

2008-1248

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE FOR TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, and
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY & COMPANY,

Defendant-Appellant.

Appeal From The United States District Court For The
District Of Massachusetts In Case No. 02-CV-11280,
Judge Rya W. Zobel.

BRIEF OF AMICUS CURIAE FEDERAL CIRCUIT BAR ASSOCIATION
IN SUPPORT OF APPELLANT

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November 19, 2009

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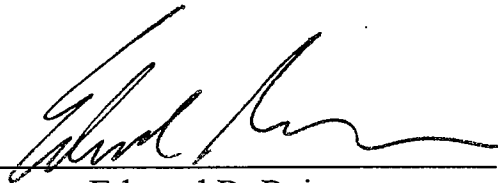
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STATEMENT OF INTEREST

This brief is submitted by the Federal Circuit Bar Association (“FCBA”). The FCBA is a national bar association with over 2,600 members from across the country, all of whom practice before or have an interest in the decisions of the Court of Appeals for the Federal Circuit. The FCBA offers a forum for discussion of common concerns of the Court and the bar. One of the FCBA’s purposes is to render assistance to the Court in appropriate instances, both in procedural and substantive practice areas.

The FCBA submits this brief pursuant to the authorization provided in the Court’s August 21, 2009 Order.

RESPONSE TO EN BANC QUESTIONS

Amicus Curiae FCBA responds to the Court's *en banc* questions as follows and as further explained in this brief:

Question 1: Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

Answer: Yes, Section 112, ¶ 1 establishes two separate, albeit related, requirements.

Question 2: If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement.

Answer: The purpose of the written description requirement is to ensure that inventors have actually invented and disclosed what they claim to own. Like the related enablement requirement, it is a question of law based on underlying facts.

While FCBA answers the above *en banc* questions, it does not take a position on the validity of Ariad's patent claims at issue in this appeal.

SUMMARY OF ARGUMENT

Written description has been, and should remain, a separate doctrine from enablement, although the two are closely related. It is often overlooked that even those who urge the elimination of a free-standing written description doctrine, such as Ariad, acknowledge that there is a legal requirement that the invention be “identified” and “disclosed” in the specification. This common ground narrows the debate helpfully. Ultimately, the real issue on written description is not whether the law requires a description of the invention in a patent application, but whether that condition is its own statutory requirement or merely an “aspect” of enablement without independent force?

On that question, both law and logic confirm that written description is a separate requirement. At the outset, principles of statutory interpretation support the continued existence of an independent written description requirement. Beyond the text of Section 112, ¶ 1, the existence of a separate written description requirement is reinforced by the unchallenged law that Section 112, ¶ 2 requires that claims only be directed to subject matter that the inventor “regards as his invention,” as that invention is described in the specification. *Allen Eng’g. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348-49 (Fed. Cir. 2002) (“Where it would be apparent to one of skill in the art, based on the specification, that the invention set forth in a claim is not what the patentee

regarded as his invention, we must hold that claim invalid under § 112, paragraph 2.”). This is consistent with the important role that Section 112 plays in ensuring that inventors are granted patents only on what they have invented. As documented below, there are some situations in which enablement is insufficient to protect against over-claiming and abusive claim amendments. While these situations are relatively uncommon, abandoning an independent written description doctrine would unnecessarily remove an important safeguard from the patent system.

In terms of scope, the development of the written description doctrine is best accomplished through case-by-case decision-making. There is no one-size-fits-all approach to written description that this Court should just decree in its *en banc* ruling here. There are, however, two important principles that should guide the development of this area of the law.

First, the touchstone of the written description analysis should be the command of Section 112 that claims are only valid if they are directed to what the inventor “regards as his invention” as established by the specification. This is the statutory standard for ensuring that an inventor is entitled to the subject matter on which he or she seeks a monopoly, and it should be the foundational standard from which the written description requirement is judged.

Second, contrary to this Court’s current jurisprudence treating it as a question of fact, written description is ultimately a question of law. The Supreme Court has long recognized that the “ultimate question of patent validity is one of law.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). This rule makes particular sense where, as with written description, the question is fundamentally focused on the text of the patent’s disclosure itself. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc) (“It follows, therefore, from the general rule applicable to written instruments that a patent is uniquely suited for having its meaning and scope determined entirely by a court as a matter of law.”). Although this Court has applied these fundamental principles in affirming that enablement is a question of law, it has, without explanation, declined to consider the closely-related written description requirement under the same standard. Both sides of the written description debate agree that there is no statutory basis for this distinction.

