

WRITTEN DESCRIPTION AND ENABLEMENT:
THE *PAS DE DEUX* CONTINUES

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I. Introduction

This article discusses the evolving case law relating to the written description and enablement requirements of 35 U.S.C. § 112. For both doctrines, the Federal Circuit appears to be toughening the standards for patentability, consistent with the general trend in patent law in recent years to disfavor patentees.

The current “written description” requirement is relatively new. The Federal Circuit has explained that § 112 has a written description requirement that is separate and distinct from “enablement.” This view of written description has engendered a strong split within the Court. In April 2009, a panel handed down *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit’s latest decision on written description.¹ The *Ariad* decision overturned a jury verdict that found the patent was not invalid for lack of written description. In finding a lack of substantial evidence to support the verdict, the Court largely rejected the extensive expert testimony provided by the plaintiffs as irrelevant to written description. The jury also found that the patent was not invalid for lack of enablement, but the Federal Circuit opinion did not address enablement. The concurring opinion contended that the case should have been decided on enablement grounds, not written description. As we discuss below, the take-home messages of *Ariad* are far from clear.

Part II of this article offers a brief discussion of § 112’s requirements for written description and enablement. Part III examines the *Ariad* decision. Part IV explores some issues raised by the evidentiary rulings in *Ariad*. First, does the written description requirement entail only a limited role for expert testimony? Second, is the person of ordinary skill in the art treated differently for purposes of written description than for enablement? Third, must the claims be adequately described to their full scope and what does that mean?

¹ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009). *Ariad* filed a petition for rehearing en banc on June 2, 2009. As of July 24, 2009, the Federal Circuit had not yet decided the petition.

II. Section 112

Section 112, in relevant part, provides that “[t]he 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 . . . to make and use the same.”² To satisfy the enablement requirement of § 112, a patentee must “describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation.”³ To satisfy the written description requirement, the patentee must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.”⁴

The overlap of these two standards has been roundly discussed inside and outside the Court. “[T]he legal criteria of enablement and written description are related and are often met by the same disclosure.”⁵ The Federal Circuit has explained that “[t]hose two requirements usually rise and fall together.”⁶ As one justice sitting on the Federal Circuit’s predecessor court put it, “I cannot see how one may in ‘full, clear, concise and exact terms,’ enable the skilled to practice an invention and still have failed to ‘describe’ it.”⁷ Criticizing the written description requirement as lacking an administrable standard, Federal Circuit Justice Rader has argued that the written description standard “seems to fall back on

² 35 U.S.C. § 112, ¶ 1 (2006).

³ *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005), *reh’g denied*, 433 F.3d 1373, (Fed. Cir. 2006).

⁴ *Ariad*, 560 F.3d at 1371-72 (internal quotation marks omitted).

⁵ *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005).

⁶ *LizardTech*, 424 F.3d at 1345.

⁷ *In re Barker*, 559 F.2d 588, 595 (C.C.P.A. 1977) (Markey, J., dissenting).

enablement, using the latter as a proxy for the former.”⁸ As construed for biotechnology inventions, where it has been most often applied, the written description seems to go beyond enablement—it has been described as a “super-enablement” standard that requires the specification to disclose more than is required to enable the invention.⁹ Indeed, one of the unresolved issues is whether a heightened written description requirement applies only in biotechnology, in other highly unpredictable arts, or in the predictable arts as well.

A. The Enablement Requirement

The patent specification must “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 make and use the same.”¹⁰ The Federal Circuit has specifically rejected the argument that the enablement requirement is met as long as the specification enables one mode of practicing the invention.¹¹ Rather, the patent specification must enable *the full scope of the claimed invention*.¹² Failure to enable

⁸ *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1380 (Fed. Cir. 2006) (denial of petition for rehearing) (Rader, J., dissenting) [hereinafter *LizardTech Reh’g Petition Denial*].

⁹ See *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1325-26 (Fed. Cir. 2003) (Rader, J., concurring) (citations omitted) (stating that *Lilly* purports to require “precise definition” of a new nucleic acid or protein by reciting its sequence and that imposes a different disclosure standard than for software inventions), *reh’g denied*, 2003 U.S. App. LEXIS 9623 (Fed. Cir. 2003).

¹⁰ 35 U.S.C. § 112, ¶ 1 (emphasis added).

¹¹ See *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007).

¹² See *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008); *Pharm. Res., Inc. v. Roxane Labs., Inc.*, 253 F. App’x 26, 30 (Fed. Cir. 2007), *reh’g denied*, 2007 U.S. App. LEXIS 28510 (Fed. Cir. 2007); *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1360-62 (Fed. Cir. 2007), *reh’g denied*, 2008 U.S. App. LEXIS 2355 (Fed. Cir. 2008); *Auto. Techs.*, 501 F.3d at 1285; *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-80 (Fed. Cir. 2007); *LizardTech*, 424 F.3d at 1344-45.

the claims to their full scope is grounds for summary judgment of invalidity.¹³

The “full scope” requirement is policy-based. “A patentee who chooses broad claim language must make sure the broad claims are fully enabled.”¹⁴ “Enabling the full scope of each claim is ‘part of the *quid pro quo* of the patent bargain.’”¹⁵ This requirement “ensure[s] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.”¹⁶

The “enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.”¹⁷ The Federal Circuit has set forth “[f]actors to be considered in determining whether a disclosure would require undue experimentation [which] include:

1. The quantity of experimentation necessary;
2. the amount of direction or guidance presented;
3. the presence or absence of working examples;
4. the nature of the invention;
5. the state of the prior art;
6. the relative skill of those in the art; and
7. the predictability or unpredictability of the art; and the breadth of the claims.”¹⁸

Enablement is determined as of the filing date of the patent. Evidence that the invention could be practiced later “by the exercise of substantial experimentation well beyond the broad concepts that appear in the specifications is not probative of

¹³ See *Sitrick*, 516 F.3d at 999; *Pharm. Res.*, 253 F. App’x at 30; *Monsanto Co.*, 503 F.3d at 1360-62; *Auto. Techs.*, 501 F.3d at 1285; *Liebel-Flarsheim*, 481 F.3d at 1378-80.

