

2-22-2022

A Decade After Ariad: What is the Written Description Standard for Emerging Bio-Pharma Patents?

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Recommended Citation

Pu-Cheng (Leo) Huang, *A Decade After Ariad: What is the Written Description Standard for Emerging Bio-Pharma Patents?*, 17 WASH. J. L. TECH. & ARTS 131 (2022).

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A DECADE AFTER *ARIAD*: WHAT IS THE WRITTEN DESCRIPTION STANDARD FOR
EMERGING BIO-PHARMA PATENTS?

Pu-Cheng (Leo) Huang *

ABSTRACT

The Federal Circuit’s en banc decision in Ariad Pharms., Inc. v. Eli Lilly & Co. diverged from its previous interpretation of the “written description” requirement under 35 U.S.C. § 112. The new requirement mandates inventors to prove that they “actually invented the invention claimed.” The court observed that this new requirement is particularly onerous for biotechnological and chemical genus claims where few species have been reduced to practice. The new requirement asks inventors to disclose detailed descriptions for more than one species in the specification to support their genus claims. The heightened standard has massively affected front-end technology research. However, the court never made clear why a heightened standard for genus claims was proposed. Were the claims too broad? Or was the specification too unclear about what the invention was? Or was the timing too early? This article explores the reasoning behind the court’s decision in Ariad and proposes an interpretation of Ariad that resolves this ambiguity and achieves the same objectives as the Ariad court.

* UCLA School of Law, Class of 2022. I would like to thank Professor Douglas Lichtman, Professor Peter Reich, Alan Heinrich, Keith Orso of Irell & Manella LLP, and the editors and staff of the Washington Journal of Law, Technology & Arts.

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INTRODUCTION

Inventors are incentivized to disclose their invention in exchange for patent protection to exclude others from the market for a period of time. Once disclosed, other researchers may build upon it to advance science and technology. Thus, it is important that the inventor disclose enough details in the patent to allow others to understand and improve the invention.

Patent protection plays an important role in emerging technology fields where research costs and risks are high. However, it is difficult to set a standard for the amount of detailed information that an inventor should disclose so that others in the emerging technology fields can understand and build upon the breakthrough invention because the technology is so advanced that little research has been published. A standard requiring too much detail may delay the disclosure of a technology breakthrough because an inventor must spend more time perfecting the research to collect enough information to file a patent. A standard too low would block innovations because once a patent is awarded, the patentee can stop others from practicing the patented technology.

In 2010, Federal Circuit tried to answer this difficult question in *Ariad v. Eli Lilly*.¹ In *Ariad*, a group of researchers discovered that reducing the activity of a gene transcription factor could alleviate symptoms of certain diseases, so they applied for a patent.² The patent covered all substances that successfully reduce the activity of the gene transcription factor with genus claims.³ When the patent was challenged in the Federal Circuit, the court found the patent invalid because the inventors did not disclose enough details in their patent application to support their broad patent claims.⁴ Despite its inventors disclosing three ways to achieve the reduction of the activity of the gene transcription factor, the Federal Circuit found that the patent did not meet the written description requirement.⁵

However, the *Ariad* court never identified a reason for why the patent failed the written description requirement, nor did it articulate a clear standard for written description.⁶ This ambiguity confused many patent practitioners and commentators, causing uncertainties in investments in advanced biotechnology and pharmaceutical research fields because their breakthrough innovations might not be patentable.

This article aims to provide an explanation to the Federal Circuit's *Ariad* decision, to discern the actual written description standard that the *Ariad* court had in mind, and to examine the effects of *Ariad*'s written description standard.

¹ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010).

² *Id.* at 1340.

³ *Id.* at 1341. Genus claims allow a patentee to claim all substances share a same feature or function. See Dmitry Karshedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. (forthcoming 2022).

⁴ *Id.* at 1358.

⁵ *Id.*

⁶ Dmitry Karshedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. (forthcoming 2022).

This article will first introduce the basics of genus claims, the statutory requirements under 35 U.S.C. § 112, and the PHOSITA standard. It will then discuss three Federal Circuit cases predating *Ariad* which demonstrate the Federal Circuit's position against research plan patents. After this, the article will establish that the *Ariad* court invalidated Ariad's patent because the patent was a research plan patent by examining the *Ariad*'s *en banc* opinion, appellant and appellee briefs, amicus briefs, and oral arguments. The uncertainty and ambiguities created by *Ariad*'s amorphous written description standard will then be discussed. Finally, the article will conclude by proposing a workable written description standard that is compatible with *Ariad* and its progeny.

