

No. 2008-1248

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

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

v.

ELI LILLY AND COMPANY,
Defendant-Appellant.

**Appeal from the United States District Court
for the District of Massachusetts, Civil Case No. 02-CV-11280
Judge Rya W. Zobel**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT
SUPPORTING REVERSAL**

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Dated: November 19, 2009

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies the following:

1. The full name of every party / *amicus curiae* represented by me is:

Washington Legal Foundation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties / *amicus curiae* represented by me are:

None

4. - There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the parties and associates that appeared for the party represented by me in the trial court or are expected to appear in this case:

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ABBREVIATIONS

Lilly	Defendant-Appellant Eli Lilly & Company
Ariad	Plaintiffs-Appellees ARIAD Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute of Technology, and The Presidents and Fellows of Harvard College, collectively
PTO	United States Patent and Trademark Office
CIP	continuation-in-part
<i>Lilly</i>	<i>Regents of Univ. of Calif. v. Eli Lilly and Co.</i> , 119 F.3d 1559 (Fed. Cir. 1997)
<i>Rochester Denial</i>	<i>University of Rochester v. G.D. Searle & Co., denial of rehearing en banc</i> , 375 F.3d 1301 (Fed. Cir. 2004)
Blue Br.	Principal Brief For Plaintiffs-Appellees On Rehearing En Banc (filed Oct. 5, 2009)
Red Br.	Principal Brief For Defendant-Appellant Eli Lilly and Company On Rehearing En Banc (filed Nov. 9, 2009)

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center that devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.¹ WLF regularly appears before the Court in cases raising important patent law issues, particularly cases in which enforcement of broad patent claims might serve to inhibit innovation. *See, e.g., Orion IP, LLC v. Hyundai Motor America*, No. 2009-1130 (Fed. Cir., dec. pending); *Microsoft Corp. v. i4i Limited Partnership*, No. 2009-1504 (Fed. Cir., dec. pending).

WLF values a healthy patent system that protects innovative technologies. Nevertheless, WLF is concerned that patents may serve to stifle innovation if patentees are permitted to create infringement cases by amending their patent claims or reinterpreting their specifications only after studying products that came to market after the initial patent filing. From that perspective, WLF submits the following views regarding the proper source, the true scope, and the essential role of the written description requirement in 35 U.S.C. § 112, ¶ 1.

¹ By its August 21, 2009 order, the Court granted leave for the filing of *amicus curiae* briefs “without leave of court.”

SUMMARY OF ARGUMENT

A separate statutory written description requirement exists, and has existed since before separate claims were required. Moreover, the written description requirement as summarized in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), should continue to be vigorously enforced to prevent opportunistic patent applicants and plaintiffs from belatedly recasting their applications and patents to encompass subject matter that they did not invent, did not claim, did not disclose, or did not discern from their own specifications.

Despite the professed confusion and disagreement over this Court's so-called "*Lilly* written description doctrine," Plaintiffs-Appellees' (hereinafter "*Ariad*") proposed solution of reconstruing § 112, ¶ 1 to excise the written description requirement for all purposes (including priority) would be a classic mistake of "throwing the baby out with the bath water." While the same solution has been posed by certain judges (*e.g.*, *Rochester Denial*, 375 F.3d at 1326 (Linn, J., dissenting)), even they agree that this Court's existing written description precedent serves a valuable purpose. *See id.* at 1311 (Rader, J., dissenting) (the written description doctrine before *Lilly* served "important purpose" of ensuring that the inventor had possession, as of the filing date relied on, of the specific subject matter later being claimed). The Supreme Court's precedent is the same,

so this Court should not undo that now.

The written description requirement cannot be read out of the statute without eliminating the “traditional mode of written description jurisprudence” that prevents applicants and litigants from obtaining claims based on the earlier filing date of a specification or application that did not describe the later-claimed subject matter. *See Rochester Denial*, 375 F.3d at 1311 n.6 (Rader, J., dissenting). Because the statutory written description requirement remains vitally important to the long-standing purpose of preventing parties from getting and enforcing patent claims on subject matter which they did not invent or disclose, this Court should reaffirm its existing written description precedent and continue to apply the separate statutory written description requirement uniformly to all types of claims, inventors, inventions, and technologies.

