation. A review of the courts' application of the written description requirement reveals strikingly different results than what is seen in prosecution. First, litigation statistics reveal that written description issues arise in a significant number of cases.[86] A review of patent litigation data[87] reveals that over 2000–2009, parties that attacked a patent on written description grounds succeeded more than forty percent of the time (Table 1).

Table 1: Success of Attack on Written Description Grounds

Year[88]	2000 - 2004	2005	2006	2007	2008	2009	Average
Challenger Prevails	52%	35%	43%	25%	39%	37%	43%

Thus, despite the fact that the PTO is obligated to assess the written description of a patent and that a granted patent can only be invalidated by a showing of clear and convincing evidence, parties that attacked a patent on written description grounds nonetheless succeed two out of every five attempts. This is a surprising result, given that the PTO is obligated to

Appeals and Inferences (BPAI) decisions sustained an outcome-determinative written description requirement rejection of originally-filed claims; the twenty-three BPAI decisions that did have an outcome-determinative written description decision "involved the rejection of claims that had been added or amended during prosecution and addressed the concern that the added limitations were not properly described in the original specification." Crouch, *supra* note 8, at 394.

86. For example, in 2009 alone, written description issues arose in 30 different patent litigations. U.S. PAT. LITIG. STAT., http://www.patstats.org/Patstats2.html (last visited July 8, 2010).

87. These data are from www.patstats.org, an organization at the University of Houston. Patstats.org provides research information on patent law decisions dating back to 2000, and tracks cases and outcomes on an issue-specific basis (e.g., obviousness, infringement under the doctrine of equivalents). *Id*.

88. These data were calculated by reviewing statistics from www.patstats.org. For example, the 37% figure in 2009 was calculated by dividing the number of written description decisions in 2009 (11) that favored the patent challenger by the total number (*11 + 19 = 30*) of written description challenges in 2009, i.e., *11 / (19 + 11) = 37%*. *Full Calendar Year 2009 Report*, U.S. PAT. LITIG. STAT., http://www.patstats.org/2009_full_year_posting.htm (last visited July 2, 2010).

review the claims and specification for compliance with the written description requirement,[89] and that patent validity can only be disproved by clear and convincing evidence.[90]

B. POSSIBLE EXPLANATIONS FOR THESE LITIGATION OUTCOMES

That nearly half of all written description issues are decided in favor of the challenger suggests that courts are—perhaps involuntarily—operating as if the PTO's conclusion that a patent claim satisfied written description can be overturned by a preponderance of the evidence (i.e., 51% probable) rather than by the applicable clear and convincing standard (i.e., 70% probable).[91] These data suggest that (1) something is amiss with the written description "strength" of patents that the PTO is allowing, (2) the courts are misapplying the law of written description, (3) the courts are misapplying the evidentiary burdens to validity challenges, or (4) some combination of these.[92]

Any or all of the foregoing may be the culprit for the current state of written description law. First, the fact that written description figures so infrequently into the PTO's decisions to grant patentability[93] may mean that the PTO itself is not applying enough written description scrutiny to patent applications. Without being "battle-tested" during prosecution, granted patent applications then become susceptible to written description challenges during litigation.

The complexity in the law and the Federal Circuit's own internal inconsistency may contribute to the challenges that

89. 37 C.F.R. § 1.104(a) (2010); MPEP § 2163(II)(A).

90. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986).

91. United States v. Fatico, 458 F. Supp. 388, 405 (E.D.N.Y. 1978) (Weinstein, J.) (noting that the "clear and convincing" standard requires 70% probability); Note, *Due Process Comes Due: An Argument for the Clear and Convincing Evidentiary Standard in Sentencing Hearings*, 77 IOWA L. REV. 1803, 1804 n.11 (1992).

92. To place the data in proper perspective, the 43% "win rate" by challengers means that the patentee wins on written description issues 57% of the time. *See supra* Part IV (A). This 57% figure, however, is closer to the 50% win rate that would be expected if the courts were applying a preponderance standard than to the 70% win rate that would be expected if the courts were applying the clear and convincing standard. *See Fatico*, 458 F. Supp. at 405.

93. Crouch, *supra* note 8, at 396 (observing that written description requirement plays little role in patent prosecution before the PTO).

the written description poses to litigants and judges alike during litigation. First, the *en banc* Federal Circuit has recognized that the existing "possession"[94] standard for compliance with written description has "never been very enlightening."[95] Thus, the contours of the test are hazy by the court's own admission. Second, the fact that courts may construe claims to be broader than the scope of the specification's preferred embodiments[96] has arguably created a situation where courts are given "unfettered power to err twice—both in construing the claims so broad as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to 'support' [the] court's own broad conception of the claimed subject matter."[97]

No matter which of the foregoing is the cause of the problem, the end result for patentees is that their patents are overly susceptible to invalidation on written description grounds. This is of concern to the PTO and to patent applicants, as it is a clear disincentive for firms to invest in research that may be beneficial to society at large: firms may, understandably, become fearful that their patents may be invalidated in litigation.