I. BACKGROUND

In patent law, patentees use claims to define the boundaries of exclusion. Genus claims are patent claims that cover not just one specific substance but a group of related substances and provide a broad scope of patent protection.⁷ With genus claims, a patentee can cover different species of chemicals or structures with functional language or a description of any general common quality.⁸ For example, instead of claiming screws, staples, nails, glue, and so on, one can use functional terms such as “fastener” to include different connecting mechanisms. The genus claiming technique is particularly useful in unpredictable fields such as pharmaceuticals and biotechnology because a minor variation to a molecule would still fall under the claim scope of the patent.⁹ Despite the benefits of genus claims, they present a challenging question for the courts: How much detail should a patentee include in their specification (the descriptive part of the patent document)¹⁰ to support a genus claim in unpredictable fields? The following statute sheds light on this question:

[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, 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 or joint inventor of carrying out the invention.¹¹

However, the Federal Circuit's interpretation of the statute generates further debate about whether its language includes merely a single “enablement” requirement or whether a separate “written description” is also embedded in the requirements of the statute.¹² This is a difficult question that patent attorneys, and even federal judges, hold inconsistent opinions about.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ 35 U.S.C. § 112(a) (2012).

¹² Donald S. Chisum, *Written Description of the Invention: Ariad (2010) and the Overlooked Invention Priority Principle*, 2010 PATENTLY-O PATENT L.J. 72 (2021).

In most cases, if a patent applicant has “enabled” the invention, it has also satisfied the “written description” requirement.¹³ In some situations, however, a patent applicant may have “enabled” its invention yet failed to “describe” the invention with enough detail in the specification.¹⁴ For example, “[c]onsider the case where the specification discusses only compound A . . . This might very well enable one skilled in the art to make and use compounds B and C, yet the class consisting of A, B, and C has not been described.”¹⁵

The dispute over whether a separate written description was required was put to rest in *Ariad*, where the Federal Circuit held that the statutory language includes both an “enablement” requirement and a “written description” requirement.¹⁶ The court held that the enablement requirement compels the patentee to teach a person having ordinary skill in the art (PHOSITA) to make and use the invention. In contrast, the written description requirement ensures that the patentee includes enough detail in the specification for the PHOSITA to conclude that “the inventor invented the claimed invention.”¹⁷ Before discussing the tongue-twister-sounding standard, the inventor invented the claimed invention, it is worth introducing the PHOSITA standard.

The PHOSITA standard is one of the hallmarks of patent law. Its use in patent law is similar to the “reasonable person” standard used in common law tort cases to determine liability. For example, if a truck driver with worn tires caused a series of car accidents on a highway, the court will ask whether a reasonable driver, rather than a cautious driver, would have known that driving with worn tires creates a danger to the public. Following similar logic, Congress holds that a PHOSITA, neither an expert nor a layperson, is in the best position to judge a patent. As with the reasonable person standard, PHOSITA refers to an imaginary person, and there is no PHOSITA out there that a court can summon for a patent case.

The term PHOSITA is also widely used in patent law. For example, to determine whether an invention is too obvious, the statute recommends turning to a PHOSITA.¹⁸ Additionally, to ensure that the patentee has disclosed adequate detail about her invention, a court or the United States Patent and Trademark Office (USPTO) must ask what a PHOSITA would think.

II. THE FEDERAL CIRCUIT PROHIBITED RESEARCH PLAN PATENTS BEFORE *ARIAD*

Before *Ariad*, the Federal Circuit ruled against issuing patents for “research plans” three times, the first of which came early in 1993.¹⁹ In *Fiers v. Revel*, the court observed the problem of granting patents to research plans and explained that the patent system exists to promote disclosure of inventions, not research plans.²⁰

¹³ *Ariad*, 598 F.3d at 1352.

¹⁴ *See In re DiLeone*, 436 F.2d 1404, 1405 n. 1 (1971).

¹⁵ *Id.*

¹⁶ *Ariad*, 598 F.3d at 1336.

¹⁷ *Id.* at 1352.

¹⁸ 35 U.S.C. § 103 (2012).