ARGUMENT

I. The Plain Statutory Language Contains a Written Description Requirement That Is Separate from the Enablement Requirement

A. This Court Should Adhere to its Settled Precedents

As *Ariad* recognizes (Blue Br. 27-30), this Court’s predecessor already considered and expressly resolved this Court’s first *en banc* question in *In re Barker*, 559 F.2d 588 (CCPA 1977). Indeed, *Barker* addressed the identical

question concerning the identical statutory language:

Appellants argue that the “enablement” requirement of the first paragraph of 35 U.S.C. § 112 cannot be read separately from the “description” requirement therein. They would interpret the phrase in section 112 “in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same” as modifying “description”; thus, a sufficient description of the invention for purposes of the statute would be a description that enables one skilled in the art to make and use the invention. We do not agree.

559 F.2d at 591. While *Ariad* attempts to downplay the significance of *Barker* by characterizing it as “fractured” and “lack[ing] a controlling opinion” (Blue Br. 27), the undeniable holding of its 3-2 majority was that the statute has a separate written description requirement. *See* 559 F.2d at 594 (Rich, J., concurring) (agreeing that “description and enablement ... are distinct though commingled requirements”).

Judge Rich viewed the problem in *Barker* to be “simple” in that new matter was inserted by amendment and a claim based on that new matter “therefore lacks support.” *Id.* To him, that result “accord[ed] with many of our prior interpretations of 35 U.S.C. § 112 and there [was] no need to justify it by extensive review of the evolution since 1790 of the language of § 112, first paragraph.” 559 F.2d at 594 (Rich, J., concurring) (the statutory words “are of ancient lineage and ... were preserved, in writing the Patent Act of 1952,

because they were familiar and had many times been construed”). His succinct observations are a strong indication that the “written description” requirement was not first created by *In re Ruschig*, 379 F.2d 990 (CCPA 1967).

Nevertheless, since *Barker*, the existence of separate written description and enablement requirements in § 112, ¶ 1 has been uniformly accepted by this Court, the CCPA, and the regional circuits. *See, e.g., Rengo Co. v. Molins Machine Co.*, 657 F.2d 535, 550-52 (3d Cir. 1981). Having thus already decided the identical issue for the identical statutory language, this Court should adhere to its settled precedent in *Barker* as a matter of *stare decisis*, regardless of whether reasonable minds then and now might disagree.

Even if a separate written description requirement had been first discerned in the statutory language in *Ruschig*, Congress has not acted during the intervening 40+ years to disagree with that interpretation or to overrule the many subsequent decisions adhering to and applying it as a separate statutory requirement. In light of such complete inaction by Congress, this Court should be hesitant to eliminate the written description requirement that has been consistently recognized as in the statute and separate from enablement.

This Court should not now reconstrue statutory language that has been unchanged since 1952 to excise the separate written description requirement

under the guise of statutory construction. On that basis alone, the Court's first question should be answered in the affirmative, and its written description precedent exemplified in *Ruschig*, *Barker*, and *Vas-Cath* should be reaffirmed.

B. The Statute Requires a Written Description of the Invention and a Separate Written Description That Enables One Skilled in the Art To Make and Use That Invention

Even if examined afresh, this Court should again construe the statute as containing a separate written description requirement. As noted, the assertion that § 112, ¶ 1 only requires a written description that enables one skilled in the art to make and use the invention is the same statutory construction that was advanced and rejected in *Barker*. See 559 F.2d at 594-95 (Markey, C.J., dissenting). As shown herein, the statutory analysis in Judge Miller's opinion was both sound and correct, and Ariad's attempt to resurrect Judge Markey's contrary interpretation should again be rejected.

By *Barker*, the CCPA had already held that there was a written description requirement in § 112 "separate and distinct from the enablement requirement." See 559 F.2d at 591 (citing *In re Bowen*, 492 F.2d 859, 864 (CCPA 1974), *In re Smith*, 481 F.2d 910, 914-15 (CCPA 1973), and *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971)). As it did then, § 112, ¶ 1 states:

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.

As explained by Judge Miller, the above language cannot legitimately be read as providing only that “[t]he specification shall contain a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same” because that would render superfluous the separate statutory language that the specification contain a written description “of the manner and process of making and using it [the invention].”

Obviously, if there were a description enabling “any person skilled in the art ... to make and use,” there would be no need to require a description of the “manner and process of making and using.” As a principle of statutory construction, it is presumed that Congress did not use superfluous words.

559 F.2d at 591-92 & n.3 (and cases cited). Without addressing or refuting that analysis of the statutory language, Ariad asserts that “[t]his Court has never set forth a grammatical analysis explaining how a separate written description requirement can be reconciled with the entire text and structure of § 112, ¶ 1.”

Blue Br. 5. However, not only did Judge Miller do exactly that in *Barker*, but no subsequent precedential decision has ever altered or deviated from his

grammatical analysis and statutory construction.

