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GILDING THE *LILLY*: THE § 112 WRITTEN DESCRIPTION REQUIREMENT SEPARATE FROM ENABLEMENT

Abstract: On March 22, 2010, the U.S. Court of Appeals for the Federal Circuit, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, held that the first paragraph of 35 U.S.C. § 112 contains a written description requirement separate from the enablement requirement. In so doing, the court affirmed recent circuit precedent holding that a patentee must demonstrate possession of its invention at time of filing, in addition to enabling one of skill in the art to practice the invention. This Comment argues that the court's stated bases for decision inadequately support its holding and appear to skew the result towards Lilly, undermining the perceived justness of the decision.

INTRODUCTION

This Comment discusses *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, decided by the U.S. Court of Appeals for the Federal Circuit on March 22, 2010.¹ In that case, Ariad Pharmaceuticals, the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively, "Ariad"), the licensee and holders, respectively, of U.S. Patent 6,410,516,² brought suit against Eli Lilly and Company ("Lilly") for alleged infringement.³ The issue in the case was whether the first paragraph of 35 U.S.C. § 112 contains a written description requirement separate from the enablement requirement.⁴

This Comment argues that the stated bases for the court's ruling in Lilly's favor provide inadequate support for its holding and result from a questionable allocation of the burden of proof.⁵ Part I provides an overview of the invention and patent at issue, the procedural posture of the litigation, and the issue before the court.⁶ Part II provides

¹ 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

² U.S. Patent No. 6,410,516 (filed Apr. 21, 1989) [hereinafter '516 Patent].

³ *Ariad*, 598 F.3d at 1340.

⁴ *Id.*; see 35 U.S.C. § 112 (2006).

⁵ See *infra* notes 76–120 and accompanying text.

⁶ See *infra* notes 9–36 and accompanying text.

an overview of the litigants' arguments.⁷ Part III analyzes the bases for the court's holding.⁸

I. THE *ARIAD* LITIGATION AND POSITIONS OF THE PARTIES

A. *The Invention at Issue*

The inventors of the '516 patent are widely credited with having discovered the transcription factor Nuclear Factor Kappa B (NF- κ B),⁹ the understanding and regulation of which is critical to developing effective treatments for cancer and a number of other diseases.¹⁰ The inventors claim in the '516 patent to have developed methods for reducing or regulating the operation of NF- κ B.¹¹ Between 1986 and 1995, they filed many patent applications related to reducing NF- κ B activity in a cell, some of which were abandoned and some of which were continued in part and formed the basis for the '516 patent.¹²

⁷ See *infra* notes 37–75 and accompanying text.

⁸ See *infra* notes 76–120 and accompanying text.

⁹ Ranjan Sen & David Baltimore, *Inducibility of Kappa Immunoglobulin Enhancer-Binding Protein NF- κ B by a Posttranslational Mechanism*, 47 CELL 921, 921–28 (1986) (disclosing discovery of NF- κ B, and authored by the patent inventors); Ranjan Sen & David Baltimore, *Multiple Nuclear Factors Interact with the Immunoglobulin Enhancer Sequences*, 46 CELL 705, 705–16 (1986).

¹⁰ Ricardo Orlando Escárcega Alarcón et al., *The Transcription Factor Nuclear Factor-kappa B and Cancer*, 19 CLINICAL ONCOLOGY (ROYAL C. RADIOLOGISTS) 154, 154, 157–59 (2007) (explaining the link between NF- κ B and cancer, and citing patent inventors Sen and Baltimore as the discoverers of NF- κ B in 1986). One of the patent inventors, Baltimore, was already a Nobel Laureate at the time of this discovery for his prior contributions to medicine and genetics. *The Nobel Prize in Physiology or Medicine 1975*, NOBELPRIZE.ORG, http://nobelprize.org/nobel_prizes/medicine/laureates/1975 (last visited Apr. 1, 2011).