¹⁹ *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

²⁰ *Id.*

The Federal Circuit ruled against research plans again in *Regents of the Univ. of California*, where it held that an adequate written description for a chemical genus claim “requires a precise definition, such as by structure, formula, chemical name, or physical properties”.²¹

In *Regents of the Univ. of California*, University of California (UC) inventors discovered complementary DNA (cDNA) that encodes insulin in rats.²² They filed an application that described the structure of rat cDNA and attempted to enumerate the cDNA structures for insulin in all mammals, as opposed to just rats.²³ They aimed to include human insulin in their patent, which has a greater commercial value than rat insulin. The court invalidated the mammalian insulin cDNA claim for inadequate written description, even though the UC inventors had identified one species (cDNA for rat insulin) within the genus.²⁴

To meet the written description requirement of the mammalian insulin cDNA claim, the specification needed to “define any structural features commonly possessed by members of the genus that distinguish them from others,” so that a PHOSITA could recognize the identity of members of the genus.²⁵ The court also noted a functional definition is insufficient for defining a genus because it indicates only what the genus does, not what it is.²⁶

The Federal Circuit reaffirmed that research plans are not suitable for patents in *University of Rochester v. G.D. Searle & Co.*, when the court rejected a patent directed toward a method of “selectively inhibiting PGHS-2 activity in a human host by administering a nonsteroidal compound that selectively inhibits the activity of the PGHS-2 gene product to or in a human host in need of such treatment.”²⁷ The court reasoned there was no evidence that a PHOSITA would be able to identify such a compound based on the disclosure of the patent, and this was nothing more than “a research plan for trying to find it.”²⁸

III. ARIAD’S PATENT WAS INVALIDATED AS A RESEARCH PLAN PATENT

In *Ariad Pharms. Inc. v. Eli Lilly & Co.*, the Federal Circuit was also wary about granting patent protection to research plans.²⁹ Their caution was evident in the *en banc* majority opinion and the oral argument.

In *Ariad*, a group of MIT and Harvard researchers discovered that reducing the activity of NF- κ B, a gene transcription factor, could reduce the symptoms of certain diseases. They filed a patent application in 1989, disclosing their discoveries and claiming methods for reducing NF- κ B activity in a cell.³⁰ The method claims are

²¹ *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).

²² *Id.* at 1562-63.

²³ *Id.* at 1562-63.

²⁴ *Id.* at 1575.

²⁵ *Regents*, 119 F.3d at 1568.

²⁶ *Id.*

²⁷ *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 918 (Fed. Cir. 2004).

²⁸ *Id.* at 927.

²⁹ *Ariad*, 598 F.3d at 1351.

³⁰ *Id.* at 1340-41.

considered genus claims because they cover all substances that successfully reduce NF- κ B activity.³¹ To support their claims, the researchers disclosed three classes of molecules within the genus.³² The patent was then assigned to Ariad Pharmaceuticals (Ariad).³³

In 2002, Ariad sued Eli Lilly for patent infringement in the United States District Court for the District of Massachusetts.³⁴ At trial, a jury found patent infringement, and Eli Lilly appealed.³⁵ A panel of the Federal Circuit reversed the decision and considered Ariad's patent invalid for lack of written description.³⁶ In response, Ariad petitioned the court for an *en banc* review of the case,³⁷ arguing that its patent's description was sufficient.

The Federal Circuit granted Ariad's petition. In its *en banc* opinion, the court first affirmed that 35 U.S.C. § 112 includes both written description and enablement requirements.³⁸ The court then observed that Ariad's patent claims were broad and contained functional language,³⁹ and ultimately determined that Ariad's patent was invalid because it failed to meet the written description requirement.⁴⁰ However, the *en banc* opinion never clarified why Ariad's genus claims failed to meet the written description requirement.⁴¹ The ambiguity confused many scholars and patent practitioners.

In light of Ariad's case history and oral arguments, this article contends that the Federal Circuit rejected Ariad's patent because it was essentially a research plan patent. As discussed above, the Federal Circuit aims to prevent patents on research plans and unfinished inventions, and in *Ariad's* oral arguments, the court voiced its anxiety about patenting a "research hypothesis" and "an unfinished invention."⁴² The *en banc* opinion further supports this interpretation, as the court emphasized precedents that prevent patents on basic research.⁴³

In oral arguments, Eli Lilly contended that "not all the ideas are legally sufficient conceptions . . . [like] research plans . . . , and it's up to the court to look at what's in that patent and determine whether this inventor actually invented what he is now claiming."⁴⁴ Furthermore, a judge asked Ariad, "Isn't this case about

³¹ *Id.* at 1341.