¹⁴ *Sitrick*, 516 F.3d at 999 (citation omitted).

¹⁵ *Id.* (citation omitted).

¹⁶ *Id.* (citation omitted).

¹⁷ *Id.* (citation omitted).

¹⁸ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

enablement.”¹⁹ However, post-filing publications may be relevant to show that persons of skill in the art could practice the invention as of the filing date without undue experimentation.²⁰

B. The Written Description Requirement

Under Section 112, a patent specification must provide not only an enabling disclosure, but an adequate “written description of the invention.” The enablement and written description requirements are independent and provide separate grounds for invalidating a patent.²¹ The purpose of the written description requirement, similar to enablement, is to “serve[] a teaching function as a quid pro quo in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.”²²

To satisfy the written description requirement, a patent applicant must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.”²³ The disclosure need not spell out every last detail

¹⁹ *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1376 (Fed. Cir. 1999), *reh’g denied*, 1999 U.S. App. LEXIS 34474 (Fed. Cir. 1999).

²⁰ *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003), *reh’g denied*, 2003 U.S. App. LEXIS 5401 (Fed. Cir. 2003).

²¹ *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 921 (Fed. Cir. 2004) (“Although there is often significant overlap between [the written description, enablement, and best mode] requirements, they are nonetheless independent of each other.”), *reh’g denied*, 375 F.3d 1303 (Fed. Cir. 2004). Looking to precedents from its predecessor court, the Federal Circuit in *Rochester* explained: “It is not a question whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device.” *Id.* at 923 (quoting *Jepson v. Coleman*, 314 F.2d 533, 536 (C.C.P.A. 1963)).

²² *Ariad*, 560 F.3d at 1371.

²³ *Id.* at 1371-72 (internal quotation marks omitted).

of the invention, but “it must do more than merely disclose that which would render the claimed invention obvious.”²⁴

The specification must “convey the detailed identity of an invention.”²⁵ As an example, “in the nineteenth century, use of the word ‘automobile’ would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc.”²⁶ Thus, the patentee has an obligation to “disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.”²⁷ Determining whether written description of the invention is adequate “is not subsumed by the ‘possession’ inquiry”—“[a] showing of ‘possession’ is ancillary to the *statutory* mandate that the specification shall contain a written description of the invention, and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.”²⁸

The written description inquiry is case and context-specific. It “depend[s] on the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.”²⁹ A number of factors guide the inquiry, including “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.”³⁰

²⁴ *Id.* at 1372.

²⁵ *Rochester*, 358 F.3d at 923.

²⁶ *Id.* (“[F]or example, in the nineteenth century, use of the word ‘automobile’ would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc. Thus generalized language may not suffice if it does not convey the detailed identity of an invention.”).

²⁷ *Ariad*, 560 F.3d at 1373.

²⁸ *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (on petition for rehearing) (internal quotation marks omitted).

²⁹ *Ariad*, 560 at 1372.

³⁰ *Id.*

Although written description is a question of fact, a patent can nevertheless invalidate itself on its face.³¹

In the context of patents claiming biological or chemical compositions, an adequate written description of a DNA generally “requires a precise definition, such as by structure, formula, chemical name, or physical properties,”³² and “[a] description of what a material does, rather than what it is, usually does not suffice.”³³ Functional descriptions of such compositions, nevertheless, can meet the written description requirement “when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”³⁴

Lastly, it should be noted that Section 112 has long been construed to require an enabling disclosure,³⁵ but the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals (“C.C.P.A.”), only relatively recently construed Section 112 to contain an additional requirement of adequate “written description of the invention.”

In 1967, in *In re Ruschig*, the C.C.P.A. first articulated a separate written description requirement in the context of policing priority, e.g., in cases where claims had been added or amended, and a question arose as to whether the newly claimed subject matter was

³¹ *Rochester*, 358 F.3d at 930 (“Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit demonstrates its own invalidity, . . . and. . . we conclude that the ‘850 patent clearly and convincingly does just that.”).

³² *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *reh’g denied*, 1997 U.S. App. LEXIS 31640 (Fed. Cir. 1997). See also *Univ. of Rochester*, 358 F.3d at 927 (holding that the *Lilly* requirement “applies just as well to non-DNA (or RNA) chemical inventions”).

³³ *Enzo Biochem, Inc.*, 323 F.3d at 968 (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

³⁴ *Id.* at 964.

³⁵ See, e.g., *LizardTech*, 424 F.3d at 1345 (citing *Tyler v. City of Boston*, 74 U.S. 327, 330 (1868)).

described in the patent application as originally filed.³⁶ Under C.C.P.A. jurisprudence, the purpose of the written description doctrine was “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.”³⁷

The written description requirement was initially only applied to police priority for later-added or later-amended claims. In 1997, the written description requirement was applied for the first time outside the context of policing priority. In *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, the Federal Circuit held originally filed claims invalid for lack of written description: in *Lilly*, the Court found that the patent specification did not adequately describe human insulin cDNA because the patent did not “describe the cDNA itself,” even though the patent described a general method of obtaining the cDNA and the amino acid sequences that the cDNA encodes.³⁸

Although *Lilly* articulated a specific written description requirement in the context of claims drawn to genetic materials, the written description requirement has since been applied to patents in a variety of fields.³⁹

³⁶ See *In re Ruschig*, 54 C.C.P.A. 1551 (C.C.P.A. 1967) (construing Section 112 to have a separate written description requirement under which the court rejected later-drafted claims, *i.e.*, claims drafted after the filing of the patent application, because these claims encompassed an invention not described in the original specification). See also *Moba*, 325 F.3d at 1323 (Rader, J., concurring) (“In *In re Ruschig*, this court’s predecessor court created a new written description requirement for the sole purpose of enforcing priority issues.”). *But cf. Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1306 (denial of petition for rehearing) (Lourie, J., concurring) (“The fact, if it is a fact, that written description has only been relied upon in recent years as a [separate] ground of invalidity does not remove that requirement from the statute. . . . It has always been there.”).