Amicus curiae FCBA hopes that this submission helps the Court resolve the important issues involved in this *en banc* proceeding.

ARGUMENT

Over the years, gallons of ink have been spilled on written description debates. The patent law community—jurists, practitioners, and academics alike—have devoted page-upon-page to the meticulous review of decade-upon-decade of legislation and case law to support their competing views. Punctuation, grammar and word choice have been picked apart. Advocates have posed doomsday scenarios of what will occur if one position is adopted over the other.

Despite this, or perhaps because of it, the two sides of the written description debate have often overlooked a central truth that provides fundamental common ground. To wit, it is, and should be, beyond controversy that a patent *must* identify what the inventor believes to be his or her invention. In a patent system based on the *quid pro quo* between patent owner and society, this is simple common sense. Consequently, as intense and impassioned as the written description debate has been at times, all parties agree with “the undisputed proposition that the *claims must be directed to an invention that is identified in the specification.*” See Principal Brief for Plaintiffs-Appellees On Rehearing En Banc (“Ariad Principal Brief”) at 23.¹

With this in mind, it is clear that this *en banc* appeal does not involve a black-and-white question of statutory construction, but, ultimately, an analysis of

¹ Emphases added throughout, unless otherwise noted.

how to give effect to the fundamental and undisputed principle that a patent specification must identify the inventor's invention. In addressing that issue, this brief starts from the common ground shared by both sides in the written description debate, and, with that foundation, seeks to address the questions that have been presented for *en banc* review.

I. There Is Substantial Common Ground In The Written Description Debate

There is consensus that a patent application must disclose what the inventor regards as his or her invention. For example, although Ariad challenges the independence of the written description requirement with zeal, it does not deny that the invention must be identified in the specification: "The specification must state *what* the invention is, for otherwise it fails to inform a person of ordinary skill in the art what to make and use." Ariad Principal Brief at 30 (emphasis in original). Ariad's acknowledgement of the legal obligation to identify the invention in the written description is not a slip of the pen or poor proofreading. On the first page of its brief, in answering the questions presented, Ariad makes clear that, in addition to an enablement requirement, the specification must describe what is the invention that is the subject of the patent: "Properly interpreted, the statute requires the specification to describe (i) *what the invention is*, and (ii) how to make and use it." *Id.* at 1.

This common ground not only results from common sense, but also flows from precedent. Long ago, the C.C.P.A. ruled that a patent could not issue if the specification failed to disclose the invention that was the subject of the claims. *See, e.g., In Re Moore*, 155 F.2d 379, 382 (C.C.P.A. 1946). This fundamental principle was repeatedly affirmed over the course of nearly two decades of C.C.P.A. precedent. *In Re Sus*, 306 F.2d 494, 497 (C.C.P.A. 1962); *see also Jepson v. Coleman*, 314 F.2d 533, 536 (C.C.P.A. 1963) (noting that the outcome of the interference proceeding turned on the “question [of] whether the application necessarily discloses that particular device”).

In addressing this well-established line of precedent, Ariad responsibly acknowledges that these C.C.P.A. cases correctly require the patent specification to “identify” the invention covered by the claims. Specifically, as stated in its principal brief, Ariad agrees that these C.C.P.A. cases “stand for the undisputed proposition that the claims *must* be directed to an invention that is *identified* in the specification.” Ariad Principal Brief at 23.

In fact, even in the context of *In Re Ruschig*—which stoked much of the historical debate—all parties agree that the specification must disclose what the inventor actually invented. *Id.* Proponents of a separate written description requirement read *In Re Ruschig* as applying a distinct statutory requirement. Opponents of a separate written description requirement, including Ariad, read it as

having been “correctly decided on the ground that the specification did not identify the later claimed specific compound as something that the applicant had invented and that one of ordinary skill in the art should make.” *Id.* But as Ariad starkly concedes in discussing *In Re Ruschig* and its progeny, there is a requirement that the application identify the invention: “Properly interpreted, the written description requirement of § 112, ¶ 1 requires, first, that the specification **describe (identify)** what the invention is” *Id.* at 43.