¹¹ See '516 Patent col. 3 ll. 54–67. Briefly, NF- κ B is a transcription factor, meaning that it causes, inside a cell nucleus, the information encoded in certain DNA molecules (i.e., genes) to be used to manufacture a particular protein. See Thomas D. Gilmore, *Introduction to NF- κ B: Players, Pathways, Perspectives*, 25 ONCOGENE 6680, 6681 (2006). NF- κ B normally exists in the human body in a bound, inactive state inside the cell but outside the cell nucleus. See *id.* NF- κ B is released and used by the immune system in warding off extracellular assault, such as from a bacterial infection. See Escárcega et al., *supra* note 10, at 154. In such an immune response scenario, NF- κ B travels into the cell nucleus where it binds to and activates the transcription of certain genes containing an NF- κ B recognition site, which constitutes one step of a healthy immune response to infection. See '516 Patent col. 2 ll. 54–63; Gilmore, *supra*, at 6681. Reducing NF- κ B activity in a cell is useful, however, for reducing the symptoms of certain diseases such as cancerous tumors in which a harmfully excessive amount of genes are activated due to NF- κ B activity. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc); '516 Patent col. 3 ll. 59–67; Escárcega et al., *supra* note 10, at 159.

¹² See '516 Patent at [60]. The actual filing date of the patent was a matter of some confusion due to the number of abandoned and re-filed applications, and was only re-

B. *The Ariad Litigation*

1. Procedural Posture

On June 25, 2002, after a “sixteen year trek through the United States Patent and Trademark Office” and the same day the patent finally issued, Ariad brought suit against Lilly for alleged infringement for two drugs which Lilly had placed on the market, Evista and Xigris.¹³ After a fourteen-day jury trial in April 2006 in the U.S. District Court for the District of Massachusetts, the jury found that Lilly infringed four asserted claims of the patent and that the patent was not invalid for lack of written description.¹⁴ The jury awarded Ariad over \$65 million in damages.¹⁵ The court denied without opinion Lilly’s motions for judgment notwithstanding the verdict and a new trial.¹⁶ After a further four-day bench trial in August 2006, the court ruled that the patent holder’s conduct during prosecution, despite the number of abandoned and re-filed applications, was not inequitable conduct.¹⁷ The court thus held the patent valid and enforceable and entered judgment in accordance with the jury verdict.¹⁸

Lilly appealed to the Federal Circuit, and on April 3, 2009, a panel of that court affirmed the district court’s finding of no inequitable conduct, but reversed the jury’s finding on written description.¹⁹ Specifically, the panel held the asserted claims invalid for lack of an adequate written description as required by the first paragraph of § 112.²⁰ Ariad petitioned for a rehearing en banc, challenging whether there exists a written description requirement in § 112 separate from the enablement requirement.²¹ Numerous previous requests for rehearing en banc had been denied on this very question,²² but due to the ongoing

solved at trial through a special jury verdict. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106, 115 (D. Mass. 2007).

¹³ 529 F. Supp. 2d at 112–13, 114.

¹⁴ *Id.* at 114–15.

¹⁵ *Id.* at 115.

¹⁶ *Ariad*, 598 F.3d at 1341.

¹⁷ *Ariad*, 529 F. Supp. 2d at 140.

¹⁸ *Id.*

¹⁹ *Ariad*, 598 F.3d at 1341.

²⁰ *Id.*

²¹ *Id.* at 1340.

²² *See, e.g.*, *Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1373 (Fed. Cir. 2005); *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1303 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 956 (Fed. Cir. 2002).

“controversy concerning the distinctness and proper role of the written description requirement,” the court granted Ariad’s petition.²³

2. Issue Before the Court

The court directed the parties to answer two questions: (1) Does § 112, paragraph 1, contain a written description requirement separate from the enablement requirement; and (2) If a separate written description requirement exists, what is its scope and purpose?²⁴ The issue was of such consequence to the business, technology, and research communities that the court received no fewer than twenty-five amicus briefs.²⁵

The first paragraph of § 112, the statute at issue, reads as follows:

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.²⁶

This paragraph is obviously fertile soil for litigation—Judge Arthur J. Gajarsa termed it a “model of legislative ambiguity,” its interpretation one over which “reasonable people . . . have . . . disagreed for the better part of a decade.”²⁷ Clearly, the written description must *enable* the invention, that is, explain how to make and use the invention so as to enable any person skilled in the art to practice it.²⁸ The specification must

²³ *Ariad*, 598 F.3d at 1341–42.

²⁴ *See id.* at 1342.

²⁵ *See id.* Seventeen of the briefs supported Lilly and the existing written description doctrine, whereas only one supported Ariad (and seven supported neither party). *Id.*

²⁶ 35 U.S.C. § 112 para. 1 (2006).

²⁷ *See Ariad*, 598 F.3d at 1360 (Gajarsa, J., concurring) (citing *Rochester*, 375 F.3d at 1303 (denying a rehearing en banc on the question of whether the statute contains one written description requirement or two); *Enzo*, 323 F.3d at 956).