³⁷ *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976) (emphasis added).

³⁸ *Regents of the Univ. of Cal.*, 119 F.3d at 1567.

³⁹ See, e.g., *LizardTech*, 424 F.3d 1336 (data compression technology); *Moba*, 325 F.3d 1306 (high-speed egg processing machines).

III. The *Ariad* Case

A. Background of the *Ariad* Case

On May 4, 2006, a jury ruled that Eli Lilly & Company infringed a patent that broadly covers drugs—arguably all drugs—that affect one of the most fundamental biological pathways in the human body.⁴⁰ The next day, Lilly’s general counsel was quoted as saying that the plaintiffs’ liability theory was “equivalent to discovering that gravity is the force that makes water run downhill and then demanding owners of all the existing hydroelectrical plants begin to pay patent royalties on their use of gravity.”⁴¹

Ariad involved U.S. Patent No. 6,410,516 (the “’516 patent”), entitled “Nuclear Factors Associated with Transcriptional Regulation.” The ’516 patent contains 203 claims that are drawn to methods for reducing the activity of a protein called Nuclear Factor Kappa B (“NF-κB”). The research on which the patent is based was carried out by a group of eminent biomedical research scientists in the 1980s. The patent was issued June 25, 2002 from an application that claimed a priority date of April 21, 1989. The patent is assigned to Harvard College, Massachusetts Institute of Technology, and the Whitehead Institute for Biomedical Research, and exclusively licensed to Ariad Pharmaceuticals.

NF-κB is a class of transcription factors that is central to stress, inflammation, and immune responses.⁴² NF-κB proteins have been shown to increase the expression of more than 175 identified genes.⁴³ In most cells NF-κB is stored in the cytoplasm in an inactive form, bound to an inhibitor protein, I-κB. When the cell is exposed to an extracellular agent that threatens to harm the cell, the inhibitor protein is degraded; and the NF-κB is freed and

⁴⁰ See Andrew Pollack, *Lilly Loses Patent Case to Ariad*, N.Y. TIMES, May 5, 2006.

⁴¹ *Id.*

⁴² See generally BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 952-54 (5th ed. 2008).

⁴³ Editorial, *A license to print money?*, NATURE BIOTECHNOLOGY, June 2006, at 593.

moves into the nucleus where it can bind to particular DNA sequences that turn on expression of particular genes. The activation of NF- κ B typically starts with the binding of a chemical substance to the surface of a cell, followed by a multi-step biochemical process that culminates in the activation of gene transcription. There are at least six or seven, and probably more, different steps or levels at which chemical inhibitors of NF- κ B might exert their actions.⁴⁴

NF- κ B has been called a “master biological switch” because we now know that it is involved in many biological processes, although it was first discovered because of its role in immunity and stress.⁴⁵ NF- κ B has been implicated in a vast range of disease processes, including atherosclerosis and heart disease, AIDS, cancer, diabetes, muscular dystrophy and neurodegeneration, rheumatoid arthritis, Alzheimer’s disease, and asthma.⁴⁶ Also, it is thought that many substances, including aspirin, glucocorticoids, Vitamin C, antibiotics, green tea, and red wine, inhibit NF- κ B at one or more steps in the associated pathways.⁴⁷ Indeed, over 200 marketed drugs with billions of dollars in annual sales may have effects on NF- κ B.⁴⁸ It was reported that Ariad sent letters offering to license the ’516 patent to more than 50 drug companies.⁴⁹

On the same day that the ’516 patent issued, Ariad and co-plaintiffs sued Lilly for patent infringement by two drugs. The first was Evista, which is a small molecule drug (raloxifene) for the treatment of osteoporosis. The second drug was Xigris, which is a recombinant protein used to treat severe septic shock. The jury found that both drugs infringed the ’516 patent. The jury verdict awarded \$65 million in back royalties and a 2.3% royalty on future U.S. sales of the drug until patent expiration in 2019. The jury

⁴⁴ Fulvio D’Acquisto et al., *Inhibition of Nuclear Factor Kappa B (NF- κ B): An Emerging Theme in Anti-Inflammatory Therapies*, MOLECULAR INTERVENTIONS, Feb. 2002, at 29.

⁴⁵ Pollack, *supra* note 40.

⁴⁶ *See, e.g.*, D’Acquisto et al., *supra* note 44.

⁴⁷ *See id.*

⁴⁸ Editorial, *supra* note 43.

⁴⁹ *See* Pollack, *supra* note 40.

also found that the patent was not invalid for anticipation, lack of enablement, or lack of written description.

Both at the close of Ariad's case-in-chief and after the jury verdict, Lilly moved for a judgment as a matter of law that the claims were invalid for anticipation, lack of enablement, and lack of written description. The lower court denied both motions, without opinion. Lilly timely appealed.

On April 3, 2009, the Federal Circuit invalidated the patent claims asserted against Lilly for lack of written description, citing the "vast scope" of the claims.⁵⁰

B. Overview of the Claims and Specification

The four patent claims tried to the jury, and eventually brought before the Federal Circuit, are all method claims for modifying the effect of external influences on a cell by "reducing NF- κ B activity." As an example, claim 95 recites:

[A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF- κ B-mediated intracellular signaling, the method comprising *reducing NF- κ B activity* in the cells such that expression of said genes is reduced], carried out on human cells.⁵¹

The lower court construed "reducing NF- κ B activity" to mean "decreasing the function of NF- κ B to act as an intracellular messenger that regulates transcription of particular genes, in response to certain stimuli."⁵² Neither party appealed claim construction.

