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AN EMPIRICAL STUDY OF THE ROLE OF THE WRITTEN DESCRIPTION REQUIREMENT IN PATENT EXAMINATION

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INTRODUCTION

An en banc Federal Circuit recently confirmed that § 112 of the Patent Act,[1] as properly interpreted, includes a written description requirement that is separate and distinct from the enablement requirement.[2] The written description and enablement doctrines both encourage applicants to fully disclose their inventions, but the doctrines respectively focus on proof that the patentee (1) has possession of the invention;[3] and (2) has enabled others to make and use the invention.[4] The en banc-challenger argued instead that the patent statute spells out a unified requirement of a written description that enables and that the separate written description requirement should be eliminated.[5]

The U.S. Patent & Trademark Office (USPTO) is the executive branch agency tasked with the responsibility of examining patent applications to determine whether patent rights should issue.[6] Once a patent issues, the constitutionally guaranteed exclusive rights[7] can be enforced in federal

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1 35 U.S.C. § 112, ¶ 1 (2006) (link).

2 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (link). The Federal Circuit's pronouncements on patent law are especially important because that court holds exclusive jurisdiction over all appeals of final decisions for cases that arise under the US patent laws. Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 829–30 (2002) (link).

3 Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998) (asking whether the application "reasonably convey[s] to one of skill in the art that the inventor possessed the [claimed] subject matter at the time the [patent] application was filed" (citation omitted)) (link).

4 AK Steel Corp. v. Sollac, 344 F.3d 1234, 1243–44 (Fed. Cir. 2003) (the original specification of a patent must enable one of skill in the art to make and use the invention) (link).

5 Brief for Plaintiffs-Apellees, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. Mar. 22, 2010).

6 *See generally* JANICE M. MUELLER, PATENT LAW 45–58 (3rd ed. 2009) (providing an overview of the patent examination process).

7 U.S. CONST. art. I, § 8, cl. 8 (giving Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries") (link).

courts.[8] Although the USPTO has no direct role in the infringement dispute between the patentee Ariad[9] and the accused infringer Eli Lilly,[10] the government submitted an amicus curiae brief indicating its continued support for the written description requirement as a tool that the USPTO uses to eliminate claims during the patent examination process.[11] The government argued in its brief that a separate written description requirement is "necessary to permit USPTO to perform its basic examination function."[12] However, when pressed during oral arguments, the government could not point to any direct evidence supporting its contention.[13]

This Essay presents the results of a retrospective empirical study of the role of the written description requirement in patent office examination practice. It is narrowly focused on rebutting the USPTO's claim that the separate written description requirement serves an important role in the patent prosecution process. To the contrary, my results support the conclusion that it is indeed "exceedingly rare that the patent office hangs its case on written description."[14]

For the study, I analyzed 2,858 Board of Patent Appeals and Interference (BPAI) patent opinions decided between January and June of 2009. Written description issues were decided in 123 (4.3%) of the decisions in my sample. Perhaps surprisingly, I found that none of the outcomes of those decisions would have been impacted by a legal change that entirely eliminated the written description requirement of § 112, so long as the USPTO would still be allowed to reject claims based on the addition of "new matter" (perhaps under 35 U.S.C. § 132).[15] A rule change that also

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[8] 28 U.S.C. § 1338(a) (2006) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . .") (link).

[9] Ariad's U.S. Patent No. 6,410,516 entitled "Nuclear Factors Associated with Transcriptional Regulation" includes over 200 claims that broadly cover methods for reducing the activity of the naturally occurring Nuclear Factor Kappa B (NF-κB) protein. The patent is jointly owned by Harvard College, Massachusetts Institute of Technology, and the Whitehead Institute, and exclusively licensed by Ariad. U.S. Patent No. 6,410,516 (filed June 5, 1995) (link).

[10] Eli Lilly has a history of involvement in disputes over the written description requirement. It was the 1997 Federal Circuit decision of *Regents of the Univ. of Cal. v. Eli Lilly & Co*., 119 F.3d 1559, 1569 (Fed. Cir. 1997), that sparked what many have seen as a heightened written description requirement for biotechnology related inventions (link).

[11] Brief for the United States as Amicus Curiae on Rehearing en banc in Support of Respondent, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (link).

[12] *Id.* at 20.