²⁸ *See* § 112 para. 1; *The Incandescent Lamp Patent*, 159 U.S. 465, 472–74 (1895) (“If the description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void.”); *Ariad*, 598 F.3d at 1343–45; ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 185–95 (5th ed. 2010) (detailing the enablement requirement). The term “art” refers to a field of technological innovation; its usage reaches back to at least the original Patent Act of 1790 and led to such turns of phrase as “state of the art.” *See infra* note 46. The term “prior art” refers to earlier inventions and disclosures of technological innovation bearing on a particular invention’s novelty and thus patentability. *See MERGES ET AL., supra*, at 185; *infra* notes 47–49 and accompanying text.

also set forth the best mode of implementing the invention.²⁹ Less clear, and the question in *Ariad*, is whether the enablement requirement is additional to a separate “written description of the invention” requirement, or is merely a further specification of the contents and purpose of that written description.³⁰

C. *The Positions of the Litigants*

Ariad in its brief argued for a reading of the statute that contains no written description requirement separate from the enablement requirement.³¹ Specifically, *Ariad* admitted that the specification must contain a written description of both (1) the invention and (2) the manner and process of making and using it.³² *Ariad* argued, however, that the measure of each of those requirements is contained in the final phrase—that together they must “enable any person skilled in the art . . . to make and use the same.”³³ Thus, *Ariad*’s parsing of the statute is as follows:

The specification shall contain

[A] a written description

[i] of the invention, and

[ii] of the manner and process of making and using it,

[B] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same, and

[C] [the specification] shall set forth the best mode contemplated by the inventor of carrying out his invention.³⁴

²⁹ See § 112 para. 1; MERGES ET AL., *supra* note 28, at 203–04.

³⁰ See *Ariad*, 598 F.3d at 1342–43. In analyzing the written description requirement, this Comment discusses the proper role for claims in relation to the written description. See *infra* notes 54–58 and accompanying text. Thus the second paragraph of § 112, the claims requirement, is relevant and reads: “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 para. 2.

³¹ *Ariad*, 598 F.3d at 1343; Principal Brief for Plaintiffs-Appellees on Rehearing En Banc at 2–8, *Ariad*, 598 F.3d 1336 (No. 2008-1248) [hereinafter *Ariad* Brief].

³² *Ariad* Brief, *supra* note 31, at 2.

³³ *Id.*

³⁴ See *Ariad*, 598 F.3d at 1343; *Ariad* Brief, *supra* note 31, at 3. The court reproduced *in haec verba* each litigant’s representation of the proper parsing of the statute from the litigant’s respective appellate brief, which rendered direct comparison between the positions difficult due to inconsistent presentation and formatting. See *Ariad*, 598 F.3d at 1343–44; *Ariad* Brief, *supra* note 31, at 4; Principal Brief for Defendant-Appellant Eli Lilly & Co. on Rehearing En Banc at 25, *Ariad*, 598 F.3d 1336 (No. 2008-1248) [hereinafter *Lilly* Brief].

Lilly argued for an alternate reading of the statute that requires both (1) a written description of the invention, and (2) a written description 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 make and use the same.³⁵ Thus, Lilly's parsing of the statutory paragraph is as follows:

[A] The specification shall contain a written description of the invention, and

[B] [the specification shall contain a written description] 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 . . . to make and use the same, and

[C] [the specification] shall set forth the best mode contemplated by the inventor of carrying out his invention.³⁶

II. DISCUSSION OF THE LITIGANTS' ARGUMENTS

Ariad's position essentially rehashed arguments made eight years prior by Federal Circuit Judge Randall R. Rader in the 2002 case of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, dissenting from the court's denial of a rehearing en banc.³⁷ This en banc reexamination in *Ariad* was the stormy culmination of many years' gathering clouds.³⁸

A. *Ariad's Arguments*

In support of its statutory interpretation, Ariad argued that the rules of grammar, prior versions of the Patent Act, and Supreme Court precedent all support its view.³⁹ Ariad further argued that a logical analysis of the respective roles of original claims and the written description supports its position, and that according to Lilly's position

For the sake of clarity, both parties' representations have been reformatted, in a manner faithful to the author's understanding of the court's and the parties' respective positions. See *Ariad*, 598 F.3d at 1343–44; *Ariad* Brief, *supra* note 31, at 4; *Lilly* Brief, *supra*, at 25.