⁵⁰ *Ariad*, 560 F.3d at 1376 (Moore, J.; Linn, J., concurring).

⁵¹ *Id.* at 1370 (alteration marks in original; rewriting claim 95 to include the claim from which it depends).

⁵² *Id.*

The specification proposes three classes of molecules for reducing NF-κB activity: (1) specific inhibitors; (2) dominantly interfering molecules; and (3) decoy molecules. The specification does not mention any other means for reducing NF-κB.

Specific inhibitors are described as molecules “able to block (reduce or eliminate) NF-κB binding” to DNA in the nucleus.⁵³ The specification gives one example of such a molecule: the naturally occurring inhibitor protein I-κB, whose job it is to bind to NF-κB and keep it inactive.⁵⁴ Figure 43 in the ’516 specification purports to provide the mammalian amino acid and DNA sequence of I-κB. For the reasons discussed below, however, the Federal Circuit found, Ariad could not rely on Figure 43 to disclose I-κB.

A dominantly interfering molecule is “a truncated form of the NF-κB molecule” that has the NF-κB DNA binding domain but not its activating domain.⁵⁵ The idea is that the interfering molecule will bind the DNA at the binding domain, but lacking the activating domain, will just sit inactively on the DNA while blocking intact, functional NF-κB molecules from reaching, binding, and activating the DNA.⁵⁶ Such interfering molecules could be made and would work only “*if* the DNA binding domain and the DNA [activating] domain of NF-κB are spatially distinct.” The specification does not disclose whether the two domains are spatially distinct in the NF-κB molecule.⁵⁷ The specification discloses no examples of dominantly interfering molecules.

Decoy molecules are “designed to mimic” the region on the DNA that NF-κB normally binds to, thereby fooling NF-κB into binding with the decoy instead of the DNA.⁵⁸ The specification does provide examples of DNA sequences for decoy molecules as shown in Table 2 reproduced below.⁵⁹ The specification does not

⁵³ U.S. Patent No. 6,410,516 col.37 ll.44-45 (filed June 5, 1995).

⁵⁴ *Id.* at col.37 ll.48-49.

⁵⁵ *Id.* at col.38 ll.11-14.

⁵⁶ *Id.* at col.38 ll.15-17.

⁵⁷ *Id.* at col.38 ll.9-10 (emphasis added).

⁵⁸ *Id.* at col.37 ll.51-54.

⁵⁹ *Id.* at col.37 tbl. 2.

provide evidence that these molecules were tested and actually used to reduce NF- κ B activity. Indeed, the specification does not disclose that any decoy molecules had actually been synthesized using the identified sequences.

TABLE 2

<u>Sequences recognized by NF-κB.</u>	
Gene	Sequence
Ig κ enhancer - mouse SV40 enhancer HIV-1 (-91) CMV (4) ^{1,2}	GGGGACTTCC
HIV-1 (-105) HIV-2 CMV (1) ¹ β 2-microglobulin serum amyloid A -g9	AGGGACTTCC
Ig κ enhancer - human CMV (3) ¹	GGGGATTCC
Interferon- β - PRDII CMV(2) ¹	GGGAAATCC GGGACTTCC
MHC class II-E α ^d	GGGACTCCC
IL-2 lymphokine	GGGATTTCAC
mouse IL-2R α	GGGGATTCCCT
human IL-2R α	GGGAATCTCC
MHC class I - H2 - κ ^b HLA - A2, A11, B7 B27, B51	GGGATTCCCC
CONSENSUS ³ :	C C GGGRATYYAC T T

C. The Federal Circuit's *Ariad* Opinion

In an opinion written by Judge Moore, the Federal Circuit held all four *Ariad* claims at issue invalid for lack of written description,⁶⁰

⁶⁰ The Court reviewed the lower court's denial of Lilly's motion for JMOL without deference. *Ariad*, 560 F.3d at 1371. Under the applicable First Circuit law, a JMOL should be granted where "there is no legally

(continued...)

never reaching the issue of enablement. It is clear that the Federal Circuit's reasoning was colored by the pioneering and underdeveloped nature of the technology. Noting that Ariad itself admitted that the claimed invention "required years of hard work, great skill, and extraordinary creativity," the Court analyzed whether Ariad adequately described how to reduce NF- κ B activity in the context of a "new and unpredictable field where the existing knowledge and prior art was scant."⁶¹ After discussing the three proposed classes of molecules described in the '516 patent for reducing NF- κ B activity, the Court concluded:

The '516 patent discloses no working or even prophetic examples of methods that reduce NF- κ B activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF- κ B 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.⁶²

Additionally and with very little analysis, the Court further concluded that "[w]hatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims."⁶³

The Court characterized Ariad's claims as "methods comprising the single step of reducing NF- κ B activity."⁶⁴ Before analyzing each of the classes of molecules for reducing NF- κ B described in

sufficient evidentiary basis for a reasonable jury to find for the non-moving party." *Id.* (internal quotations omitted). Whether the Section 112 written description requirement is met is a question of fact, and the Court reviews "the jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *Id.* at 1373.

⁶¹ *Id.* at 1372.

⁶² *Id.* at 1376.

⁶³ *Id.*

⁶⁴ *Id.* at 1372.

the '516 Patent, the Court quickly ruled against Ariad's argument that the written description requirement did not apply to these molecules because the claims at issue literally did not recite any compounds: "Regardless of whether the asserted claims recite a compound, Ariad must still describe some way of performing the claimed methods, and Ariad admits that the specification suggests only the use of three classes of molecules to achieve NF- κ B reduction."⁶⁵ Thus, Ariad was required sufficiently to disclose molecules capable of reducing NF- κ B activity to meet the written description requirement.