³² *Ariad*, 598 F.3d at 1355.

³³ Appellee Br. at 1.

³⁴ *Ariad*, 598 F.3d at 1355.

³⁵ *Id.* at 1341.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at 1344.

³⁹ *Id.* at 1348.

⁴⁰ *Id.* at 1358.

⁴¹ Dmitry Karshedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. (forthcoming 2022).

⁴² Oral Argument at 1:01:42, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (2010) (No. 08-1248), <https://cafc.uscourts.gov/home/oral-argument/listen-to-oral-arguments/>.

⁴³ *Ariad*, 598 F.3d at 1353–54.

⁴⁴ Oral Argument at 13:30, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (2010) (No. 08-1248), <https://cafc.uscourts.gov/home/oral-argument/listen-to-oral-arguments/>.

where you draw the line between research plan and invention?”⁴⁵

The *en banc* opinion also discussed the policy rationale for rejecting research plan patents. The Federal Circuit explained research plan patents “would impose costs on downstream research, discouraging later invention.”⁴⁶ The court further clarified that “the goal [of patent law] is to get the right balance between upstream and downstream innovation,” and that “written description doctrine does so by giving the incentive to the actual invention and ‘not attempts to preempt the future before it has arrived.’”⁴⁷

IV. THE *ARIAD* COURT FAILED TO ARTICULATE A CLEAR WRITTEN DESCRIPTION STANDARD

Many patent attorneys were perplexed as to why the *Ariad* court applied the “written description” requirement to reject *Ariad*’s patent claims, but not “enablement.” The *Ariad* court did not reach “enablement” analysis in its decision, rather, they rejected the patent by extending the written description requirement to a patent’s originally filed application. As pointed out by Judge Linn in his dissent, “if a person of ordinary skill is enabled to make and use a novel and nonobvious invention clearly recited in the claims, I fail to see how that invention can be said to ‘have not been invented’ or be in need of some undefined level of additional description.”⁴⁸ Judge Linn argued the case should have been decided on enablement grounds, and the majority “fail[ed] to tether [the] written description requirement to a workable legal standard.”⁴⁹

A. *The Ariad court presented multiple written description standards, which confused patent practitioners.*

The majority decreed that a patent specification must show the inventor “actually invented the invention claimed” when the application was filed.⁵⁰ Nevertheless, the meaning of the phrase “actually invented the invention claimed” remains unclear to commentators and practitioners.⁵¹ As Judge Linn also mentioned, commentators have noted how “variable and confusing” the written description test has become—opining that a patent specification requires the inventor to demonstrate “possession,” that they “invented what is claimed,” and that a PHOSITA is able to “visualize or recognize” the claimed subject matter.⁵²

Moreover, Judge Linn observed that the written description standard used by

⁴⁵ Oral Argument at 1:01:42, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (2010) (No. 08-1248), <https://cafc.uscourts.gov/home/oral-argument/listen-to-oral-arguments/>.

⁴⁶ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010).

⁴⁷ *Id.*

⁴⁸ *Id.* at 1368.

⁴⁹ *Id.* at 1367.

⁵⁰ *Id.* at 1351.

⁵¹ Donald S. Chisum, *Written Description of the Invention: Ariad (2010) and the Overlooked Invention Priority Principle*, 2010 PATENTLY-O PATENT L.J. 72 (2021).

⁵² *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010).

the majority was not altogether different from enablement. The majority stated that “the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”⁵³ These considerations, however, mirror the *Wands*⁵⁴ factors for enablement, which include “the nature of the invention,” “the breadth of the claims,” and “the predictability or unpredictability of the art.”⁵⁵

The similarities between the *Ariad* court’s written description standard and enablement introduced confusion. It remained unclear to patent practitioners under what circumstance an enabled patent would fail to meet the written description requirement.

B. The Ariad court incorrectly concluded that Ariad’s patent failed the written description standard from Regents of the University of California.

The *Ariad* court applied the written description standard from *Regents of the University of California v. Eli Lilly & Co.* (“UC”) to police *Ariad*’s broad genus claim.

In UC, the Federal Circuit held a sufficient description of a genus requires the disclosure of either (1) a representative number of species falling within the genus’s scope or (2) structural features common to genus members, such that PHOSITA can “visualize or recognize” genus members.⁵⁶ Both standards aimed to ensure that an inventor possesses enough knowledge of the claimed genus before the filing date.