In sum, as Ariad itself took great pains to acknowledge point blank in its brief, it is undisputed that the invention that is the subject of a patent *must* be identified in the specification. This common ground narrows the dispute before this Court.

II. Question 1: While Closely Related To Enablement, Written Description Is A Separate Statutory Requirement

While the above-described common ground presents a starting point from which to resolve the written description debate, it of course does not end it. Both sides, having accepted the premise that a patent application must describe the invention, are left to debate a much narrower question. Is it possible to satisfy the enablement requirement without also satisfying the requirement that the specification describe the invention? Ariad Principal Brief at 29 (identifying the central disputed issue in this area of law as whether a patent can enable an invention and “still have failed to ‘describe’ it”).

It is undisputed that written description and enablement are so closely related that, in most cases, a specification that enables an invention will also describe it. *See LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (noting that the “two requirements usually rise and fall together”); *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 921-22 (Fed. Cir. 2004) (recognizing that “there is often significant overlap between the three requirements” of Section 112).

Although Ariad concedes that the invention must be “identified” in the specification, albeit as a preliminary element of the enablement analysis, it seems to contend that there cannot be a written description violation unless the claimed invention is also not enabled. Ariad Principal Brief at 29-30. In other words, written description is in some way an “aspect of enablement” but cannot be enforced as a separate requirement. *Id.* at 23.

There are two fundamental problems with this analysis. First, it fails to provide a statutory safeguard to keep an inventor to what he or she has actually invented in the limited class of cases where enablement is insufficient to prevent abuse. Second, it is not faithful to the text of Section 112. These problems are discussed in turn.

A. Written Description And Enablement Serve Important—And Independent—Purposes

Both sides of the written description debate agree that an inventor's monopoly should only extend to his or her contribution to his or her art. *See* Ariad Principal Brief at 45 (arguing that Supreme Court precedent requires that the scope of an inventor's monopoly not exceed the inventor's contribution). But the heart of innovation is not always implementation. While there are, of course, many cases in which the implementation of an invention is the true mark of the inventor's contribution, there are also many cases in which that contribution lies in the recognition that an already-enabled system or method can be applied to solve a problem or otherwise advance a field of art. In such cases, an inventor's contribution may be tied to his or her *identification* of the solution not to his or her *enablement* of it. Thus, enablement can be inadequate to ensure that the inventor's patent monopoly is limited to his or her contribution.

Such instances are not hard to imagine.² Take for example an invention directed to the use of an easy-to-make compound for a specific medical

² This Court has repeatedly recognized that there will be instances in which an invention may be enabled even when it is not described. *Rochester*, 358 F.3d at 921-922; *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A. 1971) (“[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention.”). Indeed, “the enablement requirement is often more indulgent than the written description requirement.” *Amgen, Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003).

or biological application. In that case, the inventor's contribution to his or her field—the true innovation—may lie not in enabling those of ordinary skill in the art to make and use a compound that they can easily make and use, but in identifying for the first time that the compound will be effective for the desired application.

In many cases, the inventor will disclose this insight in his or her patent application and will have met his or her end of the *quid pro quo* for a patent monopoly. Neither the written description requirement nor enablement come into play. But what happens when the inventor's patent application, for example, evolves over the course of amendments to his or her claims? As they are amended, the inventor's claims may shift to identify for the first time—and cover—compounds that are useful in solving a problem underlying the invention, but that the inventor had not identified in his or her original application. Sometimes, the claims may be amended years later, with virtually no involvement of, or notice to, the inventor. Under these circumstances, the inventor may not be entitled to claim as his or her invention compounds that he or she failed to identify as part of the invention in the application itself. Yet enablement can be wholly inadequate as a vehicle to prevent abuse in this area—these newly-claimed compounds are undeniably enabled, even if they were never identified as part of the invention in the specification.

This is not the only scenario in which a separate written description requirement can serve to police claims where enablement cannot. Attempts to belatedly claim species within an enabled genus are another well-known example. An inventor may enable a genus in his or her patent application, only to claim—or, have a patent attorney claim—years later that his or her invention is directed to a species. The enablement requirement, standing alone, would provide no mechanism to prevent the inventor from later claiming the undisclosed species.