Turning to the classes of molecules for reducing NF- κ B activity, the Court began with the specific inhibitor molecules. As the only specific example of such a molecule, the specification disclosed the naturally occurring specific inhibitor I- κ B. The Court observed that Ariad's expert relied on Figure 43 in the '516 specification to opine that the written description requirement was met. Figure 43 was not filed, however, with the 1989 patent application to which Ariad claimed priority, but was later-filed, in 1991.⁶⁶ The jury found that Ariad was entitled to the 1989 priority date.⁶⁷ Thus, Ariad could not rely on Figure 43 to show possession at the time of filing.⁶⁸ Moreover, as the district court found, the amino acid and DNA sequences in Figure 43 were wrong and did not disclose functional mammalian I- κ B.⁶⁹ In a footnote, the Court further observed "[t]hat the inventors of the '516 patent, among the most skilled artisans in their field in the world at the time, failed to correctly disclose the structure of I- κ B even two years after the application was filed is a strong sign that one of skill in the art could not be expected to provide this knowledge in 1989."⁷⁰

⁶⁵ *Id.* at 1373.

⁶⁶ See U.S. Serial No. 07/341,436 (filed Apr. 21, 1989); *Ariad*, 560 F.3d at 1378.

⁶⁷ The effective filing date of the '516 patent was decided by the jury, who were asked to choose between two possible dates: April 21, 1989 and November 13, 1991. *Ariad*, 560 F.3d at 1374. The jury's determination that Ariad was entitled to the 1989 filing date was not appealed. *Id.* But Figure 43 was only disclosed in 1991. *Id.* at 1378.

⁶⁸ *Ariad*, 560 F.3d at 1374.

⁶⁹ *Id.* at 1371 & n.1.

⁷⁰ *Id.* at 1375 n.1.

Ariad's expert also testified that I- κ B was known to exist at the time of filing and that a person of ordinary skill could through experimentation have isolated natural I- κ B. The Court rejected, however, that possession was thereby evidenced. Rather, the Court found that, "[i]n the context of this invention," the '516 Patent's description of specific inhibitor molecules was only "a vague functional description and an invitation for further research."⁷¹

The Court began its discussion of dominantly interfering molecules by observing that "the specification provides no example molecules of this class."⁷² Dominantly interfering molecules work by sitting inactively on the DNA and blocking competent NF- κ B molecules from binding to the DNA. The Court observed that the '516 Patent stated that such molecules would work "if the DNA binding domain and the DNA [activating] domain of NF- κ B are spatially distinct," but, as Ariad's expert testified at trial, the '516 specification simply did not disclose whether the domains were "separable or spatially distinct."⁷³ Thus, the inventors did not know if the domains were separable, and therefore, could not have known in 1989 if this method would work. The Court concluded that a person of ordinary skill in the art "was at best equally ignorant," given that the inventors discovered NF- κ B, *i.e.*, given that the claimed invention was in a new field.⁷⁴ Further, the Court deemed insufficient evidence that "skilled workers actually practiced [using dominantly interfering molecules] soon after the 1989 application was filed."⁷⁵

Interestingly, the Court added: "[p]erhaps one of ordinary skill could discover this information [*i.e.*, whether the domains were distinct], but this does not alter our conclusion that the description

⁷¹ *Id.* at 1374.

⁷² *Id.* at 1375.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

of the dominantly interfering molecules just represents a wish, or arguably a plan for future research.”⁷⁶

The Court turned last to the decoy molecules, molecules designed to fool NF- κ B to bind to them instead of the cell’s DNA. The Court found that Table 2 of the “specification proposes example structures,” confirmed by Ariad’s expert to be the actual DNA oligonucleotides which constitute the decoy molecules.⁷⁷ The Court concluded, “because the specification discloses specific example sequences, there is little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art.”⁷⁸

Recognizing that the written description requirement can be satisfied with prophetic examples, *i.e.*, actual testing confirming that the decoy molecules worked was not required, the Court nevertheless held the disclosure of the decoy molecules was “not so much an ‘example’ as . . . a mere mention of a desired outcome.”⁷⁹ The Court reasoned that the specification did not describe “using” the decoy molecules beyond disclosing that “NF- κ B ‘would bind the decoy’ and thereby, ‘negative regulation can be effected.’” Further, the Court observed that Lilly’s expert testified that “there is no descriptive link between the table of decoy molecules and reducing NF- κ B activity.”⁸⁰ The Court did not elaborate further as to why additional description would have been needed for “using” the decoy molecules. The Court may have been looking for some “proof of concept” that showed that

⁷⁶ *Id.* (internal quotation marks omitted).

⁷⁷ *Id.* at 1375.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

some or all of the sequences would successfully block gene activation by NF- κ B.⁸¹

The Court also explained that the Ariad expert's reliance on a 1990 publication that reported using decoy molecules failed as a matter of law because the later-dated disclosure could not "establish that the inventor in this case possessed using decoy molecules to reduce NF- κ B."⁸² After stating apparently unequivocally that the expert testimony failed as a matter of law, in a footnote the Court stated that although the expert testified that the authors of the 1990 publication "would likely have mastered their technique prior to the filing of the '516 application in 1989," that "fact was not in evidence."⁸³ Moreover, the Court noted, additional testimony would have been needed to establish that the authors were persons of ordinary skill in the art.⁸⁴ It is thus not clear whether the expert's testimony might have been legally relevant if presented in a different context. The Court stated generally that other testimony of Ariad's expert on the use of decoy molecules failed as a matter of law.