However, neither of these standards explain why *Ariad*’s patent failed to meet the written description requirement. *Ariad*’s specification disclosed three classes of molecules that could potentially reduce NF- κ B activity. We must remember that the patent was a cutting-edge breakthrough. Early disclosure of technology breakthroughs such as curing cancer should be encouraged because it allows other inventors to further develop and perfect the new innovation. So, the typical species-genus dichotomy should apply differently to breakthroughs where conventionally insufficient representative species are actually representative in terms of the § 112 written description requirement as applied to this case. Thus, three classes of species should be representative when the patent involves technology breakthroughs.

The common structural features standard is less helpful for functional claims like those in *Ariad*. In some cases, there might be no apparent common structure for a genus. For example, there are many ways to fasten objects, and it would be difficult to think of the structural features that staples, nails, and glue have in common. Similarly, the three disclosed classes of species in *Ariad*’s patent

⁵³ *Id.* at 1368.

⁵⁴ *In re Wands*, 858 F.2d 731 (Fed.Cir.1988).

⁵⁵ *Ariad*, 598 F.3d at 1368.

⁵⁶ *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997).

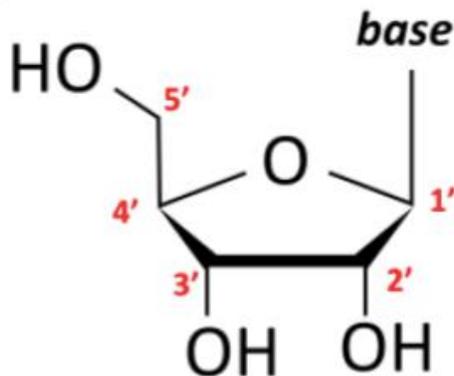
probably do not share any common structural feature. But the lack of common structural features does not undermine the scientific contribution of disclosing that interfering with NF- κ B activity could achieve therapeutically beneficial results.

Therefore, the Ariad court should not have found that Ariad's patent failed the UC written description requirement because Ariad's patent arguably satisfied the requirement by disclosing a representative number of species.

C. The Ariad standard introduces more confusion when a case can be decided based on enablement.

A few years after *Ariad*, patent practitioners began to see the complexity of applying the Ariad written description standard. The Federal Circuit, again, faced a pharmaceutical genus claim challenge in *Idenix Pharmaceuticals v. Gilead Science*.

Idenix Pharmaceuticals sued *Gilead Science* for patent infringement. The patent at issue directed toward a method of treating the hepatitis C virus (HCV) by administering nucleoside compounds with a specific chemical and stereochemical structure.⁵⁷ The claimed nucleosides contain a ring with five carbon atoms.⁵⁸ At each carbon atom, there can be substituent atoms (e.g., OH) in either the "up" or "down" position.⁵⁹ This structure is illustrated below (a 2'-down and 3'-down position):



The following is *Idenix's* independent claim⁶⁰ for this patent:

1. A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β -D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.⁶¹

⁵⁷ *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 1234 (2021).

⁵⁸ *Id.* at 1154.

⁵⁹ *Id.*

⁶⁰ An independent claim is a standalone claim that contains all the limitations necessary to define an invention. Claim Drafting, USPTO Invention-Con 2019 (Sep. 12, 2019).

⁶¹ *Id.* at 1155.

The district court determined the structural limitation “ β -D-2'-methyl-ribofuranosyl nucleoside” to require a methyl group at the 2'-up position, but this claim construction allows nearly any imaginable substituent at the 2'-down position.⁶² Gilead objected to the district court's claim construction.⁶³ Gilead's HCV drug indeed has the five-carbon sugar structure, but instead of a hydroxyl group (-OH), it has fluorine (F) at the 2'-down position.⁶⁴ Gilead argued that Idenix could not enable the full scope of 2'-methyl-up nucleosides because the patent only described nucleosides having the hydroxyl group at the 2'-down position.⁶⁵

The Federal Circuit, however, contended that the amount of experimentation required to determine which 2'-methyl-up nucleosides meet the claimed feature would be very high, favoring a finding of non-enablement.⁶⁶ The Federal Circuit also found that Idenix's patent failed the *Ariad* written description standard, as it did not provide sufficient “blaze marks” to direct a PHOSITA to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV.⁶⁷ The court reasoned that Idenix provided lists or examples of supposedly effective nucleosides but did not explain what makes them effective.⁶⁸ As a result, a PHOSITA would not have any meaningful guidance about which compounds, beyond the examples and formulas, would provide the same result.⁶⁹ Therefore, despite the many examples and formulas presented in the application, Idenix's patent had an inadequate written description to support the broad claims of using nucleosides, especially the undisclosed nucleosides that could also treat HCV.⁷⁰