[13] *See* Oral Argument, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (argued Dec. 7, 2009), *available at* http://oralarguments.cafc.uscourts.gov (enter case number 2008-1248; click audio link for 12-7-2009; oral argument from the United States on the issue runs 23:00–29:30) (link).

[14] *Id.* (Statement by Michel, C.J., as transcribed by the author), *available at* http://oralarguments.cafc.uscourts.gov. (enter case number 2008-1248; click audio link for 12-7-2009; statement from Michel, C.J. at 24:08) (link).

[15] This very small number of positive observations suggests that the distribution is well modeled with the Poisson distribution. Using a Poisson distribution, the 95% confidence interval for expected

prohibited the USPTO from making new matter rejections would alter the result in only twenty of the 2,858 cases—about 1% of the cases in my sample.[16] These results correspond to the outcomes found by Professor Holman in his 2007 article, *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] In that article, Holman identified nine examples where original claims were rejected for lacking written description.[18] However, Holman wrote that each of those rejected claims was, or "could have easily been," held invalid for lacking enablement.[19]

In *Ariad Pharmaceuticals v. Eli Lilly*, the Federal Circuit maintained the written description doctrine as a separate and distinct requirement.[20] The en banc panel based its decision on the text of the Patent Act and its accompanying jurisprudential history, rather than on the policy grounds that the doctrine plays an important role in policing patent applicant behavior.[21] The dissenting-in-part opinion by Judge Linn, joined by Judge Rader, as well as the concurring opinion of Judge Gajarsa, cite a working version of this Article in reaching their conclusions that the separate written description requirement is not justified on policy grounds.[22] As shown in this essay, the empirical data confirms the court's rejection of the doctrine's importance.

This Essay is narrowly written to provide a new set of empirical results that inform the debate over the importance of the written description in the context of patent prosecution. The strong conclusion is that, in the context of patent applications appealed to the BPAI, the impact of the separate written description requirement is negligible apart from its role in policing the addition of new matter. I posit that this study of BPAI decisions also serves as a good proxy for the relative proportion of non-appealed cases where the USPTO depends upon the written description requirement to limit claim scope. The analysis does, however, have limits. Perhaps most importantly, I only consider past decisions within a six-month window and thus do not consider the future effect of a change in the written description requirement on both applicant and patent office behavior.

These results are important as a direct rebuttal to the USPTO claims of

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proportion of affected cases is 0.0%–0.6%.

[16] The empirical study has a 95% confidence interval of 0.5%–2.6%.

[17] 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, 70 (2007).

[18] *Id.*

[19] *Id.* at 71.

[20] 598 F.3d 1336 (Fed. Cir. 2010) (link).

[21] *Id.* at 1343–45.

[22] *Id.* at 1372 (Linn, J. & Rader, J., dissenting in part); *id.* at 1360 (Gajarsa, J., concurring); *see also* Anascape, Ltd. v. Nintendo of Am., Inc., No. 2008-1500, 2010 U.S. App. LEXIS 7529, at *23–27 (Fed. Cir. Apr. 13, 2010) (Gajarsa, J., concurring).

doctrinal importance and as a means to lessen fears that elimination of a separate written description requirement would have a drastic impact on the patent prosecution practice.[23] More generally, the results prompt a consideration of the ongoing role of niche patent law doctrines.

Part I of this Essay offers a brief discussion of § 112's requirements for written description. Part II examines the *Ariad* challenge to the written description requirement presented on appeal. Part III explores the USPTO's claimed need for a strong and separate written description requirement to aid in the patent examination process. Part IV presents the empirical study and its results. Part V provides a brief set of final remarks and conclusions.

I. THE WRITTEN DESCRIPTION REQUIREMENT OF SECTION 112

The first paragraph of 35 U.S.C. § 112 focuses attention on the amount of disclosure that a patent applicant must provide in its specification:

> 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.[24]

From this paragraph, courts have derived three separate but overlapping doctrines: written description, enablement, and best mode.[25] These doctrines have been amply described by others and, as such, I provide only as much background here as is necessary for this Essay.[26]

As it stands, the written description doctrine requires that the patent specification "reasonably convey to one of skill in the art that the inventor possessed the [claimed] subject matter at the time the [patent] application was filed."[27] Patent applicants often add or amend claims during prosecution, and the primary historical function of the written description doctrine

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[23] *See* Dickerson v. United States, 530 U.S. 428, 429–30 (2000) (refusing to overrule *Miranda* based largely on the "persuasive force" of stare decisis) (link).