Like Judge Miller, Ariad agrees that a “plain reading” of the statute confirms that the specification “must contain a description (i) of the invention, and (ii) of the manner and process of making and using it.” Blue Br. 2; *see id.* at 43 (agreeing that “[p]roperly interpreted, the written description requirement ... requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention”). Nevertheless, Ariad wants to fuse those two distinct requirements into one enablement requirement. Unlike Judge Miller, Ariad erroneously assumes that the statute references only one written description and then imposes only one requirement on that description.

By holding that the specification must have a written description that independently describes the invention *and* enables one to make and use it, Judge Miller’s construction was that the statute references a written description in multiple parts or, more exactly, a written description that describes the invention and a separate written description that enables one to make and use it. In contrast to Blue Br. 3, the relevant portion of the statute is better represented as follows:

The specification shall contain

[i] a written description of the invention, and

[ii] **[a written description]** of the manner and process of making and using it, . . .

As Judge Miller explained, the second instance of the phrase “a written description” highlighted above is properly construed as implicit within the statutory structure to avoid rendering superfluous the “and of the manner and process of making and using it” phrase. *See* 559 F.3d at 591. Alternatively, the second but implicit “a written description” phrase keeps the preceding words “of the invention, and” from being superfluous so as to avoid reading the statute as providing only that “[t]he specification shall contain a written description . . . of the manner and process of making and using [the invention].” Either way, the proper statutory construction must give meaning to the “and” between the phrases “of the invention” and “of the manner and process of making and using it.”

Properly construed, the statute requires a written description of the invention *and* a written description sufficient to enable one to make and use the invention. *See Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373, 1374 (Fed. Cir. 2006) (Lourie, J., concurring) (highlighting the statutory word “and” as supporting the separate requirement for “a written description of the

invention”). When the entirety of § 112, ¶ 1 is correctly diagramed, it reveals the following structure:

The specification

[A] shall contain

[i] a written description of the invention, and

[ii] [a written description] of the manner and process of making and using [the invention], in such full and concise terms as to enable any person skilled in the arts to which it pertains, or with which it is most nearly connected, to make and use the same, and

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

Contrary to Blue Br. 5, the statutory phrase “written description of the invention” of clause [i] above is a “stand-alone” and “independent” requirement. More importantly, the above representation is consistent with, explains, and fully justifies this Court’s long-standing written description precedent.

For that reason, decisions like *In re Alonso*, 545 F.3d 1015, 1019 (Fed. Cir. 2008), and *Carnegie Mellon Univ. v. Hoffman-LaRoche, Inc.*, 541 F.3d 1115, 1121 (Fed. Cir. 2008), correctly describe § 112, ¶ 1 as separately requiring “a written description of the invention.” As shown, the statute also has a second and distinct requirement for a written description “of the manner and process of

making and using [the invention] ... so as to enable any person skilled in the art ... to make and use the same.” That the latter “written description” requirement, which constitutes the entirety of clause [ii] above, has become known as the “enablement requirement” does not mean that the former “written description” in clause [i] is not separately required.

The above representation of the correct statutory structure thus refutes Ariad’s facile mischaracterization of this Court’s long-standing statutory construction. Blue Br. 5. Similarly, their three related criticisms of this Court’s construction (Blue Br. 6-7) also become illusory. First, the statute was never intended to provide standards for the legal adequacy of its distinct requirements. The statute requires a specification to describe, enable, and set forth the best mode, but the standards for complying with each statutory requirement have always been developed by courts when construing and applying the statute to particular cases. *See, e.g., In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (listing the relevant enablement factors).

Second, Ariad’s complaint about the statute’s allegedly unparallel grammatical structure disappears because recognition of the second but implicit reference to “a written description” renders the statute internally consistent as a matter of ordinary sentence structure. Third, the allegedly “inexplicable” extra

comma is thus easily explainable on grounds that the comma is neither unnecessary nor extraneous when the set-off portion is properly confined to being part of the separate enablement requirement in clause [ii].

Ariad also relies on the pre-*Ruschig* decision in *In re Gay*, 309 F.2d 769 (CCPA 1962), to justify limiting § 112, ¶ 1 to having only enablement and best mode requirements, but not written description. According to Ariad, Judge Rich in *Gay* characterized § 112, ¶ 1 as having only two requirements: [A] enablement and [B] best mode. Blue Br. 21-22; see *Rochester Denial*, 375 F.3d at 1310 (Rader, J., dissenting). However, identifying every requirement within § 112, ¶ 1 was not even what *Gay* was addressing.