Judge Newman filed a dissenting opinion in this case. She argued that Idenix's claim should not fail enablement simply because “the large number of unclaimed chemical variants in the specification are not described, not synthesized, and not tested for antiviral activity.”⁷¹ She opined that a reasonable jury could have understood the claims as directed toward the specific nucleosides that are described in the specification. Further, the “billions and billions” of unsynthesized and unevaluated variants are irrelevant. Thus, the specific claimed compounds met the enablement requirement in § 112.

Likewise, this article contends that Idenix's claims met the enablement requirement. Reading the claim alongside its specification, a PHOSITA would recognize the specific compounds invented. The claim's scope would then be limited to those specific compounds, and whether those specific compounds covered Gilead's fluorine (F) variant would be a question for the jury. The patent should not be invalidated for lack of enablement as it sufficiently demonstrated

⁶² *Id.*

⁶³ *Id.* at 1155.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.* at 1157.

⁶⁷ *Id.* at 1164.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.* at 1165.

hundreds of variants that could achieve the claim featured in the specification to support the genus claim. Additionally, the majority failed to delineate the level of detail or number of examples that would suffice the enablement requirement. Following the majority's logic, genus claims would be unenforceable. If an inventor could list every chemical in the genus, then the inventor could claim each chemical individually, and a genus claim would not be needed for protection. Eliminating genus claim protection would also harm the patent system because inventors would be more reluctant to file early, instead waiting for more examples to develop to attain broader protection. Consequently, such a policy hinders technology development.

Nevertheless, the *Idenix* court's application of the *Ariad*'s written description standard suggests that it is essentially a test of whether an application persuades the PHOSITA that the invention works. The *Idenix* court reasoned that a PHOSITA would not "visualize or recognize the members of the genus" to include 2'-fluorodown as the patentee proposed.⁷² The court further stated that "[the patentee] provide[s] lists or examples of supposedly effective nucleosides, but do[es] not explain what makes them effective, or why."⁷³ This illustrates that the court was concerned about patentees trying to use genus claims in cutting-edge research, as the court wants to delay granting licenses until all variants within the genus have been invented. Therefore, the *Idenix* court, like in *Ariad*, was concerned about a patentee not disclosing enough detailed information for the PHOSITA to learn and build upon the patented invention.

V. THE ACTUAL WRITTEN DESCRIPTION STANDARD USED IN *ARIAD*: "THAT THE SPECIFICATION PROVIDES A REASON TO BELIEVE THE INVENTION FUNCTIONS AS CLAIMED"

What exact standard for written description did the *Ariad* court have in mind? Considering *Ariad*'s patent likely enabled a PHOSITA to accomplish the invention without undue experimentation, this raises the question of what more was needed to satisfy the written description requirement.

The USPTO presented policy arguments in favor of having a written description requirement in its amicus brief submitted to the Federal Circuit in *Ariad*. The USPTO noted that written descriptions facilitate patent examination. Furthermore, the USPTO argued enablement is not alone sufficient to police research plan patents, stating that though "a biological or chemical molecule . . . claimed solely by reference to its function or effect" may be enabled, "[the] USPTO is not an experimental laboratory: it lacks both the facilities and the statutory mandate to determine, through empirical testing, whether any of millions of prior art inventions may have exhibited the recited function."⁷⁴ The following passage illustrates why the USPTO was also concerned about how a genus claim may take advantage of

⁷² *Id.* at 1165.

⁷³ *Id.* at 1164.