Yet another example is where the specification describes a feature of the invention that is indispensable to the inventor's contribution but where the inventor—or his or her patent attorney—has failed to include it in the claims as properly construed. *See, e.g., LizardTech*, 424 F.3d at 1337-39; *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376-78 (Fed. Cir. 2009). In that case, neither principles of enablement nor claim construction would always keep the scope of the patent monopoly faithful to the inventor's invention—the claims could be completely untethered to his or her technical contribution, and the law would provide no vehicle to tie the patent to that limited contribution.

As these examples illustrate, a separate written description requirement is critical to ensure that patent claims “be directed to an invention that is identified in the specification.” Because an inventor's written description serves as a snapshot in time of the invention and of the inventor's contribution to

the field, it is indispensable that it identify the invention. Whatever amendments are made to the claims—whether months or years later, in the original application or a continuation, by the inventor or an unconnected patent attorney—that description ensures that the monopoly granted the inventor is that to which he or she is fairly entitled. Enablement alone is not always enough.

B. Basic Principles Of Statutory Construction Confirm That Written Description Should Be A Separate Requirement

Section 112 requires that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

Although this provision is far from a model of clarity, decades of precedent from this Court and its predecessor have found that the better reading of the statute is that it requires both a written description requirement and a separate, but related, enablement requirement. *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967); *Rochester*, 358 F.3d at 920-925. This reading flows not only from the statutory text and history, but importantly, from the overall context of the patent statute including Section 112 itself.

1. A Separate Written Description Requirement Flows Naturally From The Statutory Context

Because the written description debate has so often focused on parsing the specific language of Section 112, ¶ 1, the fundamental tenet of statutory construction that statutory text should be construed in the context of the overall statutory scheme is often overlooked. *See Brown v. Gardner*, 513 U.S. 115, 118 (1994) (“[T]he meaning of statutory language, plain or not, depends on context.”) (citations omitted). Indeed, even in the context of this *en banc* appeal, the discussion has focused in large part on grammatical deconstruction while overlooking the important context that supports an independent written description requirement.

Section 112, ¶ 2 provides that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter *which the applicant regards as his invention.*” 35 U.S.C. § 112, ¶ 2. As a matter of unchallenged Federal Circuit authority, this provision contains two distinct legal requirements: (1) that the claim must set forth what the applicant regards as his invention; and (2) that it do so with sufficient particularity and distinctness. *Allen Eng’g. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348-49 (Fed. Cir. 2002); *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1376 (Fed. Cir. 2000). Although the second requirement is more commonly applied, the first provides powerful proof that an inventor’s claim scope is tied directly to his or her

invention as defined in his or her patent specification. Indeed, “[w]here it would be apparent to one of skill in the art, based on the specification, that the invention set forth in a claim is not what the patentee regarded as his invention, we must hold that claim invalid under § 112, paragraph 2.” *Allen Eng’g.*, 299 F.3d at 1349. And that is exactly what this Court did in *Allen Engineering*.

This precedent is important to the written description debate for two reasons. First, it confirms the common-sense principle that the evaluation of whether a claim sets forth what the inventor regards as his or her invention is rooted in the patent specification. Indeed, because the adequacy of the claims in meeting the first requirement of Section 112, ¶ 2 is judged with the specification in mind, it is all the more important that the specification describe the invention. Second, it confirms that, in promulgating and amending Section 112 over the years, Congress intended (and this Court confirmed) that the patent specification must identify what the inventor actually invented. Although this intent was codified in the parallel provisions of Section 112 that an inventor describe his or her invention and claim what he or she regards as his or her invention, both requirements flow naturally from that central premise.

Not surprisingly, that same central premise is emphasized in other provisions of the patent statute. Among the other conditions for patentability, the patent statute requires that the person to whom a patent is issued must be the

person who himself invented the subject matter claimed in the patent. 35 U.S.C. § 102(f) (“a person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented”).

2. The Text Of Section 112 Is Better Read As Including A Separate Written Description Requirement

As noted above, opponents of an independent written description requirement contend that it is in conflict with the grammatical structure of the statute. Ariad argues, for example, that “this Court has never set forth a grammatical analysis explaining how a separate written description requirement can be reconciled” with the statutory text, and instead has “solely focused” on the phrase “written description of the invention.” Ariad Principal Brief at 5. This critique is not well-placed. The Court has, of course, focused on the phrase “written description of the invention” as mandating a separate written description requirement because it is this language that defines a requirement distinct from the enabling disclosure of the manner and process of making and using the invention.