[24] 35 U.S.C. § 112, ¶ 1 (2006) (link).

[25] *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123 (2006). This Essay focuses on the enablement and written description doctrines, without regard to the best mode doctrine.

[26] *See, e.g.*, DONALD S. CHISUM, CHISUM ON PATENTS § 7 (2009); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539 (2009) (link); Holbrook, *supra* note 25; Holman, *supra* note 17; Sean A. Passino, Amy M. Rocklin & Stephen B. Maebius, *Written Description Traps for Antibody Claims*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 317 (2004); Guang Ming Whitley, *A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617 (2004).

[27] Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998) (considering whether later-claimed subject matter had been properly disclosed in the parent application) (citation omitted) (link).

has been to police the addition of "new matter" into the patent claims.[28] Section 132 of the Patent Act also provides a prohibition against "introduc[ing] new matter into the disclosure of the invention."[29] Because the claims of a patent are considered part of the disclosure,[30] the plain language of § 132 could also apply to limit changes in claim scope. However, in an effort to avoid confusion between these two statutory provisions, the predecessor to the Federal Circuit held that the written description requirement of § 112 served as "the proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure" and relegated § 132 to the role of policing improper amendments to the specification.[31]

Originally-filed patent claims are typically self-describing. Patent claims ordinarily exhibit the requisite evidence of "possession" by simply spelling out the metes and bounds of the patent right. However, several recent Federal Circuit opinions have held that originally-filed patent claims also lack sufficient written description if possession of the invention is not demonstrated.[32] This newer wing of the written description requirement is often termed Lilly Written Description (LWD), as homage to the 1997 *Eli Lilly* decision[33] that expanded the doctrine.[34] Original-claim failings may be

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[28] *See id.*; s*ee also In re* Rasmussen, 650 F.2d 1212 (C.C.P.A. 1981) (link); Application of Smith, 458 F.2d 1389, 1395 (C.C.P.A. 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads); Application of Lukach, 442 F.2d 967 (C.C.P.A. 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range) (link); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV 1619, 1663 (2007) (written description requirement "has traditionally applied to amendments to claims made during the prosecution of an application." (citation omitted)) (link).

[29] 35 U.S.C. § 132 (2006) (link).

[30] Application of Gardner, 480 F.2d 879, 879 (C.C.P.A. 1973).

[31] *In re* Rasmussen, 650 F.2d at 1214. This Essay focuses on the role of the written description in patent office practice. However, it is important to note the open question of whether the new matter restriction of § 132 properly serves as a basis in federal court for an invalidity defense to charges of patent infringement. *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1305–07 (Fed. Cir. 2004) (Lourie, J., concurring) (denying motion for en banc rehearing and noting that the listing of statutory defenses to patent infringement found in 35 U.S.C. § 282 does not include the new matter doctrine of § 132) (link); Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech., 543 F.3d 657, 659 (Fed. Cir. 2008) (finding that improper revival is not an available defense) (link); Dennis Crouch, *Erroneous Revival by PTO is not a Cognizable Defense in an Infringement Action*, PATENTLY-O, Sept. 22, 2008, http://patentlyo.com/patent/2008/09/erroneous-reviv.html (link).

[32] *See, e.g.*, Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567–68 (Fed. Cir. 1997) (link); *see generally* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH L.J. 615 (1998) (describing the development of the written description requirement); U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 2163 (8th ed., July 2008) ("a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.") (link). It is important to remember that the originally-filed claims are themselves part of the original specification. N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 938 (Fed. Cir. 1990) (link).