As to all three methods for reducing NF- κ B activity, the Court also noted that it considered insufficient the conclusory testimony by Ariad's expert that he believed the inventors were in possession of the claimed invention.⁸⁵ The Court added that to meet the

⁸¹ Lilly's Opening Brief argued that in order to use the decoy molecules, "[o]ne would need to stabilize a decoy molecule so that it would not be chopped up by the cell. Neither the [parent application] or the '516 patent shows how that could be done, particularly in a human." Brief of Defendant-Appellant at 11-12, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. Apr. 3, 2009) (No. 2008-1248). Ariad responded that methods were known in 1989 for preparing stable DNA decoy molecules. Reply Brief of Plaintiffs-Appellees at 25-26, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. Apr. 3, 2009) (No. 2008-1248). The Court did not address this issue.

⁸² *Ariad*, 560 F.3d at 1375-76.

⁸³ *Id.* at 1376 n.2.

⁸⁴ *Id.*

⁸⁵ *Id.* at 1376 & n.3.

written description standard, “possession” must be shown in the specification.⁸⁶

The question of whether the decoy molecules were adequately disclosed may have been a closer question for the other two categories of molecules. The Court held that the disclosure of the decoy molecule method failed to “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventors were] in possession of the invention.” However, the Court apparently qualified its conclusion by explaining that “[w]hatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims.”⁸⁷ It thus appeared that the Court thought the disclosure might have merited a different conclusion if the asserted claims had been much narrower. After citing a string of cases, including *LizardTech*, the Court’s factual analysis was limited to the following terse analysis and conclusion:

Here, the specification at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF-κB activity. Yet the asserted claims are far broader. We therefore conclude that the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description, and thus hold the asserted claims invalid.⁸⁸

IV. Written Description v. Enablement

In holding the ’516 patent invalid for lack of written description, the *Ariad* Court rested on evidentiary rulings that limited the weight given expert testimony, rejected the use of post-filing evidence, and discounted the ability of the person of skill in the art to fill gaps in the specification. Whatever expert testimony was left was unable to support the “vast scope” of the claims.

⁸⁶ *Id.* at 1376 n.3.

⁸⁷ *Id.* at 1376.

⁸⁸ *Id.*

A. Evidence That Skilled Workers Practiced an Invention After the Time of Filing Was Held Legally Irrelevant To Determine Knowledge of One of Ordinary Skill at the Time of Filing

The Court held that much of Ariad's written description evidence was "legally irrelevant" because evidence of what one of ordinary skill in the art knew after the patent was filed "cannot provide substantial evidence to the jury that the asserted claims were supported by adequate written description."⁸⁹

The Court twice refused to consider post-filing evidence from which Ariad urged the knowledge of one of ordinary skill in the art *at the time of filing* could be inferred.⁹⁰

First, in the context of the dominantly interfering molecules, Ariad argued that "skilled workers actually practiced this teaching soon after the 1989 application was filed."⁹¹ Citing to *Vas-Cath Inc. v. Mahurkar* for the proposition that "a written description analysis occurs 'as of the filing date sought,'" the Court, without further analysis, held that Ariad's argument was not "sufficient."⁹²

Second, for the decoy molecules, Ariad's expert, Dr. Kadesch, relied on a post-filing publication evidencing that a group of scientists had successfully used decoy molecules to reduce NF-κB activity. Based on this 1990 publication, Dr. Kadesch opined that in 1989, at the time the '516 was filed, these scientists "would

⁸⁹ *Ariad*, 560 F.3d at 1373-74 ("Because written description is determined as of the filing date—April 21, 1989 in this case—evidence of what one of ordinary skill in the art knew in 1990 or 1991 cannot provide substantial evidence to the jury that the asserted claims were supported by adequate written description.") (relying *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)).

⁹⁰ The Court noted that the post-filing evidence might have been relevant if the jury had not awarded the earlier of the two priority dates in dispute. Given the earlier priority date, however, such evidence was irrelevant as a matter of law to written description. *See Ariad*, 560 F.3d at 1373-74.

⁹¹ *Id.* at 1375.

⁹² *Id.*

likely have mastered their [decoy molecule] technique.”⁹³ The Court held that “because the priority date was determined to be 1989,” Dr. Kadesch’s “reliance on this evidence [*i.e.*, the 1990 publication] as support for his opinion is . . . [as a matter of law] erroneous.”⁹⁴

Seeming to confirm that post-filing publications cannot be used to draw inferences about the state of knowledge of one of ordinary skill at the time of filing, the Court added in a footnote that whether these scientists “would likely have mastered” the decoy molecule technique by the time of filing was a “fact . . . not in evidence”—notwithstanding the 1990 post-filing publication, which was in evidence, and Dr. Kadesch’s admissible testimony about it.⁹⁵ However, it should be noted that the footnote also rejects the legal relevance of Dr. Kadesch’s testimony regarding the 1990 publication on the grounds that the authors cannot be assumed to represent persons of ordinary skill in the art: “[E]ven if it were true [that the group of scientists had mastered their decoy molecule technique at the time the ’516 was filed], one research group does not necessarily represent the knowledge of one of ordinary skill in the art without further testimony to support that contention.”⁹⁶

In contrast, for purposes of showing enablement, Federal Circuit case law holds that post-filing publications can be relevant evidence from which to infer the knowledge and capabilities of a person of ordinary skill at the time a patent was filed. In *Amgen Inc. v. Hoechst Marion Roussel*, the Federal Circuit upheld the lower court’s finding “that a skilled artisan could readily have used various cultured vertebrate and mammalian cells to produce human EPO,” a “fact [which] was buttressed by numerous post-filing publications that demonstrated the extent of the enabling disclosure.”⁹⁷ In *Gould v. Quigg*, the Federal Circuit held that “[i]t

⁹³ *Id.* at 1376 & n.2.

