

IN THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees/Petitioners,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant/Respondent.

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS, CASE NO. 02-CV-11280,  
JUDGE RYA W. ZOBEL

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**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE  
ON REHEARING EN BANC  
IN SUPPORT OF RESPONDENT**

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**INTEREST OF THE UNITED STATES**

The United States respectfully submits this amicus brief in response to the Court's invitation, see Rehearing Order at 3, and pursuant to Fed. R. App. P. 29(a). The United States Patent and Trademark Office ("USPTO") applies the requirements of 35 U.S.C. § 112, ¶ 1 to every utility patent application it examines. Petitioners' arguments, if accepted, would repudiate more than two centuries of law and practice

under the federal patent laws, require significant changes in USPTO's public guidance and examination procedures, and necessitate retraining more than six thousand patent examiners.

## QUESTIONS PRESENTED

1. Whether 35 U.S.C. § 112, paragraph 1, contains a written-description requirement separate from the enablement requirement.
2. If a separate written-description requirement is set forth in the statute, what is the scope and purpose of that requirement?

## ARGUMENT

### I. SECTION 112, PARAGRAPH 1 REQUIRES A WRITTEN DESCRIPTION OF THE INVENTION DISTINCT FROM ENABLEMENT.

The essential function of the specification is to describe what is claimed. A complete and exact description of the claimed invention is the *sine qua non* of the patent system: it allows USPTO to examine applications, the courts to construe claims, and the public to recognize and avoid the boundaries of the patentee's exclusive rights. As one commentator observed more than a century ago: "The specification is the most important portion of the application. Not only does it serve as the basis of all the proceedings in the Patent Office and thus determine the right of the inventor to a patent, it also becomes a portion of the patent when granted, and as such fixes and defines the rights of the inventor and the public as against each other."

2 Robinson, The Law of Patents for Useful Inventions § 480, at 69 (1890). The Supreme Court has thus repeatedly recognized that the function of the written description is not merely to enable, but also to describe the claimed invention itself and thereby provide notice to the public of the boundaries of the patentee's rights. See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002); Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 58-59 (1938); Permutit Co. v. Graver Corp., 284 U.S. 52, 60 (1931); Gill v. Wells, 89 U.S. 1, 25-26 (1874); Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34 (1822).

To construe Section 112, ¶ 1 as a bare enablement requirement would defy the text and history of the statute and disregard nearly two hundred years of judicial and administrative interpretation. The first paragraph of Section 112 requires that a patent applicant must not only teach others how to make and use the invention, but also describe in writing *the actual invention itself*. See 35 U.S.C. § 112, ¶ 1 (specification must include “a written description of the invention” in addition to “the manner and process of making and using it”). This basic requirement is as venerable as the patent system and remains instrumental to its operation. Petitioners identify no basis for discarding it now.

**A. The Patent Laws Have Always Required a Complete and Exact Description of the Invention.**

The plain language of Section 112, ¶ 1 makes explicit what common sense would suggest: the specification of a patent must describe the actual thing or process that is patented. The statute provides:

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. The Act thus instructs inventors seeking federal patent protection not merely that they must explain how to make and use their invention, but also that they must describe the invention itself. Section 112’s careful distinction between a “written description of the invention” and a description of the “manner and process of making and using it” is of “ancient lineage.” In re Barker, 559 F.2d 588, 594 (CCPA 1977) (Rich, J., concurring). The history and interpretation of this “ancient” distinction demonstrate that enablement has never been the sole measure of the written description in a patent.

1. As petitioners acknowledge, the Patent Act of 1790 required more than bare enablement. The statute required the inventor to supply “a description, accompanied with drafts or models \* \* \* of the thing or things, by him or them invented or discovered,” that was sufficient “*not only* to distinguish the invention or discovery

from other things before known and used, *but also* to enable a workman or other person skilled in the art or manufacture \* \* \* to make, construct, or use the same.” Act of April 10, 1790, ch. 7, § 2, 1 Stat. 109, 110-111 (emphases added). From the outset of the patent system, therefore, the purpose of the written description was not merely to enable, but also to provide notice to the public of the boundaries of the claimed invention by “distinguish[ing] the invention or discovery from other things before known and used.”