⁷⁴ Brief for the United States as Amicus Curiae Supporting Respondent at 21, *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (No. 2008-1248).

the patent system without a separate written description requirement:

“[I]f an applicant’s description of how to make and use a new chemical compound enabled others skilled in the art to make and use five, fifty, or even five hundred thousand additional compounds, it would be irrelevant that *the applicant had neither described those compounds nor provided any reason to believe they would function as claimed*. The applicant could claim them all—or, more likely, amend his claims later when it became clear that a particular compound was commercially valuable.”⁷⁵

Lastly, the USPTO noted research plan patents could abuse the patent system if enablement was their only requirement:

“[a]ny scientist with a promising plan of research need only file a patent application describing her research plan and its expected outcome. If the plan produces the desired outcome, the application may have enabled others skilled in the art to make and use the ‘invention.’ And if the research plan fails, all that is lost is the filing fee and the cost of preparing the patent application.”⁷⁶

The majority in *Ariad* provided a plausible standard for the written description requirement: a specification should provide a reason to believe the invention functions as claimed. Although *Ariad*’s research plan enabled the PHOSITA to accomplish the claimed result without undue experimentation, it nevertheless was not eligible for protection because research plans, like the one in *Ariad*, fail to assure skilled artisans that the plan would work as claimed. One can enumerate the steps to build a time machine so that people can make a time machine, yet still, fail to provide any reason to believe the time machine would work. Under the majority’s written description standard, this time machine patent would fail the written description requirement because its specification does not persuade a PHOSITA that the invention could actually travel time.

As discussed above, the *Ariad* court was concerned about research plan patents, and it wanted to distinguish the written description requirement from enablement. Thus, “asking a PHOSITA whether a specification provides a reason to believe the invention functions as claimed” appears to be the standard the majority had in mind in holding that *Ariad* did not meet the separate written description requirement.

A. *Ariad*’s patent specification failed to show the PHOSITA that the invention functioned as claimed.

The Federal Circuit found *Ariad*’s claimed invention did not amount to something more than a wish or plan.⁷⁷ The specification hypothesized three classes of molecules potentially capable of reducing NF- κ B activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. However, the patentees did not disclose enough information in their application to meet the written

⁷⁵ *Id.* at 15-16 (emphasis added).

⁷⁶ *Id.*

⁷⁷ *Ariad*, 598 F.3d at 1355.

description requirement.⁷⁸

First, the court observed that the structure of specific inhibitors was not known until two years after the application was filed. Therefore, the inventors did not (and could not) identify the structure of specific inhibitors when they filed the application.⁷⁹

Second, the specification acknowledged that dominantly interfering molecules could work only “if the DNA binding domain and the DNA polymerase domain of NF- κ B [are] spatially distinct in the molecule.”⁸⁰ The conditional language made the court suspect that the claimed invention was merely a wish because, if the inventors did not know whether the two domains are distinct, one of ordinary skill in the art would, at best, be equally ignorant.

Third, the court observed that although the inventors disclosed examples of decoy molecules, they failed to prove that the decoy molecules reduced NF- κ B activity when they filed the application.⁸¹ Instead, Ariad’s expert witness relied on a 1990 publication that reported using decoy molecules to reduce NF- κ B activity.⁸²

Among the three hypothesized classes of molecules, the inventors either could not identify the structure of the molecules or could not prove that the molecules would work as they had hoped.⁸³ Therefore, the court decided that Ariad’s patent claims were directed toward research plans and wishes, which are ineligible for patent protection under *UC* and *University of Rochester v. G.D. Searle & Co.* This article’s proposed interpretation of Ariad’s written description standard, “whether a specification provides reason to believe the invention functions as claimed,” allows the courts to screen for enabled research plan patents and invalidate them.

B. Fair results can be achieved by applying this proposed Ariad standard.

Under this article’s proposed Ariad written description standard, an enabled research plan patent would be invalidated for failing to persuade a PHOSITA that the invention would function as claimed. In a Federal Circuit case after Ariad, an applicant disclosed 300 species in the specification to support the patent’s genus claim, yet the Federal Circuit still found that the genus claim invalid because the claim was nothing but a wish.⁸⁴

In *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, concerned a functional genus which claimed all human antibodies that help bind and neutralize the activity of human interleukin 12 (IL-12).⁸⁵ Reduction of IL-12 activity level can alleviate psoriasis and rheumatoid arthritis.⁸⁶ In the specifications, the patents first

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 1356.

⁸¹ *Id.* at 1357.

⁸² *Id.*

⁸³ *Id.* at 1356-57.

⁸⁴ *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014).

⁸⁵ *Id.* at 1292.