³⁵ See *Ariad*, 598 F.3d at 1344; *Lilly* Brief, *supra* note 34, at 25.

³⁶ See *Ariad*, 598 F.3d at 1344; *Lilly* Brief, *supra* note 34, at 25.

³⁷ See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976–83 (Fed. Cir. 2002) (Rader, J., dissenting). See generally *Ariad* Brief, *supra* note 31.

³⁸ See *Enzo*, 323 F.3d at 976–83 (Rader, J., dissenting). See generally *Ariad* Brief, *supra* note 31.

³⁹ See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1343, 1345 (Fed. Cir. 2010) (en banc).

there is no statutory standard for evaluating the written description.⁴⁰ Admitting that prior decisions of the Federal Circuit had rejected its interpretation, Ariad argued that such decisions were based on an incorrect reading of earlier circuit precedent.⁴¹

1. Grammar

Ariad first argued that its statutory interpretation is necessitated by the rules of grammar.⁴² It argued that prepositional phrases are modifiers and must relate the object of a preposition to some other noun in the sentence.⁴³ Thus in § 112, the prepositional phrase “in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same” must modify the noun phrase that precedes it, namely the “written description.”⁴⁴

Ariad further argued that according to Lilly’s suggested construction that “in such . . . terms as to enable” modifies only “of the manner and process of making and using it,” the comma between the two phrases is superfluous and its presence “inexplicable.”⁴⁵

2. Earlier Versions of the Patent Act

Ariad next argued that the prior versions of the patent statutes contained the ambiguous language in the modern § 112 and do not support a separate written description requirement.⁴⁶ The Patent Acts

⁴⁰ *Id.* at 1349.

⁴¹ *Id.* at 1347–49.

⁴² *Ariad* Brief, *supra* note 31, at 3–5.

⁴³ *Id.* at 3–4 (citing RODNEY HUDDLESTON & GEOFFREY K. PULLUM, *THE CAMBRIDGE GRAMMAR OF THE ENGLISH LANGUAGE* 598 (2002)).

⁴⁴ *Id.* at 4.

⁴⁵ *Id.* at 6–7.

⁴⁶ *Id.* at 8. The relevant portion of the Patent Act of 1790, the first patent act, provided as follows:

SEC. 2. [T]he grantee or grantees of each patent shall . . . deliver . . . a specification in writing, containing a description, accompanied with drafts or models . . . which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term . . .

Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 109, 110–11. The relevant portion of the Patent Act of 1793, which repealed the first patent act, provided as follows:

of 1790 and 1793 each provided that the written specification must distinguish the invention from the prior art, and enable a person skilled in the art to make and use the invention.⁴⁷ The 1793 act introduced the ambiguous language used in today's § 112, providing that the inventor must deliver "a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms"⁴⁸ Thus, Ariad argued, under the 1790 and 1793 Patent Acts no written description requirement separate from enablement existed (other than distinguishing the invention from prior art, a role transferred in 1836 to the claims), and the § 112 language is but a historical product of those earlier acts.⁴⁹

3. Supreme Court Precedent

Ariad, and Judge Rader in his dissent in *Enzo*, cited the 1822 decision by the U.S. Supreme Court in *Evans v. Eaton* in support of the contention that the written description requirement is measured solely by enablement, aside from the distinguishment requirement later subsumed by the claims.⁵⁰ Ariad argued that the statute the Court in *Evans*

SEC. 3. [E]very inventor, before he can receive a patent, shall . . . deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.

Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321.

⁴⁷ Ariad Brief, *supra* note 31, at 8.

⁴⁸ Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321–22. Ariad claimed that the U.S. Supreme Court in its 1822 decision in *Evans v. Eaton* dealt with that statutory ambiguity and resolved there to be but one written description requirement: enablement (other than distinguishing from the prior art). See 20 U.S. (7 Wheat.) 356, 380–81 (1822); Ariad Brief, *supra* note 31, at 9–10 (citing *Enzo*, 323 F.2d at 977 (Rader, J. dissenting)).

⁴⁹ Ariad Brief, *supra* note 31, at 8–10, 12–13 (citing *Evans*, 20 U.S. at 380–81 (interpreting 1793 statute to emphasize description's dual role of distinguishment and enablement)); see *Enzo*, 323 F.2d at 977 (Rader, J. dissenting) (explaining that distinguishment role of written description transferred to claims section by Patent Act of 1836).