Gay involved a rejection for failure to comply with the statutory “best mode” requirement and with PTO Rule 71(b), which supposedly tracked the “best mode” provision. See 309 F.2d at 730-32 & n.4. Before dividing § 112, ¶ 1 into his [A] and [B] sections, Judge Rich observed that the PTO’s rejection was contrary to “two of the several requirements of the first paragraph of 35 U.S.C. § 112.” 309 F.2d at 772. By referencing “two of the *several* requirements,” Judge Rich recognized that there were more than two statutory requirements but that the case merely required contrasting the “best mode” requirement with everything else. Later, the opinion explained that compliance

with the best mode requirement is “separate and distinct” from “the sufficiency of his disclosure to satisfy the *requirements* of portion [A].” *Id.* Once again, Judge Rich understood that his portion [A] had not one but multiple “requirements.”

Judge Rich’s opinion in *Gay* rejected Rule 71(b), *inter alia*, for incorrectly incorporating the requirements of his portion [A] of the statute into his portion [B]. 309 F.2d at 773. Upon finding no support for a “best mode” rejection, Judge Rich then addressed the only other possible statutory basis, *i.e.*, a failure to comply with portion [A]. *Id.* By holding that “one skilled in the art would be enabled to make and use appellant’s invention without undue experimentation” (*id.* at 774), the opinion addressed the enablement requirement. However, the opinion in *Gay* had already held that there was no issue of “new matter” (*see* 309 F.2d at 771), so in fact *Gay* did address the separate “written description” requirement. Properly read, *Gay* confirms there are more than two requirements in § 112, ¶ 1, including the “written description” requirement of *Ruschig* and *Barker*.

C. Earlier Versions of the Patent Act Confirm That There Has Always Been a Written Description Requirement Separate from an Enablement Requirement

If § 112, ¶ 1 has a separate written description requirement, it is entirely

irrelevant whether earlier Patent Acts did. Nevertheless, the earlier patent statutes (Blue Br. 8-13) also contained a written description requirement separate from the enablement requirement.

As Ariad acknowledges, the Patent Act did not require claims until 1836. Blue Br. 10. However, the 1790 Patent Act required “a specification in writing, containing a description ... of the thing or things, by him or them invented or discovered, and described as aforesaid.” Act of Apr. 10, 1790, 1 Stat. 109, 110-11, ch. 7, § 2. Such statutory language anticipated the role of claims by requiring a description in writing of what the inventor had alleged invented. The 1790 statute then separately provided that the “specification shall be so particular as ... to enable a workman or other person skilled in the art ... to make, construct, or use the same.” *Id.*

Three years later, the statute was amended to include, *inter alia*, the term “written description” for the first time, although separate claims were still not required. *See* Blue Br. 9 (quoting Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11, § 3). By its terms, the 1793 Patent Act still required “a written description of his invention,” *i.e.*, what the inventor was asserting to be the invention. In *Barker*, Judge Miller cited *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822), as interpreting the 1793 statute as having two purposes:

(1) to make known the manner of constructing the invention in order to enable artisans to make and use it, and (2) to put the public in possession of what the party claims as his own invention in order to ascertain whether he claims anything in common use, or already known, and to protect the public from an inventor “pretending that his invention is more than what it really is.”

559 F.2d at 592 n.4. Notably, although claims were not yet required, the Supreme Court in *Evans* expressly viewed the “notice” purpose as requiring the inventor to put the public “in possession of what he *claims* as his invention” to allow the public “to ascertain if he *claims* any thing in common use.” *See* 20 U.S. at 434.

Directly contradicting *Evans*, *Ariad* characterizes the two purposes of the “written description” in 1793 as (1) distinguishing the prior art and (2) enablement. Blue Br. 9, 17-18. From that premise, *Ariad* then asserts that after claims were required in 1836, the requirement to “distinguish the [invention] from all other things” was deleted and the written description was left with only one purpose—to enable. Blue Br. 10 (citing Act of July 4, 1836, 5 Stat. 117, 119, ch. 357, § 6). However, *Evans* did not tie the object of “put[ting] the public in possession of what the party claims as his own invention” solely to “distinguish[ing] the [invention] from all other things.” Blue Br. 17-18. Instead, the Court explained that the “written description” also served the purposes of

warning others of infringement and of preventing the inventor from “pretending that his invention is more than what it really is.” *See* 20 U.S. at 434. Notably, these distinct and important purposes were not affected or undone by the language deletion cited by Ariad.