While the presumption of validity and the attendant "clear and convincing" evidentiary standard may exist, courts have difficulty applying the doctrine in litigation, particularly where there is no express reasoning by the PTO to which the court can defer. As a practical matter, while "[t]he court must give deference to the PTO's reasoning in its decisions"[98] it is difficult, if not impossible, to see how courts can give proper deference to the PTO without the court always having before it

94. Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009), *aff'd en banc* 598 F.3d 1336, 1351, 1351 (Fed. Cir. 2010) (explaining the "possession" test as "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date").

95. *Id.*

96. *E.g.*, Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.").

97. *Ariad*, 598 F.3d at 1365 (Rader, J., dissenting).

98. Peter Zura, *Looking For Fire Amidst The Smoke - Is The Federal Circuit Really Exceeding Its Appellate Authority In Patent Infringement Cases?*, 12 U. BALT. INTELL. PROP. L.J. 1, 15 (2003).

some express reasoning from the PTO.

V. SOLUTION

The above-described problems highlight the need for a solution that will stabilize the courts' application of written description. The solution would most preferably align with the existing evidentiary framework that requires a challenger to disprove the PTO's findings by clear and convincing evidence.

A solution to this problem—and one that puts the issue of written description squarely back before the PTO, where the issue should be evaluated in the first place—is for applicants to affirmatively identify the written description support for their claims in the application and for the PTO to either approve or question the applicant's statement of support. In this way, the PTO will necessarily provide a factual finding at the conclusion of prosecution, thus providing express reasoning to which courts may accord proper deference when a patent is challenged in litigation.[99]

Asking applicants to identify support in their specification in prosecution has precedent. More specifically, an applicant who appeals a final rejection to the Board of Patent Appeals and Interferences (BPAI) must identify for the BPAI where the specification provides support for the claims on appeal.[100] There is already rule-based support for this proposal. Title 37, section 1.56 of the C.F.R. already requires that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability."[101] Given the requirements of 35 U.S.C. § 112 and the recent reaffirmation of the use of the written description requirement to police the "support" for new claims, it is difficult to imagine any information more "material" to the written description requirement for patentability than

99. Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359–60 (Fed. Cir. 1984).

100. 37 C.F.R. § 41.37(c)(1)(v) (2010) (requiring that an appellant's opening brief to the BPAI include a "concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing[s], if any, by reference characters").

101. 37 C.F.R. § 1.56 (2010).

identification of the support for the claims at issue.

A. BENEFITS

By requiring applicants to affirmatively identify those sections of their specification and drawings that describe their claimed invention, the proposed solution brings more consistency and predictability to the patent process at both the prosecution and litigation stages. This yields benefits to patent applicants, patentees, and the public.

First, the solution stands to reduce the number of overbroad patents. In a regime where an applicant must—from the outset of prosecution—identify the support for her claims, applicants will take care (1) to draft complete disclosures and (2) draft claims that are congruent with that disclosure. Patent applicants will be less likely to try and overreach with their claims because if they do, the applicants will have to justify—during prosecution—how and why their claims are supported. With more patents being aligned to their disclosures, fewer patents with overbroad claims will result. This represents a positive outcome for the public, as there is a cost to society from overbroad patents.[102]

A second benefit to patent applicants is that, once a patent is issued, the prosecution history of the patent will include express reasoning by the PTO on the issue of written description. This will in turn provide the courts with a PTO analysis to which the courts can more easily defer, as the PTO's express reasoning will act as a psychological guidepost to courts.[103] From the patent applicant's perspective, this is a positive result, as applicants-turned-patentees will have more security that their patents will be accorded the proper respect in litigation. This will in turn encourage technology firms to seek patent protection, as they will have new confidence that a patent granted by the PTO will stand up to a litigation challenge.

Having applicants provide a statement of written

102. *See, e.g.*, Benjamin K. Sovacool, *Placing A Glove On The Invisible Hand: How Intellectual Property Rights May Impede Innovation In Energy Research And Development (R&D)*, 18 ALB. L.J. SCI. & TECH. 381, 406 (2008) ("Strong broad patent rights entail major economic costs while generating insufficient additional social benefits") (citing Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 281 (1998)).

103. *Am. Hoist.*, 725 F.2d at 1360 .

description support to the PTO at the outset of prosecution is analogous to having applicants self-police. For self-policing to be effective, the actor in question must have a "positive incentive" to self-police.[104] The proposed solution provides such a positive incentive: in return for self-policing and supplying the PTO with an affirmative statement of written description support, applicants will receive patents that are stronger in their written description compliance than under the current system. A litigant who challenges a patent must show where the PTO erred,[105] and it will be more difficult to demonstrate such an error when the PTO has reviewed the applicant's own affirmative representation of where support for the patent claims is found in the specification.