[33] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (link).

found where the invention is claimed and described in a functional form without identifying underlying structures of operation. Likewise, broad original claims have been held invalid for failing the written description requirement when the specification did not include detail sufficient to "convince a person of skill in the art that the inventor possessed the invention."[35] For instance, the 2005 *LizardTech* case involved a patent claim directed to a method of compressing digital images using seamless discrete wave transformation (DWT).[36] Although the specification only described one method for creating a seamless DWT, the claim was not limited to that particular method.[37] The appellate panel in *LizardTech* held the claim invalid for failing the written description requirement, finding that the specification did not provide sufficient evidence that the patentee invented the generic method.[38]

As is common, the *LizardTech* decision included a parallel finding that the generic claim was not enabled.[39] The enablement doctrine requires that the original specification of a patent enable one of skill in the art to make and use the invention.[40] Although typically overlapping, the written description and enablement requirements are distinct.[41]

II. THE *ARIAD* CHALLENGE TO THE WRITTEN DESCRIPTION REQUIREMENT

A. Questions on Appeal

In *Ariad*, an en banc Federal Circuit considered the continued role of the written description requirement as a doctrine separate and distinct from enablement. The questions presented read as follows:

> 1. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?
> 2. If a separate written description requirement is set forth

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[34] Holman, *supra* note 17, at 4; *see* Mueller, *supra* note 32, at 633 (arguing that written description as applied to original claims is an inappropriate "super-enablement" requirement).

[35] LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (link).

[36] *Id.* at 1337.

[37] *Id.* at 1342–43.

[38] *Id.* at 1345–46.

[39] *Id.* at 1345. *See also* Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009) (holding that the enablement question was moot because claims were rendered invalid for failing the written description requirement) (link); Holman, *supra* note 17, at 78; Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1157, 1172 (2002) (link).

[40] 35 U.S.C. § 112, ¶ 1 (2006) (link); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1238 (Fed. Cir. 2003) (link); Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1327 n.3 (Fed. Cir. 2008).

[41] Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 921 (Fed. Cir. 2004) (although "there is often significant overlap," the requirements are distinct) (link).

> in the statute, what is the scope and purpose of the requirement?[42]

These legal questions had been brewing for years.[43]

B. Background of the Dispute

The inventors of Ariad's asserted U.S. Patent No. 6,410,516 (the '516 patent) discovered a transcription factor protein that they named Nuclear Factor Kappa B (NF-κB).[44] The presence of NF-κB within a cell causes the cell to produce cytokines that are important for a cell's immune response.[45] The '516 patent does not claim invention of the NF-κB protein itself, but rather, the method of reducing a cell's response to external influences by reducing the NF-κB binding.[46]

After an infringement trial, a Massachusetts jury found that two of Lilly's products infringed Ariad's asserted U.S. Patent No. 6,410,516.[47] The jury also rejected Lilly's arguments that the patent was anticipated, that the patent lacked an enabling disclosure, and that the patent failed the written description requirement.[48] Although Lilly appealed each of these issues, the Federal Circuit panel focused on the written description requirement, finding Ariad's claims invalid for failing to provide a written description of the invention.[49]

The heart of the *Ariad* written description problem centers around the fact that the '516 patent discloses no working or even prophetic examples of methods that reduce NF-κB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity. The state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure.[50]

The appellate panel refused to consider the parallel questions of enablement and anticipation, finding those issues moot based on the written

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[42] Ariad Pharms., Inc. v. Eli Lilly & Co., 595 F.3d 1329, 1330 (Fed. Cir. 2009) (en banc order) (link).

[43] *See* Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 970–75 (Fed. Cir. 2002) (denying en banc rehearing) (link); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1303–04 (Fed. Cir. 2004) (denying en banc rehearing) (link); LizardTech, Inc. v. Earth Res. Mapping, 433 F.3d 1373, 1374–76 (Fed. Cir. 2006) (denying en banc rehearing) (link); Holman, *supra* note 17.

[44] Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1369 (Fed. Cir. 2009) (link).

[45] *Id.* at 1370.

[46] *Id.*

[47] *Id.*

[48] *Id.* at 1370–71.

[49] *Id.* at 1373–77 (holding that the verdict lacked substantial evidence to support its conclusion). The court also rejected Lilly's inequitable conduct challenge. *Id.* at 1377–80.