⁵⁰ Ariad Brief, *supra* note 31, at 16–18. In *Evans*, the Court wrote:

It is the business and duty of the inventor, then, at the time of applying for his patent, and before he can receive a patent, to deliver a "written description of his *invention*, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same."

was interpreting, the 1793 Patent Act, is essentially identical to the modern § 112, and thus the Supreme Court clearly established the precedent that once the claims requirement is subtracted off, the sole written description requirement is enablement.⁵¹

Ariad further cited the 1938 Supreme Court decision in *Schriber-Schroth Co. v. Cleveland Trust Co., Chrysler Corp.*, interpreting the Patent Act of 1870.⁵² Ariad asserted that the provision in the 1870 act, using language parallel to the modern § 112, required a written description measured only by the enablement standard, in addition to the claims and best mode requirements.⁵³

4. Analysis of the Respective Roles of Claims and Written Description

Ariad next argued that a logical analysis of the respective roles of original claims and the written description supports its position.⁵⁴ It argued that in the case of original claims—and thus in the typical case—any written description requirement to demonstrate possession separate from enablement is redundant and meaningless.⁵⁵ Looking at the four corners of the patent specification, Ariad argued, the material claimed in original claims will obviously be specified, since the claims

20 U.S. at 380–81 (quoting Patent Act of 1793) (emphasizing essential aspects). The Court further wrote that:

The specification, then, has two objects; one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim any thing that is in common use, or is already known

Id. at 433–34.

⁵¹ *Ariad* Brief, *supra* note 31, at 16–18 (interpreting Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321–22).

⁵² 305 U.S. 47, 57 (1938); *Ariad* Brief, *supra* note 31, at 12. The Court in *Schriber-Schroth* stated:

The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

305 U.S. at 57.

⁵³ *Ariad* Brief, *supra* note 31, at 12.

⁵⁴ *Id.* at 32–33, 43–44.

⁵⁵ *Id.* at 43–44.

are themselves part of the patent specification.⁵⁶ Thus, original claims constitute their own description.⁵⁷ Ariad asserted that the proper role for the written description requirement is to prevent applicants from inserting new material into an old patent application and claiming the older priority date.⁵⁸

5. Lack of a Statutory Standard

Finally, Ariad asserted that only according to its construction does the statute contain a standard for assessing the written description, namely that it “enable.”⁵⁹ By contrast, goes the argument, Lilly’s interpretation renders the “written description of the invention” bereft of statutory definition, measure, or purpose, leaving the inventor to guess at to what end to direct her written description.⁶⁰ In place of a clear statutory enablement standard, argued Ariad, the Federal Circuit has created an unfathomable judicially construed standard: that the applicant must convey a sense of being “in possession of the invention.”⁶¹ Ariad termed this a “super-enablement” requirement that judges and commentators alike have decried for lack of judicial definition and inconsistent and arbitrary results.⁶² Ariad argued in sum that the proper role of the written description doctrine is for policing priority, and that the doctrine has “taken on a life of its own.”⁶³

B. Lilly’s, and the Court’s, Response

The court based its holding on statutory ambiguity, parallelism of the statutory language, Supreme Court precedent, and stare decisis.⁶⁴

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.* at 32–33, 43–44. Priority is the term used for ensuring, when a patentee amends claims to encompass new aspects of an invention not claimed in the original application, that evidence in the original specification supports his or her claim to have actually invented the newly claimed aspects by the original filing date. See MERGES ET AL., *supra* note 28, at 182–83, 230–31.

⁵⁹ Ariad Brief, *supra* note 31, at 4, 6, 36 (citing *Enzo*, 323 F.3d at 976 (Rader, J., dissenting) (arguing that written description is measured by enablement)).

⁶⁰ See *id.* at 4, 6–7, 36.

⁶¹ *Id.* at 36 (citing Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1371–72 (Fed. Cir. 2009) (panel decision)).

⁶² *Id.* at 37 (citing *Enzo*, 323 F.3d at 981–82 (Rader, J., dissenting)); see *id.* at 40 (citing *Rochester*, 375 F.3d at 1327 (Dyk, J., concurring) (“[The court has] yet to articulate satisfactory standards [for the written description] that can be applied to all technologies.”)).

⁶³ *Id.* at 41.

⁶⁴ See Ariad, 598 F.3d at 1344, 1345–47.