In any event, the grammatical argument against a written description requirement largely revolves around the presence of a comma between the phrases “of the manner and process of making and using it” and “in such ... terms.” *Id.* at 3-7. According to opponents of a separate written description requirement, this comma renders the “in such ... terms” phrase a prepositional phrase that modifies both “of the invention” and “of the manner and process for making and using it.”

Id.; see also *In Re Barker*, 559 F.2d 588 (C.C.P.A. 1977) (Markey, C.J., dissenting);³ *University of Rochester v. G. D. Searle & Co., Inc.*, 375 F.3d 1303, 1326 (Fed. Cir. 2004) (Linn, J., dissenting). Some have suggested that any other interpretation would be “inexplicable.” Ariad Principal Brief at 6. Quite the contrary.

At the outset, the reading proffered by opponents of a separate written description requirement assumes that the comma between the phrases “of the manner and process of making and using it” and “in such ... terms” can be read only to set off the clause “and of the manner and process of making and using it.” Not so. An at least equally-plausible reading of this phrase is that the comma between the phrases “of the manner and process of making and using it” and “in such ... terms” represents a natural pause between the two clauses. This reading is confirmed when one considers how the statute would read if the drafters removed the phrase “written description of the invention” from Section 112. The comma would still play a meaningful role as a signal for a pause:

The specification shall contain a written description of [] the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to

³ Although Chief Judge Markey “heartily” dissented from the opinion in *In Re Barker* reaffirming an independent written description requirement, he had previously joined in opinions that recognized that written description and enablement were separate requirements. See, e.g., *In Re Morehouse*, 545 F.2d 162, 164 (C.C.P.A. 1976) (applying written description, enablement and definiteness as separate requirements).

which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (modified). In other words, the comma between the phrases “of the manner and process of making and using it” and “in such ... terms”—relied upon so heavily by opponents of a separate written description requirement—does not undermine a separate written description requirement because proper English would include it in the statute even if the statute did not include language requiring a written description of the invention.

Moreover, had the statute been intended to require only an enablement requirement, it could have been drafted to require that in a far more straightforward manner. For example, Congress could have made clear in direct and simple terms that the specification must provide a disclosure sufficient to enable the invention. Or, as shown above, Congress could have made a couple of minor revisions to the statute to clearly require only an enabling disclosure (“The specification shall contain a written description of the manner and process of making and using the invention, in such full, clear, concise, and exact terms”). 35 U.S.C. § 112, ¶ 1 (modified).⁴

⁴ Ariad also suggests that a significant problem with a separate written description requirement is that “the statute provides no standard for testing the legal adequacy of the ‘written description of the invention.’” Ariad Principal Brief at 6. But the patent statute is of course a broad statute allowing for case law development.

In any event, the intense focus on the comma between the phrases “of the manner and process of making and using it” and “in such ... terms” unduly overshadows another important comma in the statutory text. The phrase “of the invention” is itself segregated from “the manner and process of using it” by its own comma. In other words, “the invention” is specifically offset as a discrete item to be described. Here again, had Congress intended that the invention to be described be tantamount to the manner and process of using it, it could easily have achieved that end by omitting this comma.

Setting aside this comma conundrum, a grammatical deconstruction of the phrase “of the manner and process for making and using it” further confirms that the statutory text is better read to provide for a separate written description of the invention. It can hardly be a coincidence that the enablement requirement directly parallels the requirement that the specification contain the manner and process of making and using the invention but not the written description of the invention:

The specification shall contain a written description of the invention, and of the manner and process of *making and using* it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *make and use* the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1. This parallelism of language reflects a parallelism in thought—an enabling disclosure must allow those of ordinary skill in art to make

and use the manner and process of making and using the invention. A “written description of the invention” is a different requirement altogether.

In short, while opponents criticize a separate written description requirement as fundamentally inconsistent with the statutory text, a fair reading of the text confirms that an independent written description requirement results from not only a plausible reading, but the better reading.