[50] *Id.* at 1376 (citation omitted).

description invalidity holding.[51] Judge Linn wrote a separate concurring opinion in which he reiterated his belief that the court's "engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided."[52]

The Federal Circuit subsequently granted Ariad's motion for an en banc rehearing of the written description issue.[53] Over twenty-five amici filed briefs, including the U.S. government.[54] At the December 7, 2009 oral arguments, the U.S. government was also granted time to argue its position.[55]

III. THE USPTO'S CLAIM OF A NEED FOR THE WRITTEN DESCRIPTION REQUIREMENT

In its amicus curiae brief, the U.S. government indicated its continued support for a separate written description requirement as a tool that the agency uses to eliminate claims during patent prosecutions.[56] The government made its position clear: that a separate written description requirement is "essential to the operation of the patent system";[57] plays an "indispensable role in the administration of the patent system";[58] is "fundamental to the operation of the patent system";[59] and is "necessary for USPTO to perform its examination function."[60] These conclusions are grounded in the USPTO's "practical experience" in "appl[ying] the requirements of Section 112, ¶1 to more than 400,000 patent applications each year . . . ."[61] Although the government did not provide any actual examples, it did explain two situations where the written description requirement becomes important.[62] First, the government argues that for claims written in purely func-

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[51] *Id.* at 1380 ("Because we hold that claims 80, 95, 144, and 145 of the '516 patent are invalid for lack of written description, we need not address infringement or the other validity issues on appeal.").

[52] *Id.* (citation omitted) (Linn, J., concurring); s*ee also* Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1325–27 (Fed. Cir. 2004) (Linn, J., dissenting from denial of rehearing en banc) (link); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 987–89 (Fed. Cir. 2002) (Linn, J., dissenting from denial of rehearing en banc) (link).

[53] Ariad Pharms., Inc. v. Eli Lilly & Co., 595 F.3d 1329 (Fed. Cir. 2009) (link).

[54] *See* Briefs for Amici Curiae, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

[55] Oral Argument, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (argued Dec. 7, 2009), *available at* http://oralarguments.cafc.uscourts.gov (enter case number 2008-1248; click audio link for 12-7-2009) (link).

[56] Brief for the United States as Amicus Curiae on Rehearing en banc in Support of Respondent, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (link).

[57] *Id.* at 19.

[58] *Id.*

[59] *Id.* at 20.

[60] *Id.*

[61] *Id.* at 19.

[62] *Id.* at 23–25. Similar arguments are raised in the USPTO's Guidelines for Examination of Patent

tional terms, the USPTO is better able to judge written description than enablement:

> Though such [functional] claims may be enabled, USPTO is not an experimental laboratory: it lacks both the facilities and the statutory mandate to determine, through empirical testing, whether any of millions of prior art inventions may have exhibited the recited function. By insisting that each applicant provide a full and exact "written description of the invention" as part of the specification, Congress protected the ability of USPTO to perform its essential function of distinguishing patentable inventions from the prior art. Indeed, this is one of the original and enduring purposes of the written description requirement: to "distinguish the invention or discovery from other things before known and used."[63]

The government also argued that the written description requirement is necessary to police priority claims and ensure that patent applicants do not improperly add new matter during the prosecution process:

> The written-description requirement permits USPTO and the courts to resolve priority disputes in an expedient and judicially reviewable fashion by comparing the specifications of the patents or applications in question. Similarly, "[e]very patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office." *Enzo Biochem, Inc. v. Gen-Probe, Inc*., 323 F.3d 956, 977 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing); *see* 35 U.S.C. § 132. "Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original crea-

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Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (notice on Jan. 5, 2001) (link). *See also* Brief of the Washington Legal Foundation as Amicus Curiae in Support of Defendant-Appellant Supporting Reversal at 22, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (a purpose of the written description requirement is to "prevent applicants . . . from obtaining claims to inventions that they did not invent") (link); Brief of the Federal Circuit Bar Association as Amicus Curiae in Support of Appellant at 22–23, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) ("A separate written description requirement is an important tool to permit the Patent Office and courts to enforce this foundational principle.") (link).

[63] Brief for the United States as Amicus Curiae on Rehearing en banc in Support of Respondent at 21, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (quoting Act of 1790, ch. 7, § 2) (link).

> tion." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991) (citation omitted).[64]

During oral arguments, the court pressed the government attorney, Mr. Freeman, for specific evidence supporting the contention that the separate written description requirement serves a practical purpose. As in its brief, the government did not point to any evidence supporting the conclusory statements. The following colloquy at oral arguments between Chief Judge Michel and Mr. Freeman emphasized this point:

> Chief Judge Michel: Why does the patent office care? I mean, how many applications that can't be rejected on other statutory grounds will fail only if we [retain the current written description requirement]? . . . I'm asking about impact . . .
>
> Mr. Freeman on Behalf of the Government: I don't know an absolute number, your Honor, but I think that number must be high . . .
>
> Chief Judge Michel: 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.
>
> Mr. Freeman: Your Honor, I don't have a single case in mind . . .
>
> Chief Judge Michel: . . . [I]t seems like the practical impact is miniscule, negligible.
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> Mr. Freeman: Your Honor, with all respect, one cannot assume away four-hundred thousand applications where the written description doctrine comes into play in a great many of them.[65]

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[64] *Id.* at 22.