The court first held that nothing in the language or grammar of the statute “unambiguously dictates” the written description to be measured solely by enablement.⁶⁵ Recognizing that prepositional phrases modify noun phrases, it noted that “in such full, clear, concise and exact terms as to enable . . .” modifies the implied noun phrase immediately preceding it, “*the written description . . . of the manner and process of making and using [the invention].*”⁶⁶ The court also noted the statutory parallelism in Lilly’s interpretation, that “and of the manner and process of *making* and *using* it” parallels “as to enable any person skilled in the art . . . to *make* and *use* the same.”⁶⁷

Next, the court discussed precedent, focusing on the 1938 Supreme Court decision in *Schriber-Schroth*.⁶⁸ The court held that, although the Supreme Court did not explicitly state that a separate written description requirement exists, it applied such a standard in its holding.⁶⁹ According to the *Ariad* court, the Supreme Court in *Schriber-Schroth* invalidated a patent reciting a gas engine with flexible webs, because it only described extremely rigid webs.⁷⁰ The Supreme Court noted that even had the original specification enabled the use of flexible webs, the patent would still be invalid due to lack of written description.⁷¹ Thus, according to the court, the Supreme Court applied a written description doctrine separate from enablement.⁷²

Finally, the court held that stare decisis compels a ruling in Lilly’s favor.⁷³ The court noted *Ariad*’s admission that the law for over forty years has supported Lilly’s position, and the import of not upending the settled expectations of the business and inventing communities, which have acted according to that precedent.⁷⁴ The court finally emphasized the special force of stare decisis when dealing with statutory interpretation, where Congress’s decision to leave judicial interpretation undisturbed suggests its acquiescence to that interpretation.⁷⁵

⁶⁵ *Id.* at 1344.

⁶⁶ *Id.* (emphasis added).

⁶⁷ *Id.* (emphasis added).

⁶⁸ *Id.* at 1345–47.

⁶⁹ *Id.* at 1346.

⁷⁰ *Ariad*, 598 F.3d at 1346.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.* at 1347.

⁷⁴ *Id.*

⁷⁵ *Id.* (citing *Watson v. United States*, 552 U.S. 74, 82 (2007)).

III. THE *ARIAD* COURT'S STATED BASES FOR DECISION INADEQUATELY SUPPORT ITS HOLDING

The Federal Circuit, in ruling for Eli Lilly, endorsed a grammatically unexact reading of 35 U.S.C. § 112.⁷⁶ It predicated its holding on avoiding supposed harms to the business community that are unstated, undocumented, and unempirical.⁷⁷ It also contradicted itself regarding the respective roles of the written description and the claims.⁷⁸ Finally, the court undermined the perceived justness of its ruling by skewing the result towards Lilly and in placing the burden of proof on Ariad.⁷⁹

A. *Statutory Construction and Virtual Grammar*

The court in *Ariad* displayed remarkable flexibility—or perhaps contortionism—in its grammatical justification for Lilly's reading of the statute.⁸⁰ In response to the assertion that a prepositional phrase must modify a preceding noun phrase, the court nonchalantly produced a *virtual* noun phrase—“[a written description] of the manner and process of making and using it.”⁸¹ Admittedly, when construing a statute noted for ambiguity and ancient lineage, which Congress has been loath to modify, employing virtual grammar is perhaps not unreasonable.⁸² The same could be said of the court's indifference to the extraneous comma: statutes of ancient lineage are perhaps allowed a certain flexibility.⁸³

B. *Stare Decisis*

The court bases its ruling on *stare decisis* and the settled expectations of the business community, which is questionable in the absence of empirical or even theoretical support for the supposed harms to ensue were Ariad's position adopted.⁸⁴ It is unclear what harm the business and inventing community would suffer were the court to overrule its

⁷⁶ See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

⁷⁷ See *id.* at 1347.

⁷⁸ See *id.* at 1346–47.

⁷⁹ See *id.* at 1344, 1347.

⁸⁰ See *id.* at 1344.

⁸¹ See 35 U.S.C. § 112 para. 1 (2006); *Ariad*, 598 F.3d at 1344.

⁸² See *Ariad*, 598 F.3d at 1344; *Lilly* Brief, *supra* note 34, at 26–27 (quoting *In re Barker*, 559 F.2d 588, 594 (C.C.P.A. 1977) (Rich, J., concurring)).

⁸³ See *Ariad*, 598 F.3d at 1344; *Lilly* Brief, *supra* note 34, at 26–27 (quoting *Barker*, 559 F.2d at 594 (Rich, J., concurring)); *supra* text accompanying note 45.