The multiple objectives identified in *Evans* can only be upheld by requiring and then holding an inventor to the specification’s original written description of his invention. An inventor has never been entitled to everything not in the prior art or to everything that the specification may enable, but has always been limited to only what the written description tells the public is the invention, provided that such invention is also not in the prior art and is adequately enabled. Moreover, the statutory language on which the Supreme Court’s analysis in *Evans* was truly based did not change when claims began to be required.

The 1836 Patent Act required “a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same.” Blue Br. 10 (citing Act of July 4, 1836, 5 Stat. 117, 119, ch. 357, § 6). The 1870 Patent Act required “a written description of the [invention], and of the manner and process of making, constructing, and using it.” Blue Br. 11 (citing Act of July 8, 1870, 16 Stat. 198, 201, ch. 230, § 26).

Despite requiring claims, each statute still required both a written description of the invention *and* a written description of how to make and use that invention. As Judge Miller recognized in *Barker*, “[e]ssentially the same language has been carried over into the present statute.” 559 F.2d at 593.

Properly traced, the statutory evolution does not support the view that once the Patent Act assigned the notice function to claims, enablement became the sole standard in § 112, ¶ 1 for an adequate disclosure. *See Rochester Denial*, 375 F.3d at 1310 & n.5 (Rader, J., dissenting). Given that the specification had to describe the invention in writing before the Patent Act required claims, that requirement did not change after 1836 because the claims are also part of the specification and thus part of the written description. As shown, the pre-1836 statutory requirement for “a written description of the invention” remained in the post-1836 Patent Acts even after claims were required. Thus, as Judge Rich viewed as established long before *Barker*, every Patent Act has been entirely consistent with the current statutory structure set forth above.

D. The Statutory Requirement That the Specification Describe the Invention Is Not Subsumed Within the Enablement Requirement

After claims were required in 1836, the “invention” referenced in § 112, ¶ 1 (and its post-1836 predecessors) became “the claimed invention.” *See Vas-*

Cath, 935 F.2d at 1560 (“the invention is, necessarily, the subject matter defined in the *claims* under consideration”). Ariad declares there is no “real case ‘where the patent can enable an invention that is not described by the specification.’” Blue Br. 29 n.7. However, where a specification enables more than what was originally claimed, numerous such “real” cases have been reported since the first Patent Act.

In *Barker*, Judge Miller cited *Gill v. Wells*, 89 U.S. (22 Wall.) 1 (1874), as confirming the separate written description requirement. *See* 559 F.2d at 592 n.5. In *Gill*, a patentee obtained a reissue patent for a machine involving a combination of three elements, whereas the original patent was to a combination of four elements. 89 U.S. at 15-26. By 1874, the Patent Act prohibited new matter from being introduced into the specification to ensure that a reissued patent be for the same invention as the original patent. *Id.* at 15-16. As the Court explained, “Congress never intended that a patent ... should be reissued merely to afford the patentee an opportunity to expand the exclusive privileges which it secures, to enable him to suppress subsequent improvements which do not conflict with the invention described in the surrendered patent. *Id.* at 19.

Although believing such examples would be “very few,” the Supreme Court noted that the specification in *Gill* “does not contain the slightest evidence

that the patentee ever made any other combination than that which embodies the four described ingredients.” *Id.* at 23-24. Recognizing that the statutory prohibition against new matter had not been in effect when the reissued patent-in-suit was granted, the Court held that the result was no different under the prior acts, which provided that a reissued patent shall be for the same invention, and further required “a written description of the [invention] and of the manner of making, constructing, and using the same, in such full, clear, concise, and exact terms as to enable any person skilled in the art to make, construct, and use the invention.” *Id.* at 25.

Notably, the Supreme Court in *Gill* did not rely on the enablement requirement or treat it as the only statutory requirement. Instead, the Court stressed that where a patent consists of a combination of old ingredients, “it is of the greatest importance that the description of the combination, which is the invention, should be full, clear, concise, and exact.” 89 U.S. at 26. Undoubtedly, a specification that enabled one to make and use a mechanical device comprising four old elements would have enabled one to make and use a device containing only three of those old elements. Nevertheless, instead of agreeing that the original specification enabled and thus supported the new claim, the Court searched in vain for a description of any other invention in the original patent other than the

combination of all four ingredients. *Id.*

Judge Miller correctly understood *Gill* as holding that the statutory requirement for a written description of the invention provided independent grounds for invalidating a reissued patent which claimed a different invention than was described in the original application, even before the separate statutory “new matter” prohibition. *See* 559 F.2d at 592 n.5. Post-*Gill*, the patent laws have consistently prohibited “new matter” in a reissue application. *See* 35 U.S.C. § 251. However, the statutory language requiring “a written description of the invention” continues to serve the identical purpose outside the reissue context.