[65] Oral Argument, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (argued Dec. 7, 2009), *available at* http://oralarguments.cafc.uscourts.gov (enter case number 2008-1248; click audio link for 12-7-2009; colloquy is from 22:40–24:30) (excerpt reproduced as transcribed by the author) (link).

This Essay is directed to the particular questions of Chief Judge Michel—How often does the separate written description requirement actually make a difference in patent cases? As revealed in Part IV, Chief Judge Michel's notional recollections from the bench are far more accurate than the government's contentions.

IV. THE IMPORTANCE OF THE WRITTEN DESCRIPTION REQUIREMENT IN PATENT PROSECUTION

This study analyzes the comparative impact that a change in the written description requirement would have had on ex parte BPAI appeals decided in the first half of 2009. I posit two potential doctrinal changes and their impact on USPTO practice: (1) elimination of a separate written description requirement, including elimination of the USPTO's ability to reject claims that include "new matter";[66] and (2) elimination of a separate written description requirement, with the exception that the USPTO may still reject claims for the inclusion of new matter.[67]

To be clear, Ariad has not argued for complete elimination of the written description requirement. Rather, the petitioner's position is that written description and enablement form a combined resulting doctrine that would have more power than the current enablement doctrine.[68] For this study, however, we did not consider a strengthened enablement doctrine. Thus, our results overstate the impact of eliminating a separate written description requirement, since a strengthened enablement doctrine would limit that impact.

A. Study Design

I broadly searched 2,858 ex parte BPAI decisions that were decided January through June 2009, and identified 365 decisions that mention "written description."[69] Each identified decision was reviewed by hand to deter-

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[66] I expect this potential outcome (eliminating the USPTO's ability to issue new matter rejections) to be unlikely for several reasons. Most notably, elimination of the separate written description requirement as a mechanism for policing new matter would abrogate *In re Rasmussen*, 650 F.2d 1212, 1214 (C.C.P.A. 1976) and, at least, open the door for the USPTO to reject claims under the new matter prohibitions of 35 U.S.C. § 132. The *Rasmussen* opinion was premised on the notion that Section 112 includes a written description requirement. *See* 650 F.2d at 1214. Elimination of the written description requirement would likewise eliminate the justification for precedential value of *Rasmussen*. More recent Federal Circuit case law has already strained the *Rasmussen* holding by considering claims to be properly rejected under Section 132. In *Moba B.V. v. Diamond Automation, Inc*, 325 F.3d 1306, 1319 (Fed. Cir. 2003), for instance, the Federal Circuit explained that, "a rejection of an amended claim under Section 132 is equivalent to a rejection under Section 112, first paragraph." (citation omitted) (link). Nevertheless, because this point is apparently in serious dispute, I consider it as a potential doctrinal change.

[67] Other potential outcomes, such as a strengthening of the written description requirement, were excluded.

[68] Brief for Plaintiffs-Apellees, Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

[69] These represented all of the ex parte BPAI decisions available via WestLaw as of February 16,

mine the particular type of written description rejection at issue and to determine whether a doctrinal change in the written description requirement would have impacted the outcome of the appeal.[70] See Table 1.

Table 1: Doctrinal Change Classification Methodology.

Potential Doctrinal Change	Classification Methodology
Doctrinal Change 1: elimination of a separate written description requirement, including elimination of the USPTO's ability to reject claims that include "new matter."	Decisions were classified as being impacted by Doctrinal Change 1 if the decision included a written description requirement issue that was sustained on appeal for at least one claim, and no other rejections of that claim were sustained on appeal.[71]
Doctrinal Change 2: elimination of a separate written description requirement except that the USPTO may still reject claims for the inclusion of new matter.	Decisions were classified as being impacted by Doctrinal Change 2 if the decision included a written description requirement issue that was sustained on appeal for at least one *original* claim, and no other rejections of that claim were sustained on appeal.[72]

B. Study Outcomes

Written description issues were decided in 123 (4.3%) of the 2,858 decisions.[73] A written description requirement rejection was sustained in 50 (1.7%) of the decisions,[74] but was outcome-determinative in only 23 (0.8%) of the decisions.[75] All twenty-three of these outcome-determinative deci-

2010.