⁸⁶ *Id.* at 1291.

identified Joe-9, an antibody that has some binding affinity for IL-12.⁸⁷ Then, the specification described 300 other antibodies having a range of IL-12 binding affinities, to support the broad genus claim.⁸⁸ However, all 300 of the described antibodies were structured almost exactly like Joe-9, as they were derived from Joe-9.⁸⁹ They all shared VH3-type heavy chains and Lambda-type light chains.⁹⁰

Despite only disclosing Joe-9-type of antibody, AbbVie used its functional genus claim to attempt to cover all antibodies with binding affinity for IL-12. Thereafter, a competitor called Centocor developed its own human IL-12-neutralizing antibody drug, using transgenic mice technology to produce human antibodies. The antibody in Centocor's drug has VH5-type heavy chains (not VH3-type) and Kappa-type light chains (not Lambda-type) with about 50% sequence similarity in the variable regions, as compared to the Joe-9 antibodies.⁹¹

AbbVie sued Centocor for infringement. At trial, the jury determined that AbbVie's patent claims were invalid for inadequate written description, lack of enablement, and obviousness.⁹² AbbVie appealed this decision.

In its subsequent ruling, the Federal Circuit began by quoting *Ariad* to explain that "the purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" ⁹³ The court then reaffirmed the *Ariad* standard of possession had been shown by disclosure in the patent.⁹⁴ The court quoted *Regents of the Univ. of California v. Eli Lilly & Co.* to articulate its genus claim standard:

[A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.⁹⁵

The court also noted that all of the antibodies described in AbbVie's patents were derived from Joe-9, had VH3-type heavy chains and Lambda-type light chains, and shared 90% or more sequence similarity in the variable regions.⁹⁶ The court further pointed out the patents did not disclose any other example or possibility that antibodies other than the Joe-9-type would work.⁹⁷ Moreover, the court recognized that Centocor's invention "differed considerably" from the Joe-9 antibodies, yet it was captured by AbbVie's broad genus claim.⁹⁸

The court explained that the high quantity of species described in the

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.* at 1294.

⁹³ *Id.* at 1299.

⁹⁴ *Id.*

⁹⁵ *Id.* (quoting *Regents of the Univ. Of California v. Eli Lilly*, 119 F.3d at 1568-69).

⁹⁶ *Id.* at 1300.

⁹⁷ *Id.*

⁹⁸ *Id.*

specification could not save the genus claim because “the described species are all similar types and do not qualitatively represent other types of antibodies encompassed by the genus.”⁹⁹ Therefore, the court concluded that the patents failed to meet the written description requirement because they did not describe representative examples to support the full scope of the functional genus claims.¹⁰⁰

Applying this proposed “persuading-the-PHOSITA” standard here, AbbVie’s genus claim would be invalidated for lack of written description.¹⁰¹ The standard holds that the application must disclose enough detail to convince the PHOSITA that the invention works. AbbVie’s patent only demonstrated that the Joe-9 structure would achieve the desired result. Thus, the jury would ask: “After learning about the Joe-9 structure, could a PHOSITA determine other antibody structures that may also achieve the same desired result?”

Suppose that a patentee explains how the antibody binds the IL-12 cytokine in great detail, and a PHOSITA is convinced that this specific antibody would work, generating another antibody that would bind IL-12 in the same way. This article’s proposed standard contends that granting a genus claim that covers different structures to the patentee would be warranted. Only if the patent convinces a PHOSITA that other structures, including Centocor’s structure, would achieve the same goal of binding the IL-12 should the patent be deemed to capture Centocor’s invention.

However, as the evidence in *AbbVie* suggests AbbVie’s patent only described the Joe-9 structure, and a PHOSITA would not know that Centocor’s structure had the same desired results simply by reading the instructions presented in AbbVie’s patent. Therefore, AbbVie’s genus claim should only be read to cover the Joe-9 structure.

This shows that the proposed “persuading-the-PHOSITA” standard works as the *Ariad* court desired; it provides a workable standard unlike the obscure and amorphous tests in *Ariad*. Additionally, the proposed standard avoids the self-serving problem, as it does not stipulate whether the patentee was aware of other variants at the time of filing. It simply asks whether a PHOSITA could be persuaded and learn from the disclosure.

CONCLUSION

The *Ariad* court was particularly wary about granting patents to “research plans” and “unfinished invention.”¹⁰² This was the main reason why the court rejected *Ariad*’s genus claims. This article proposes a plausible written description standard that aligns with the court’s objectives in deciding *Ariad*. That is, whether the specification can persuade the PHOSITA that the invention would work. This proposed standard also leads to the same result as the Federal Circuit cases which applied *Ariad*.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014).

¹⁰² *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010).