Under Ariad’s construction, an applicant could claim anything that the specification enabled, regardless when such enablement is discerned or when the claims based on the enabled subject matter are presented. However, that has never been the law. *See, e.g., U.S. Industrial Chemicals v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 676 & nn.6-11 (1942) (“[It is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification.”); *Miller v. Brass Co.*, 104 U.S. (14 Otto) 350, 352 (1881) (“[I]t must be remembered that the claims of a specific device or combination, and an omission to claim other devices or combinations

apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed.”). Thus, as in *Barker*, this Court should reject the false premise that everything enabled by a specification has necessarily been described as the applicant’s invention.

Moreover, the Supreme Court has never applied only a single “written description” requirement that is measured solely by enablement. Blue Br. 18. Like *Gill*, Supreme Court precedent has many examples of enabled subject matter that was not described as “the invention” by an applicant’s original specification such that new claims directed to that enabled but undescribed subject matter were void. *See, e.g., Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 58-59 (1938) (“Even if those skilled in the art would have known that a piston with webs ... would work most effectively if the webs were laterally flexible rather than rigid, that was not the invention which Gulick described by his references to an extremely rigid web.”); *Mahn v. Harwood*, 112 U.S. 354, 356-61 (1884) (enlarged reissue claims to a baseball cover invalid where specification was unchanged because original “claim actually made operates in law as a disclaimer of what is not claimed”); *Russell v. Dodge*, 93 U.S. (3 Otto) 460, 463-64 (1876) (invalidating reissued patent which omitted “heated fat liquor” ingredient in original patent). Because the Supreme Court has never

limited the written description requirement as now in § 112, ¶ 1 to only enablement, this Court should reaffirm the existence of the separate written description requirement.

II. The Scope and Purpose of the Statutory Written Description Requirement Is To Prevent Applicants and Litigants from Obtaining Claims to Inventions That They Did Not Invent

A. The Written Description Requirement Prevents Applicants and Litigants from Obtaining Priority Based on an Earlier Application That Did Not Describe a Later-Claimed Invention

One essential purpose of the written description doctrine is “that a patent cannot claim priority to earlier applications if it includes new matter not present in those earlier disclosures.” *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004) (citing *Vas-Cath*).

The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise, applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention. *See* 35 U.S.C. § 132.

363 F.3d at 1255. Thus, restricting an applicant to the original written description of the invention has long been an important purpose for the statutory written description requirement, which should not be undermined or eliminated through unwarranted statutory reinterpretation.

Even by 1822, the Supreme Court in *Evans* understood that requiring a “written description of the invention” protected the public from an inventor “pretending that his invention is more than it really is.” 20 U.S. at 434. In 1881, the Court again decried amendments or reissues being used to encompass the subsequent work or improvements of others:

It will not do for the patentee to wait until other inventors have produced new forms of improvement, and then, with the new light thus acquired, under pretense of inadvertence and mistake, apply for such an enlargement of his claim as to make it embrace these new forms. Such a process of expansion carried on indefinitely, without regard to lapse of time, would operate most unjustly against the public, and is totally unauthorized by the law.

Miller, 104 U.S. at 355. Consistent with that purpose, § 251 prohibits seeking broadened claims after two years and prohibits any “new matter” from being added to a reissue application. See *In re Wilder*, 736 F.2d 1516, 1520-21 (Fed. Cir. 1984). Similarly, § 132 prohibits an amendment from introducing “new matter” into the disclosure of an invention, a statutory prohibition which *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981), held is properly enforced under § 112, ¶ 1.

In PTO interferences, written description is a “threshold issue” that is addressed before the merits because, absent an adequate written description, the opponent lacks standing and cannot establish priority. *Berman v. Housey*, 291

F.3d 1345, 1351 (Fed. Cir. 2002); *see* 37 C.F.R. § 41.201 (2005). The PTO utilizes written description (but not enablement) as a threshold issue to prevent applicants from copying claims to provoke interferences regardless of whether they actually invented the same subject matter. 69 Fed. Reg. 49,960, 49,991 (Aug. 12, 2004). Clearly, that important purpose in resolving competing priority claims should not be undone.