[70] To be clear, I only considered cases where claims were *rejected* under the written description requirement. There are two other contexts where written description issues regularly arise. First, written description is applied in the prior art context to limit the prior art that is asserted. Second, an applicant's attempt to assert rights back to a parent filing, for instance under 35 U.S.C. § 120, is limited by the written description of the parent filing.

[71] We coded new reasons for rejection raised by the BPAI as sustained on appeal.

[72] For this study, a claim is considered "original" if the claim was included in the original non-provisional application filing. When the appeal involves a continuation application, a claim is "original" only if the language was found in the original non-provisional parent application. A patent applicant is allowed to amend claims during prosecution. However, written description requirement rejections of amended claims are typically treated under the new matter wing of the doctrine. *See supra* text accompanying notes 29–32.

[73] As a point of reference, a recent study found that 90% of appeals included at least one obviousness issue that was decided on appeal. Dennis D. Crouch, *Understanding the Role of the Board of Patent Appeals: Ex Parte Rejection Rates on Appeal* 10 (Univ. of Mo. Sch. of Law Legal Studies Research Paper No. 2009-16, 2009), *available at* http://ssrn.com/abstract=1423922 (link).

[74] A rejection was considered sustained if a rejection of at least one claim was sustained.

[75] The written description issue was judged outcome-determinative if the decision included a writ-

sions 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. More pointedly, none of the outcomes of those decisions would have been impacted by a hypothetical change that eliminated the written description requirement, so long as new matter rejections were still allowed under the same standard available today. These impacts of a doctrinal change in the written description requirement are shown in Table 2, with a 95% confidence interval (CI) of the expected proportion of affected cases.[76]

Table 2: Retrospective Impact of Doctrinal Change on 2009 BPAI Appeal Decisions.

Potential Doctrinal Change	Number of Affected Cases	95% CI
Doctrinal Change 1: elimination of a separate written description requirement including elimination of the USPTO's ability to reject claims that include new matter.	23 (0.8%)	0.5% -1.2%
Doctrinal Change 2: elimination of a separate written description requirement except that the USPTO may still reject claims for the inclusion of new matter.	0 (0.00%)	0.0% -0.3%

Twelve of the BPAI decisions did involve written description requirement rejections based on originally-filed claim language that could be classified as LWD rejections. However, the written description requirement was not outcome-determinative in any of these cases because the examiner's rejection was either reversed (nine of the cases) or else the claims were also rejected under another statutory doctrine (three of the cases). The three decisions where the LWD written description rejection was affirmed all involved inventions related to chemistry[77] or biotechnology.[78] This is the same situation discussed in the Federal Circuit case of *In re Kubin*.[79] Table

ten description requirement issue that was sustained on appeal for at least one claim and if no other rejections of that claim were sustained on appeal.

[76] The outcomes are modeled with the Poisson distribution.

[77] *Ex parte* Hottovy, No. 2008-4938, 2009 WL 798882 (B.P.A.I. 2009) (polymerization of olefin monomers in a liquid diluent); *Ex parte* Harboe, No. 2008-5837, 2009 WL 1683026 (B.P.A.I. 2009) (reducing the glucoamylase activity in a milk clotting composition).

[78] *Ex parte* Carney, No. 2008-4806, 2009 WL 64628 (B.P.A.I. 2009) (stimulating cartilage growth by administering an agonist of an activated thrombin receptor). In his 2007 study, Holman found nine BPAI decisions affirming LWD rejections—all in the area of biotechnology. Holman, *supra* note 17, at 70.

[79] *In re* Kubin, 561 F.3d 1351, 1361 (Fed. Cir. 2009) (affirming obviousness rejection and not de-

3 shows written description issues grouped by the USPTO technology center of origin. As shown in the table, the chemistry and biotechnology related technology centers are associated with a greater prevalence of written description issues.[80] However, even in those areas, the outcome-determinative written description issues were always associated with the new matter wing of the requirement.