The proposed solution also applies the emerging theory of behavioral economics[106] to patent law. Under the behavior economics approach, actors are administratively "nudged" or otherwise impelled toward behaviors that ultimately benefit them. As one example of such an approach, employees may be automatically enrolled in a particular retirement plan so as to ensure that they save for retirement; employees who must affirmatively choose among multiple plans frequently fail to elect any plan and consequently save far less money for their retirements.[107]

The proposed solution likewise nudges patent applicants toward a beneficial behavior by having applicants positively identify as part of the application process the location or locations in their specification that support their claimed invention. In this way, a minor adjustment to the patent application process stands to reduce the number of overbroad patents (conversely increasing the unclaimed subject matter available to others for further research) and reduce the number of granted patents that are invalidated during litigation. Applicants will then have greater confidence in the written description strength of their patents, which will in turn bring more predictability to invalidity challenges in patent litigation.

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104. Jay P. Kesan, *Symposium: Innovations in Environmental Policy: Encouraging Firms to Police Them-Selves: Strategic Prescriptions to Promote Corporate Self-Auditing*, 2000 U. ILL. L. REV. 155, 162 (2000).

105. *Am. Hoist*, 725 F.2d at 1360 .

106. *See generally* BARRY SCHWARTZ, THE PARADOX OF CHOICE (2004); CASS SUNSTEIN & RICHARD THALER, NUDGE (2008).

107. SCHWARTZ, *supra* note 106, at 27–29.

B. OBJECTIONS

There are some objections to this proposed solution. First, the proposed solution may slow prosecution and make prosecution more costly.[108] While applicants will undoubtedly bristle at the prospect of increased prosecution costs, that additional cost brings with it patents that should more easily withstand written description challenges in litigation.

Second, patent examiners are already overburdened.[109] Tasking examiners with making express findings on written description in every case will undoubtedly increase that burden. But unless the PTO plans to hire additional examiners, this extra burden will be the trade-off for higher quality patents.

Another objection is that the solution may cause inventors to limit themselves to patent claims drawn narrowly to the examples in the specification or to claim less than they could have, out of caution or out of interest in speeding prosecution. This objection need not prevent implementation of the proposed solution.

First, while asking applicants to affirmatively identify the written description support for their claims could lead some applicants to narrow their claims, that is the choice of those applicants. Applicants who desire broader claims can simply draft an accordingly broad specification. Further, if an applicant receives patent claims she believes are narrower than the claims to which she believes she was entitled, the applicant can file a broadening reissue patent to secure the previously unclaimed subject matter.[110]

Second, the concern that applicants' claims will be limited to the embodiments of their invention that may be described in the "Examples" section of the patent application is misplaced because the law allows for claims that are broader than the examples. For example, in the chemical world, the Federal Circuit concluded *en banc* that a claim to a genus is proper when the specification "disclos[es] either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the

108. Sovacool, *supra* note 102, at 398.

109. *E.g.*, Devlin, *supra* note 5, at 334–45.

110. 35 U.S.C. § 251 (2006); Tillotson, Ltd. v. Walbro Corp., 831 F.2d 1033, 1037 n.2 (Fed. Cir. 1987); *see also* MPEP § 1412.03.

members of the genus."[111] Thus, even under the proposed written description scheme, an applicant need not limit her claims to the examples set forth in their specification.

VI. CONCLUSIONS

While the written description requirement is barely an afterthought during patent prosecution,[112] the fact that the requirement makes frequent and important appearances during litigation underscores the need to align the courts' application of the doctrine during litigation with the PTO's application of the doctrine during prosecution.[113]

Proper application of the written description doctrine is challenging. First, the Federal Circuit's development of the law surrounding the written description requirement has been turbulent[114] and—in the view of some of the court's own judges—is inconsistent with other areas of the court's jurisprudence.[115] Thus, the contours of the legal test for written description are ever-evolving.[116] The proper level of deference to grant to the PTO's written description conclusion and the evidentiary burden that the patent challenger must carry to invalidate a patent on written description grounds are also complex and difficult to apply.[117]

But if applicants and the PTO are empowered to affirmatively frame and resolve written description issues at the earliest possible stage during prosecution, patentees could secure patents that are more likely to withstand litigation challenges. Having applicants affirmatively set forth their

111. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (citing Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568–69 (Fed. Cir. 1997)).

112. Crouch, *supra* note 8, at 396.

113. *See supra* Part IV.

114. LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting); Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting); MOBA, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976, 987 (Fed. Cir. 2002) (Rader, J., dissenting) (criticizing application of written description requirement).

115. *Ariad*, 598 F.3d at 1361–67 (Rader, J., dissenting); *LizardTech*, 433 F.3d at 1376 (Rader, J., dissenting from denial of rehearing *en banc*).

116. *See supra* Part II.C.

117. *See supra* Part III.

written description support during prosecution would achieve this, as well as reduce the number of potentially harmful overbroad patents by encouraging applicants to align their patent claims with their specification at the earliest possible stage of the patent process.

Introducing affirmative claim support statements into prosecution may not be a perfect remedy. The PTO is undeniably overburdened, and adding additional analysis to the patent prosecution process will not reduce that burden. Drafting affirmative statements of written description support may also increase prosecution costs for applicants. But a patenting process that produces solid patents and properly manages patentees' expectations is worth investment from both the PTO and patent applicants.