Apart from suggesting without support or explanation that whether an earlier-filed specification identified the same invention as later-added or amended claims is “an aspect of enablement” (Blue Br. 23), Ariad does not seriously dispute that the written description requirement is properly applied against later-filed or amended claims seeking the benefit of an earlier-filed specification. *See* Blue Br. 31. At a minimum, this Court should reaffirm its precedent enforcing the statutory written description requirement to police new matter violations and priority contests, and to enforce the traditional policies underlying the “possession” test.

B. This Court Should Clarify When Claims Are Invalid for Violating the Written Description Requirement and When Such Invalidity Results Under Another Statutory Provision

Patent applicants or litigants can seek the benefit of the filing date of an earlier application under either 35 U.S.C. § 119 or § 120 for claims filed in a

later application. *See Vas-Cath*, 935 F.2d at 1560. However, if what is later claimed was not “disclosed in the manner provided by [§ 112, ¶ 1],” including its written description requirement, then § 120 prevents the later claim from being entitled to the filing date of the earlier application for purposes of priority.

Where a later claim is not entitled to an earlier priority date under § 120 because its predecessor application does not satisfy the written description requirement for the later-claimed subject matter, the later claim is often invalid under 35 U.S.C. § 102 due to intervening prior art or a statutory bar. In that situation, the invalidity results from anticipation under § 102 rather than from the written description violation itself. *See, e.g., PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306-11 (Fed. Cir. 2008); *Chiron*, 363 F.3d at 1252; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158-60 (Fed. Cir. 1998).

In *PowerOasis*, this Court explained that different claims of a CIP application may receive different effective filing dates because the new subject matter filed in the CIP does not receive the benefit of the parent’s filing date. *See* 522 F.3d at 1306 (and case cited). Under *Reiffin v. Microsoft*, 214 F.3d 1342, 1346 (Fed. Cir. 2000), an analysis of the “written description” disclosure in ancestor applications is appropriate only when benefit of an earlier filing is sought under § 120. This Court explained that where claims originally filed in a

later application are not supported by an ancestor application in terms of § 112, ¶ 1, the later claims are not invalidated, they simply do not receive the benefit of the earlier application's filing date. 214 F.3d at 1346.

The same is not true where an applicant, without filing a CIP application, adds new claims or broadens claims to encompass subject matter not adequately described in the originally-filed specification. *See Rasmussen*, 650 F.2d at 1214 (“[t]he proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure ... is § 112, first paragraph, not § 132”). Thus, in *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1118-20 (Fed. Cir. 2001), the applicant had not filed a CIP application, so he could not rely on any alternative filing date for newly-added claim 2, which was therefore held invalid because the originally-filed specification did not describe what claim 2 was later claiming to be part of the invention.

This distinction explains the written description invalidity conclusion in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998), *aff'g-in-part*, 939 F. Supp. 98, 105 (D. Mass. 1996), a decision left unaddressed by Ariad. Gentry's specification described a one-armed sectional sofa with two reclining chairs and control means on a console between the recliners. 939 F.

Supp. at 105. After filing, twelve claims were amended so as not to limit the control means location to the console, apparently in response to competitive products introduced with controls not on the console. *Id.* Notably, there was no contention that the specification did not enable putting the controls either on or off the console. Nevertheless, this Court held the twelve broadened claims were invalid under § 112, ¶ 1 because the original disclosure described the invention only as having controls on the console. 134 F.3d at 1478-80.

Just as one can originally claim less than everything that the specification may enable, this Court in *Gentry* rejected the proposition “that an applicant can broaden his claims to the extent that they are effectively bounded only by the prior art.” 134 F.3d at 1480. As in *TurboCare*, an applicant cannot add or amend claims that are broader than the specification’s original description without filing a CIP application. As recognized in *Reiffin*, the invalidity for lack of written description in *Gentry* resulted because, absent a CIP application, there was no prior application and the “original disclosure” lacking a description of the later-claimed invention was that of the issued patent. 214 F.3d at 1346.

Consistent with *Rasmussen*, the claims in *Gentry* that had been amended to encompass the non-console subject matter not originally described in the underlying specification were invalid under § 112, ¶ 1. Similar written

description invalidity holdings include *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F.3d 1368, 1376-79 (Fed. Cir. 2009) (asserted spike-optional claims held invalid under the written description requirement where specification described only medical valves with spikes); *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235, 1247-48 (Fed. Cir. 2002) (added claim 33 to a spaced, sequential application of two chemicals invalid for violating written description requirement where original application only indicated mixing the chemicals); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1324-28 (Fed. Cir. 2000) (claims in later '360 patent invalid for written description violation where specification of earlier '577 patent did not disclose the C_{\max}/C_{24} limitation as being within the invention).