Table 3: 2009 Written Description Appeals Grouped by Technology Center.

Technology Center		BPAI Decisions[81]	Written Description Decisions[82]	Written Description Outcome-Determinative	
				Affected by Doctrinal Change I	Affected by Doctrinal Change II
1600	Biotechnology and Organic Chemistry	202	23 (11.4%)	2 (1.0%)	0 (0.0%)
1700	Chemical and Materials Engineering	571	29 (5.1%)	10 (1.8%)	0 (0.0%)
2100 - 2400	Computer Architecture, Software, Security	479	16 (3.3%)	3 (0.6%)	0 (0.0%)
2600	Communications	249	4 (1.6%)	0 (0.0%)	0 (0.0%)
2800	Semiconductors, Electrical and Optical Systems	333	8 (2.4%)	1 (0.3%)	0 (0.0%)

ciding question of written description) (link); *see also Ex parte* Kubin, 83 U.S.P.Q. 2d (BNA) 1410 (B.P.A.I. 2007) (affirming obviousness and written description rejection but reversing enablement rejection) (link).

[80] *See* Dan L. Burk, *Biotechnology in the Federal Circuit: A Clockwork Lemon*, 46 ARIZ. L. REV. 441 (2004) (link).

[81] The total number of BPAI decisions categorized in this table is slightly less than the 2,858 reviewed decisions because some of the decisions did not indicate a technology center in the header information. If all of the decisions had been properly categorized, the reported percentages would drop slightly.

[82] This refers to the number of BPAI decisions that decided a written description requirement issue.

Technology Center		BPAI Decisions[81]	Written Description Decisions[82]	Written Description Outcome-Determinative: Affected by Doctrinal Change I	Written Description Outcome-Determinative: Affected by Doctrinal Change II
3600	Transport, Construction, E-Commerce, Agriculture	467	18 (3.9%)	4 (0.9%)	0 (0.0%)
3700	Mechanical Engineering, Manufacturing	456	21 (4.6%)	1 (0.2%)	0 (0.0%)
3900	Reexaminations	39	4 (10.3%)	2 (5.1%)	0 (0.0%)

V. DISCUSSION AND CONCLUSIONS

None of the 2,858 BPAI decisions that I analyzed sustained an outcome-determinative written description requirement rejection of originally-filed claims. This result indicates that Chief Judge Michel's perspective is correct, that—apart from new matter and late-claiming issues—the USPTO actually relies on the written description requirement to support examiner rejection in only a miniscule number of cases (at least at the level of appeals).[83] Although not an exact reflection, the BPAI appeals numbers likely serve as a good proxy for the proportion of non-appealed prosecution files where the USPTO depends upon the written description requirement to limit claim scope.[84]

This study comes with several important caveats. It does not answer

[83] *See supra* text accompanying note 66, for a discussion of why new matter claim rejections will still be viable even if the separate written description requirement is eliminated.

[84] Although not conclusive, several factors suggest that written description rejections may be appealed at a greater rate than ordinary obviousness rejections. First, an accurate practitioner perception that BPAI appeals of written description requirement rejections have a higher-than-average reversal rate could lead to a larger proportion of those types of rejections appealed. Crouch, *supra* note 73. Second, the recent tumultuous nature of the written description requirement and the associated uncertainty adds to the likelihood that a rejection on that issue would be appealed. Finally, written description rejections—especially those relating to LWD—tend to arise from biotechnology and chemical-related patent applications. Because patents in those areas tend to be more valuable than average, we would expect a higher rate of appeal.

As a cross-check, I examined the file histories of a small group of randomly selected and publicly available patent applications with serial numbers 11/000,000–11/999,999. For each application, I looked at the most recent final office action (if any) to determine the reasons for rejection. Only one of the twenty final office actions in my sample included a written description rejection, and that rejection was based on subject matter that had changed due to an amendment during prosecution.

any questions about the proper role of the written description requirement during litigation. Likewise, this study is not intended to either indict or support the *potential* use of the written description requirement during patent examination. Rather, the study is directed only toward rebutting the USPTO's statements that the written description requirement is necessary for the agency to perform its examination function. Based on the results presented here, it is safe to treat the USPTO's statements of the doctrine's importance as incorrect. The *Ariad* court was correct in its rejection of this argument.