⁸⁴ See *Ariad*, 598 F.3d at 1347.

recent written description precedent.⁸⁵ The court cited those communities' reliance on a separate written description requirement in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions.⁸⁶ The harm in overruling that precedent, however, may be negligible: a likely insignificant number of imprudently drafted patents would nonetheless be held valid, whereas no patents would be suddenly invalidated for excessive description.⁸⁷

Of course, business transactions may have been conducted in reliance on patent attorneys' opinions that certain patents were likely invalid, due to noncompliance with the separate written description requirement.⁸⁸ Were the court to overturn that precedent, certain intellectual properties would turn out undervalued, unexpectedly changing market values.⁸⁹ Nevertheless, given the high degree of uncertainty in assessing patent validity, with how much confidence could a prudent attorney issue an opinion of invalidity?⁹⁰ At any rate, without empirical evidence, the degree of any such market shift is simply unknown.⁹¹

There may be patents, however, which disclose more than would be necessary under a pure enablement rule.⁹² The quid pro quo of patent doctrine mandates that inventors disclose their inventions to the public in exchange for patent protection.⁹³ The enhanced written description requirement may have caused inventors to disclose valuable information that, under a pure enablement rule, could remain secret, retaining a higher market value.⁹⁴ Overturning that precedent may indeed disrupt such settled expectations in the inventing community.⁹⁵ In any case, an empirical study quantifying these hypothetical disruptions would provide a more reliable basis for the court's holding in *Ariad*.⁹⁶

⁸⁵ See *id.*

⁸⁶ *Id.*

⁸⁷ See *id.*

⁸⁸ See *id.*

⁸⁹ See *id.*

⁹⁰ See, e.g., Christina Bohannon & Herbert Hovenkamp, *IP and Antitrust: Reformation and Harm*, 51 B.C. L. REV. 905, 926, 928–29, 934 (2010) (discussing “abysmal” lack of clarity of patent boundaries, problems of validity uncertainty, and unacceptably high rate of reversals and Federal Circuit dissents in claim construction decisions).

⁹¹ See *Ariad*, 598 F.3d at 1347.

⁹² See *id.*

⁹³ See *id.* at 1345, 1347; MERGES ET AL., *supra* note 28, at 180, 203–04.

⁹⁴ See *Ariad*, 598 F.3d at 1347. An example of this is genus claims, where fewer individual species would need to be disclosed under a pure enablement rule. See *id.* at 1349–53.

⁹⁵ See *id.*

⁹⁶ See *id.*

C. *The Separate Roles of Written Description and Claims*

The court contradicted itself with regard to the independent roles of the written description and claims.⁹⁷ The court itself quoted the U.S. Supreme Court's 1938 opinion in *Schriber-Schroth Co. v. Cleveland Trust Co.* that the written description has two functions:

[1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.⁹⁸

Nevertheless, the court in *Ariad* later stated that the "principal function" of *claims* is to "provide notice of the boundaries of the right to exclude and to define limits"—a role functionally identical to statement [2] in *Schriber-Schroth* regarding the *written description*.⁹⁹

Thus, if we are to adhere to the Supreme Court's statement in *Schriber-Schroth*, a separate written description requirement does indeed conflict with the function of the claims, contrary to the court's assertion in *Ariad* that no such conflict exists.¹⁰⁰ According to the Supreme Court, the only function of the written description beyond enablement is "to inform the public . . . of the limits of the monopoly asserted"—exactly the role the court in *Ariad* reserved for claims.¹⁰¹

D. *Burden of Proof*

Finally, the court placed the burden of proof almost entirely on *Ariad*, whose failure to shoulder that burden resulted in Lilly's victory nearly by default.¹⁰² A fairer allocation of the burden would require Lilly, the party claiming the existence of an extra requirement, to prove its existence through precedent and a superior reading of the statute.¹⁰³

⁹⁷ See *id.* at 1346–47.

⁹⁸ *Id.* at 1346 (citing *Schriber-Schroth Co. v. Cleveland Trust Co.*, Chrysler Corp., 305 U.S. 47, 57 (1938)).

⁹⁹ See *id.* at 1347.

¹⁰⁰ See *Ariad*, 598 F.3d at 1346–47 ("A separate written description requirement also does not conflict with the function of the claims. . . . Claims define and circumscribe, the written description discloses and teaches.")

¹⁰¹ See *Schriber-Schroth*, 305 U.S. at 57; *Ariad*, 598 F.3d at 1347.