⁹⁴ *Id.* at 1375-76 & n.2.

⁹⁵ *Id.* at 1376 n.2.

⁹⁶ *Id.*

⁹⁷ *Hoechst Marion Roussel*, 314 F.3d at 1336-37 (noting that the lower court relied on *Gould v. Quigg*, 822 F.2d 1074 (Fed. Cir. 1987), for the

(continued. . .)

was not legal error for the district court to accept the testimony of an expert who had considered a later publication in the formulation of his opinion as to whether the disclosure was enabling as of the time of the filing date of the [patent] application.”⁹⁸

The written description inquiry, like the enablement inquiry, turns on what the person of ordinary skill knew at the time of filing. But the *Ariad* Court offered no reason why the evidentiary standard for written description ought to be different than enablement in considering post-filing evidence as potentially probative.

B. The Specification Described a Mere Research Plan or Wish for an Outcome and the Gaps Could Not Be Filled by Persons of Ordinary Skill in the Art

Under Section 112’s enablement standard, a person of ordinary skill is quite resourceful and presumed to engage in due experimentation⁹⁹—but does this judicially created presumption apply in the context of Section 112’s written description standard? As confirmed in *Ariad*, the written description inquiry is fact-based and, as for enablement, “will depend on the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.”¹⁰⁰ In *Ariad*,

proposition that an expert may consider post-filing publications in forming his opinion regarding whether a claimed invention was enabled).

⁹⁸ *Gould*, 822 F.2d at 1078.

⁹⁹ Under Section 112’s enablement standard, a patentee must enable the invention by “describ[ing] the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation.” *LizardTech*, 424 F.3d at 1345. In other words, enablement law presumes that the person of ordinary skill will engage in due experimentation. The “without under experimentation” element is the result of judicial construction of Section 112—the plain text of Section 112 does not mention experiments or experimentation.

¹⁰⁰ *Ariad*, 560 F.3d at 1372. The Federal Circuit has characterized the written description standard as “analogous to enablement.” *Regents of the Univ. of Cal.*, 119 F.3d at 1569.

however, the Court summarily rejected expert testimony about the person of ordinary skill in the art.

First, in holding the specific inhibitors method was not adequately described, the Court considered testimony from Ariad's expert that the specific inhibitor I-κB existed in 1989 and that "one of ordinary skill could *through experimentation* isolate natural[ly occurring] I-κB."¹⁰¹ The Court concluded that, "[i]n the context of this invention, a vague functional description and an invitation for further research does not constitute written disclosure of a specific inhibitor."¹⁰² The Court did not analyze whether the experimentation required suggested by Ariad's expert was too extensive, or undue. Further complicating the issue is the Court's reference to the "context of this invention," *i.e.*, the '516 invention was "made in a new and unpredictable field."¹⁰³ This qualification could mean that due experimentation is permitted and that what is due is more limited where the field is new and unpredictable.

In a footnote, the Court additionally cited evidence that the inventors failed to correctly and completely disclose the nucleotide sequence of I-κB two years after the '516 filing date as a further indication that a person of ordinary skill could not fill the gap in the specification at the time of filing:

That inventors of the '516 patent, among the most skilled artisans in their field at this time, failed to correctly disclose the structure of I-κB even two years after the application was filed is a strong sign that one of skill in the art could not be expected to provide this knowledge [*i.e.*, sequence of DNA that encodes I-κB] in 1989.¹⁰⁴

¹⁰¹ *Ariad*, 560 F.3d at 1374 (emphasis added).

¹⁰² *Id.* It should be noted that the Court additionally found Figure 43 probative evidence that a person of ordinary skill did not know the structure of I-κB at the time of filing. *See id.* & n.1.

¹⁰³ *See id.* at 1372.

¹⁰⁴ *Id.* at 1375 & n.1. The disclosure referenced by the Court is Figure 43 of the '516 patent purports to disclose the DNA sequence for mammalian

(continued...)

Here, the Court seemed to impute the inventor's knowledge, or apparent lack thereof, on the person of ordinary skill in the art. Although in the context of its finding that the invention was in a new field, the Court's analysis rested largely on evidence from the patent itself and its prosecution history—but as already discussed, the Court did not analyze whether, from the perspective of one of ordinary skill in the art, the experimentation described by Ariad's expert was undue.

Second, in its analysis of the dominantly interfering molecule method, the *Ariad* Court found that the '516 patent itself conceded that this method can work only “if the DNA binding domain and the DNA [activating] domain of NF-κB are spatially distinct in the molecule.”¹⁰⁵ The Court also noted that Ariad's expert conceded that the text of the '516 patent did not disclose whether the two domains were distinct. From its analysis of the plain text of the '516 patent, the Court concluded, “[c]onsidering that the inventors of the '516 patent discovered NF-κB, if they did not know whether the two domains are distinct, one of ordinary skill in the art was at best equally ignorant.”¹⁰⁶

Yet the *Ariad* Court went on to say that “[p]erhaps one of ordinary skill could discover this information [*i.e.*, whether the domains were distinct], but this does not alter our conclusion that the description of the dominantly interfering molecules ‘just represents a wish, or arguably a plan’ for future research.”¹⁰⁷ Again, it seems that the *Ariad* Court may be limiting the person of skill in the art—and marginalizing the role of expert testimony—for written description purposes. The Federal Circuit has told us that a patent

I-κB, but actually shows the sequence of an avian, or chicken, protein called pp40 and is incomplete. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F.Supp.2d 106, 122-23 (D. Mass. 2007), *aff'd in part, rev'd in part*, 560 F.3d 1366 (Fed. Cir. 2009). Figure 43 was not disclosed in the original application—Figure 43 was filed in 1991, two years after the 1989 patent application to which Ariad obtained priority.