In each case, including *Gentry*, the applicant filed new or amended claims to cover the subject matter later accused of infringement while relying on the filing date of the original application lacking a written description of the later-claimed invention. *See, e.g., PIN/NIP*, 304 F.3d at 1239 (claim 33 added after inventors learned after their filing date that defendant had publicly-disclosed the subsequently-accused method). Because the later claims were not added in a CIP application, the claims were invalid under § 112, ¶ 1. If the later claims had been added in a CIP application, such claims would not get the benefit of an

earlier filing date under § 120, but the end result would still be invalidity because the accused product or method would necessarily anticipate the later-filed claim. *See Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (that which infringes if later, anticipates if earlier).

This Court's precedent could benefit from being clarified to make clear the circumstances under which "written description" violations lead to invalidity conclusions under § 102 for intervening prior art or statutory bars and when the invalidity results directly under § 112, ¶ 1. The same distinctions should similarly be maintained for PTO written description rejections in the non-reissue context. *See, e.g., Hyatt v. Doll*, 576 F.3d 1246 (Fed. Cir. 2009) (upholding the PTO's rejection of 79 claims for lack of written description). In each of these contexts, the proper purpose of the statutory written description requirement is to prevent an applicant from claiming more than what he has invented and described. *See O'Reilly v. Morse*, 56 U.S. 62, 120-21 (1853).

C. The Written Description Requirement Applies Equally to All Types of Claims, Inventors, and Technologies

Ariad's petition should have been limited to whether this Court's written description precedent based on *Lilly* should apply against "original" claims; *i.e.*, unamended claims that were initially-filed in the earliest application to which the

applicant is asserting priority. Given that the “written description” requirement had been applied to original claims before *Lilly* was decided (*see* Red Br. 33), this Court should not hold that an original claim can never violate the written description requirement merely because such claims have been described to “constitute their own description.” *In re Koller*, 613 F.2d 819, 823 (CCPA 1980).

If an original claim, together with the rest of the specification, cannot establish with reasonable clarity to those skilled in the art that, as of the filing date sought, that the inventor was in possession of the invention as claimed or that the inventor had actually invented what is claimed, then an original claim will not satisfy the written description requirement. *See Vas-Cath*, 935 F.2d at 1563-64. Just as the statute should not be reconstrued to eliminate the written description requirement entirely, a holding that original claims can never violate that requirement would be equally overbroad.

Other than rearguing that a separate written description requirement does not exist apart from enablement, Ariad offers no rationale for undoing *Lilly*. Merely listing the differences between enablement and written description (Blue Br. 45-46) proves nothing other than there are two separate statutory requirements that serve different purposes measured at different times from

different perspectives based on different evidence. Ariad also contends that *Lilly*'s written description analysis applies a "super-enablement" standard (Blue Br. 37-38), but it concedes that the holdings in *Lilly* and *Rochester* were correct without identifying any "super" deviation from established enablement law necessary to reach that result. Blue Br. 34-35. It may be true that each "written description" invalidity decision based on *Lilly* also could have been rendered on alternative grounds. However, statutory grounds of invalidity are not mutually exclusive, and do not have to be resolved in any particular order.

Behind its professed desire to clarify the law, Ariad really just wants to eliminate an entire statutory defense to make it easier for entities like itself to obtain and enforce broad claims to future developments that they did not describe or invent. As shown by *Evans* and *Morse*, that has never been the law. Moreover, the law must apply equally to all types of inventors, inventions, and technologies. Thus, the written description requirement should continue to be applied whenever appropriate to prevent applicants from filing claims (original or otherwise) that undeservedly seek to preempt the future, to cover all future results, or to encompass all means for achieving a specified function.

CONCLUSION

The Court should answer its first *en banc* question “yes,” and reaffirm its precedent upholding and enforcing the important purposes for the written description requirement independent of enablement, including ensuring that claims added after an application’s original filing date are supported by the original disclosure and requiring the specification, including its claims, to convey with reasonable clarity that the inventor was in possession of and had actually invented the claimed subject matter. For the reasons stated by the panel, WLF requests that the Court reverse the district court judgment in part and hold that four claims of the ’516 patent are invalid for lack of written description.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation.

Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced CG Times type. According to the word processing system used to prepare this brief (WordPerfect 12.0), the word count of the brief is 6,995, not including the certificate of interest, table of contents, table of authorities, certificate of service, and this certificate of compliance.

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of November, 2009, two copies of the foregoing brief of *amicus curiae* WLF in support of Defendant-Appellant were deposited in the U.S. mail, with first-class postage affixed, addressed as follows:

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