¹⁰² See *Ariad*, 598 F.3d at 1344, 1347.

¹⁰³ See *id.*

Notably, the court did not state that Lilly's statutory construction is the better reading.¹⁰⁴ The court stated that "we see nothing in the statute's language or grammar *that unambiguously dictates* that the adequacy of the 'written description of the invention' must be determined solely by whether that description identifies the invention so as to enable"¹⁰⁵ Likewise, the court stated that "[t]he prepositional phrase 'in such full . . . ' modifies only 'the written description . . . ' as Lilly argues, *without violating* the rules of grammar."¹⁰⁶ Clearly, the court resolved ambiguity in the statute in Lilly's favor.¹⁰⁷

Similarly with regard to precedent, the court indicated that absent a clear and striking statement to the contrary, Lilly's position would be adopted.¹⁰⁸ The court stated that "[w]hile *Ariad* points to statements in other cases that support its view, *not one disavows* the existence of a separate written description requirement."¹⁰⁹

Why the court put its thumb on the scale in this way is unclear.¹¹⁰ The court seemed to assume that the statute must unambiguously dictate one requirement or else there are two, and that a case must disavow the existence of a separate written description requirement or else it exists.¹¹¹ But perhaps the burden of proof should fall the other way: to create the requirement of a separate written description one must unambiguously show it in the statute or have a case explicitly require it.¹¹² Nonexistence is notoriously difficult to prove; certainly the lack of cases disavowing existence is no proof of existence.¹¹³ A fairer allocation would either require that Lilly prove existence or would divide the burden equally between the parties.¹¹⁴

The court's emphasis on written description ultimately seems grounded in policy concerns.¹¹⁵ The separate written description requirement serves a notice function, alerting would-be competitors and

¹⁰⁴ *See id.*

¹⁰⁵ *Id.* at 1344 (emphasis added).

¹⁰⁶ *Id.* (emphasis added).

¹⁰⁷ *See id.*

¹⁰⁸ *Ariad*, 598 F.3d at 1347.

¹⁰⁹ *See id.* (emphasis added) (internal citations omitted).

¹¹⁰ *See id.* at 1344, 1347. Perhaps the court held that precedent lies with Lilly and doubts must be resolved in its favor; yet, according to *Ariad*, the older precedent supports its position, which begs the question of which position maintains the status quo. *See id.* at 1347, 1349.

¹¹¹ *See id.* at 1344, 1347; *supra* text accompanying notes 104–109.

¹¹² *See Ariad*, 598 F.3d at 1344, 1347.

¹¹³ *See id.*

¹¹⁴ *See id.*

¹¹⁵ *See id.* at 1350–53.

inventors to the existence of already claimed intellectual property.¹¹⁶ Given the tortuous road of the patent prosecution in this case and the mystifying number of continuations and continuations-in-part, as well as the functional genus nature of the claims, other inventors may not have received adequate notice as to Ariad's claimed entitlement.¹¹⁷ The court may thus have held the possession requirement an appropriate method to police the equities of the situation and ensure that Ariad was not swindling competitors.¹¹⁸ The court alludes to this policy concern in its defense of the possession requirement,¹¹⁹ but if that is what is grounding its holding, it would be preferable for the court to say so forthrightly, rather than maintaining the impression that the role of written description is an easily decided issue of statutory interpretation.¹²⁰

CONCLUSION

The question of whether 35 U.S.C. § 112 requires a written description separate from enablement has been brewing for years, if not centuries. The Federal Circuit in *Ariad* held in 2010 that recent and longstanding precedent supported Lilly's position that § 112 contains such a requirement. Ariad presented compelling arguments that the older precedent in fact supported its position, which if accepted by the court would require an evaluation of the arguments in a new light. Although the court cited the disruptive effect on the business and inventing communities of a contrary holding, the lack of empirical basis for the court's assertion practically assures that the superior long-term policy will be debated for many years to come.

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¹¹⁶ See *Hyatt v. Boone*, 146 F.3d 1348, 1354 (Fed. Cir. 1998) ("It is insufficient as written description, for purposes of establishing priority of invention, to provide a specification that does not unambiguously describe all limitations of the count."); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) ("The purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.").

¹¹⁷ See *Ariad*, 598 F.3d at 1350-53; *supra* notes 11-13, 17 and accompanying text.

¹¹⁸ See *Ariad*, 598 F.3d at 1350-53.

¹¹⁹ See *id.*

¹²⁰ See *id.* at 1344, 1345-47.