3. The Statutory History Confirms That Congress Intended That The Specification Describe The Invention, Even After Claims Were Required

Beyond these grammatical criticisms, opponents of the written description requirement also rely on the statutory history of Section 112 to support a reading of the statute that excludes a separate written description requirement. Here, the primary argument is that, prior to the advent of claims, the written description served both to enable the invention and distinguish the invention from the prior art, but that the latter purpose was eliminated when claims were introduced as a separate requirement. *Ariad Principal Brief* at 9-13; *see also* Act of July 4, 1836, 5 Stat. 117, 199, ch. 357, § 6; Act of July 8, 1870, 16 Stat. 198, 201, ch. 230, § 26.

This theory reads far too much into the statutory history of Section 112. The claiming requirement added in 1836, and more formally in 1870, might have mooted the requirement that the specification distinguish the invention from

the prior art. But that did not eliminate the requirement that the inventor describe “the invention.” Compare Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11 § 3 with Act of July 4, 1836, 5 Stat. 117, 199, ch. 357, § 6. Indeed, even in amending Section 112 expressly to remove the requirement that the specification distinguish the invention from other inventions, Congress affirmatively chose not to amend the statute to remove the requirement that the specification including a “written description of the invention,” *and* “the manner and process of making and using” the same.

This statutory history confirms that Congress intended that claims serve to distinguish the inventor’s invention or discovery from that which came before, but not that the existence of claims somehow eliminates the requirement that the inventor describe his or her invention or discovery in the specification. See *Rochester*, 358 F.3d at 922 (rejecting argument that the public notice function of the written description became redundant after the advent of claims because “[s]tatutory language does not become redundant unless repealed by Congress”).

In sum, the plain text and evolution of Section 112 over the years, including the advent of claims and the promulgation of Section 112, ¶ 2, serve to confirm Congress’ focus on ensuring that inventors may only claim to own what they actually invented and described. A separate written description requirement

is an important tool to permit the Patent Office and courts to enforce this foundational principle.

III. Question 2: Although The Contours Of The Written Description Requirement Should Evolve Naturally Through Case-By-Case Decision-Making, Two Basic Principles Should Guide That Development

As explained above, all agree that enablement and written description will, in most cases, go hand-in-hand. But there will be some cases where a separate written description requirement will be dispositive. To the extent specific interest groups have concerns about the disproportionate impact of such a requirement on specific technologies (e.g., concerns about the “precise definition” test or a “super-enablement” requirement) or about the uncertainty associated with a separate written description requirement, these concerns go to the standards for written description, not to the threshold question of whether written description is a statutory requirement separate from enablement.

Of course the standards for written description cannot—and should not—all be developed in one day. That said, *amicus curiae* FCBA submits that there are two fundamental principles that should form the basis for the application of a separate written description requirement.

A. Written Description Should Be Tied To What The Inventor Regards As His Or Her Invention

The key to a fair and balanced written description requirement is to ensure that the natural evolution of the doctrine progresses carefully and

consistently with its underlying goals.⁵ *Amicus curiae* FCBA submits that this is best accomplished by tying the written description requirement to the statute itself. Section 112 requires that an inventor describe and claim what he “regards as his invention.” This is the statutory standard for ensuring that an inventor is entitled to that on which he or she claims a monopoly, and it should be the foundational standard from which the written description requirement develops. Under this standard, a patent will validly cover only the contribution that the inventor regards as his or her invention, as he or she has described it in the specification. *See, e.g., LizardTech*, 424 F.3d at 1345-46 (“After reading the patent, a person of skill in the art would not understand how to make a seamless DWT generically and would not understand LizardTech to have invented a method for making a seamless DWT, except by “maintaining updating sums of DWT coefficients. ... [W]e hold that the description of one method for creating a seamless DWT does not entitle the inventor of the ‘835 patent to claim any and all means for achieving that objective.”).

⁵ Although Ariad embraces an “identification” subtest as part of an enablement analysis in its principal brief, it never grapples with the application of this standard in real cases. Ariad does not describe how an invention is “identified” from the specification, or how this “identification” process should interplay with the statutory requirement that the claims particularly point out and distinctly claim the invention or with the scope of the invention that is to be defined in claims construction. Whatever the standard, a test that implements “identification” as an implicit component of enablement rather than a separate requirement is likely to mean that identification will often remain in the shadows of the enablement analysis.

In short, however it may be applied in specific cases, the written description requirement should ensure that the inventor has both described and claimed what he or she regards as the invention.