¹⁰⁵ *Ariad*, 560 F.3d at 1375.

¹⁰⁶ *Id.* (emphasis added).

¹⁰⁷ *Id.*

can “invalidate itself” by virtue of a specification that is lacking in written description on its face.¹⁰⁸ However, what the specification conveys on its face is a question about the understanding and capabilities of a person of skill in the art. One might expect the Court to have been more interested in the experts’ opinions whether a person of ordinary skill in the art could “discover” the information necessary to fill gaps in the specification without undue experimentation.

C. The Written Description Was Insufficient To Support the “Vast Scope” of the Claims

The *Ariad* Court seemed to suggest that whether the evidence relating to the decoy molecules was “substantial evidence” presented a closer question than for the other two categories. Unlike *Rochester*, the *Ariad* specification presented specific structures for compounds to carry out the claimed methods using the decoy molecules. The Court concluded, however, that the claims’ “vast scope” could not have been supported by the description of only the decoy method as the description was written. The Court may simply be relying on the principle that written description, like enablement, must be adequate to the “full scope” of the claims. Presumably, the written description would be deemed inadequate to support the “full scope” unless each of the proposed approaches set out in the specification was adequately described. The simplest reading of the Court’s statement is that the description of the decoy method, even if sufficient for that approach, could not make up for the deficiencies in the descriptions of the other two approaches.

As the concurrence points out, it appears that this case might have been decided on a different ground, namely, that the claims were not enabled to their full scope.¹⁰⁹ Judge Linn argues in his

¹⁰⁸ *Rochester*, 358 F.3d at 930 (“Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit demonstrates its own invalidity, . . . and . . . we conclude that the ‘850 patent clearly and convincingly does just that.”).

¹⁰⁹ *Ariad*, 560 F.3d at 1381.

concurrency that the Court should have addressed Lilly's argument that any method claim that purports to claim all methods for accomplishing a result is invalid because one cannot enable unknown methods, as a matter of law.¹¹⁰ Here, however, it seems that the Court could have taken an even simpler tact and concluded from its analysis that the three identified, "known" approaches were not all enabled. In the past several years, the Federal Circuit has stressed that patent claims must be enabled to their "full scope" and has repeatedly affirmed summary judgment of invalidity on this basis, as mentioned earlier. If even one of the three approaches was not enabled, then the claims would not have been enabled to their full scope. To the extent that enablement was a potential alternative ground of decision, *Ariad* may provide little support for the necessity or value of a separate written description requirement.

Finally, it bears mention that claim construction issues were lurking right below the surface. The *Ariad* Court commented that "the situation presented in this case should not often occur, because in simple terms, a court would properly interpret the claims as limited."¹¹¹ *Ariad* "chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification of the '516 patent."¹¹² The Federal Circuit repeated its admonition from *Liebel-Flarsheim*, "[t]he motto, 'beware of what one asks for,' might be applicable here."¹¹³ In *Liebel-Flarsheim*, the plaintiff prevailed on claim construction, then lost on invalidity, because the broad claims were not enabled to their full scope.

The *Ariad* opinion does not directly address what is the "full scope" of the '516 claims-in-suit. The Federal Circuit observed that "Ariad claims methods comprising the single step of reducing NF-κB activity."¹¹⁴ The Federal Circuit further noted that the district court construed "reducing NF-κB activity" as "decreasing the function of NF-κB to act as an intracellular messenger that

¹¹⁰ *Id.*

¹¹¹ *Id.* at 1377 (internal quotation marks omitted).

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 1372.

regulates transcription of particular genes, in response to certain stimuli.”¹¹⁵ The Federal Circuit did not, however, expressly adopt Lilly’s position that the asserted claims purported to claim every possible method of inhibiting NF-κB’s role in promoting gene expression for medical uses.¹¹⁶ There is no doubt, however, that the *Ariad* court found the claims to be overreaching.¹¹⁷

As Judge Rader indicated in his dissent from the denial of en banc review in *LizardTech*,¹¹⁸ the law of claim construction and written description may be seen to be in conflict.¹¹⁹ Under *Phillips*,¹²⁰ claim language may be properly construed to exceed the scope of the preferred embodiments. Yet written description cases (like *LizardTech*) may appear to foreclose claims to embodiments not disclosed in the specification.¹²¹ This apparent conflict provides yet another reason that the Federal Circuit may at some point decide to take up the written description issue en banc.

¹¹⁵ *Id.* at 1370 (referencing *Ariad*, No. 02-cv-112809, 2004 U.S. Dist. LEXIS 3170, at *3 (D. Mass. Mar. 3, 2004)).

¹¹⁶ *E.g.*, Brief of Defendant-Appellant at 2, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. Apr. 3, 2009) (No. 2008-1248) (“[T]he inventors sought and eventually obtained (after sixteen years of prosecution) broad claims covering **any and all** methods of inhibiting NF-κB’s role in promoting gene expression.”).

¹¹⁷ *See id.* Notably, in another case involving the ’516 patent, albeit different claims, the Federal Circuit rejected *Ariad*’s claim construction arguments and affirmed the district court’s judgment of noninfringement. *Amgen, Inc. v. Ariad Pharms., Inc.*, No. 2009-1023, 2009 U.S. Dist. LEXIS 11704 (Fed. Cir. June 1, 2009) (nonprecedential).

¹¹⁸ *See LizardTech Reh’g Petition Denial*, 433 F.3d at 1376-78 (Rader, J., dissenting, joined by Gajarsa, J.).

¹¹⁹ *See id.* at 1377.

¹²⁰ *See id.* (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 1332 (2006)). Judge Rader suggests that the written description standard is unclear in numerous respects and most closely resembles I-know-it-when-I-see-it. *See id.*

¹²¹ *See id.* at 1377-78.