B. Written Description Should Be Decided As A Matter Of Law

It is beyond legitimate dispute that written description and enablement—whether separate requirements or somehow joined in a single requirement—go hand-in-hand. Both questions turn on the adequacy of an inventor's disclosure within the four-corners of the patent specification. Both questions require a black-and-white analysis of what the inventor has disclosed, rather than a subjective inquiry into the inventor's state of mind. And both questions are directed at ensuring that a patent owner has met his or her end of the *quid pro quo* that underlies the patent laws. In short, the requirements are closely-related and often overlapping.

Despite this close connection, this Court's precedents have treated enablement and written description in polar opposite ways in one important respect. While enablement is a question of law based on underlying facts, written description has instead been categorized as a pure question of fact.⁶ Compare *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n. 6 (Fed. Cir. 1983) with *Vas-*

⁶ This Court has also evaluated compliance with Section 112, ¶ 2 as a question of law based on underlying questions of fact. See *Allen Eng'g.*, 299 F.3d at 1344.

Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). And while the patent bar has often noted the dichotomy, this Court has never really addressed it:

Given the noted similarities between enablement and written description, and especially because they arise from the same statutory sentence, it is perhaps curious that the two have differing fact/law classifications. Yet, when attempting to find the reason behind this difference, the curious researcher is left unsatisfied, as she will find case citation after case citation proclaiming only that enablement is a question of law, or written description is a question of fact. Sadly, no court rationale accompanies such simple statements.

Keene, J., *Fact Or Fiction: Reexamining The Written Description Doctrine's Classification As A Question Of Fact*, 18 Fed. Cir. B.J. 25 (2008); see also Ariad Principal Brief at 46 (“This Court has never identified a statutory basis for this distinction.”). *Amicus curiae* FCBA submits that this *en banc* rehearing presents a golden opportunity for the Court to address the inconsistency in its treatment of written description and enablement, and clarify that written description is also a question of law.

Both law and logic compel this conclusion. The Supreme Court has unambiguously ruled that the “ultimate question of patent validity is one of law.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966); see also *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280 (1976). While this Court has given effect to this basic principle in enablement and other invalidity analyses such as obviousness, it has inexplicably deviated from it in evaluating the written description of an invention. To be sure, one might conclude that a written

description analysis can include underlying questions of fact relating to the level and understanding of those of ordinary skill in the art. But, this does not take it out of the ambit of a legal conclusion. If anything, written description presents *fewer* potential factual questions than enablement. For example, written description does not implicate the issue of undue experimentation that can be very fact-intensive. *See In Re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (identifying examples of the “many factual considerations” weighed in an enablement analysis, including the quantity of experimentation necessary, predictability or unpredictability of the art, amount of direction or guidance presented, etc.).

Treatment of written description as a question of law is also consistent with this Court’s jurisprudence on patent interpretation in claim construction. As this Court recognized in *Markman*, the interpretation of a written document to determine what it does and does not say has historically, and rightly, been a task assigned to judges as questions of law:

The *patent is a fully integrated written instrument*. By statute, the patent must provide *a written description of the invention* that will enable one of ordinary skill in the art to make and use it. 35 U.S.C. § 112, para. 1. Section 112, para. 2, also requires the applicant for a patent to conclude the specification with claims “particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” It *follows, therefore, from the general rule applicable to written instruments that a patent is uniquely suited for having its meaning and scope determined entirely by a court as a matter of law.*

Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc). No less can be said of the written description requirement. Indeed, regardless of whether the requirement is separate from enablement or a part of it, the assessment of whether an inventor has adequately disclosed his or her invention ultimately boils down to an evaluation of the four corners of the patent's disclosure as "a fully integrated written instrument." It is not properly considered a pure question of fact.

CONCLUSION

For the aforementioned reasons, *amicus curiae* FCBA respectfully submits that this Court should reaffirm once and for all that Section 112 includes two distinct requirements for enablement and written description and that the purpose of the written description requirement is to ensure, as a matter of law, that inventors in fact invented what they claim to have invented.

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CERTIFICATE OF SERVICE

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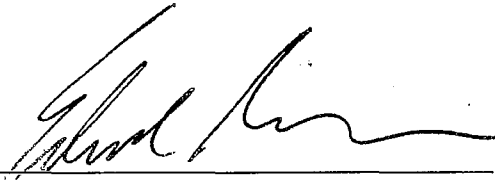
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