In 1793, Congress substantially reconfigured the patent system, moving from an examination system to a simple registration scheme. Nonetheless, Congress preserved the disclosure requirements from the 1790 statute. The new Act required:

a written description of [the] invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science \* \* \* to make, compound, and use the same.

Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321-22. In construing this provision in the Evans case, the Supreme Court explained that the specification required by the 1793 Act had “two objects.” 20 U.S. (7 Wheat.) at 433. The first was to “enable artizans to make and use” the invention. Id. at 433-34. But the second, the Court explained, was distinct from enablement:

The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim any thing that is in common use, or is already known, and to guard against prejudice or

injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Id. at 434. It was on this latter ground that the Court found the patent asserted in Evans deficient: although there was no dispute that the invention was enabled, see ibid., the patentee had failed to identify his improvement with specificity. See id. at 435; see also Grant v. Raymond, 31 U.S. (6 Pet.) 218, 247 (1832) (Marshall, C.J.) (the 1793 Act “requires, as preliminary to a patent, a correct specification and description of the thing discovered”).

2. None of this is controverted. In petitioners’ view, however, the 1836 Act, which restored the examination system and introduced the first requirement for claims, eliminated the “written description of the invention” as a requirement distinct from enablement and relegated all public-notice functions of the specification to the claims. Ariad Br. 10-13.

This contention is untenable. Although the 1836 Act dropped the express reference to “distinguish[ing] the [invention] from all other things before known,” Congress specifically *retained* the requirement for a “written description of [the] invention or discovery,” separate and apart from the “the manner and process of making, constructing, using, and compounding the same.” See Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119. Petitioners offer no explanation for Congress’s preservation of this dichotomy, which is difficult to reconcile with their insistence

that “in the 1836 Act, the written description no longer served to distinguish the invention from prior art.” Ariad Br. 11. Petitioners cite nothing in the legislative history of the 1836 Act suggesting that Congress sought to abrogate Evans or otherwise dilute the disclosure requirements of the patent laws. Indeed, it is particularly unlikely that Congress intended such a change in the 1836 Act, which abolished the registration scheme created under the 1793 statute and established the foundations of the modern examination system — thereby placing on the government the burden of determining whether applicants had disclosed a patentable advance over the prior art.

Petitioners’ construction of the 1836 Act, moreover, rests on a false distinction between the claims and the specification. Then as now, the claims formed part of the applicant’s written specification. Cf. In re Gardner, 480 F.2d 879 (CCPA 1973). Under the 1836 Act, the claim requirement appeared merely as the final clause of the sentence establishing the scope of the required written description. See 5 Stat. 119. It consequently makes no sense to argue that “[f]rom 1836 onwards, the function of defining the patented invention was assigned to claim(s)” but “the written description no longer served to distinguish the invention from prior art.” Ariad Br. 10, 11. By retaining the requirement for a “written description of the invention” and adding an additional requirement for written claims as part of that description, Congress

*enhanced*, rather than diminished, the obligation of inventors to describe their inventions with particularity.

This is precisely how the Supreme Court interpreted the 1836 Act. In Miller v. Bridgeport Brass Co., 104 U.S. 350 (1881), after discussing the written-description requirement under the 1793 Act, the Court stated: “This careful and elaborate requirement was substantially repeated in the sixth section of the act of 1836, with this addition: ‘And shall particularly specify and point out the part, improvement, or combination which he claims as his own invention or discovery.’ Although it had been customary to append a claim to most specifications, this was the first statutory requirement on the subject.” Id. at 353-54. Contrary to petitioners’ interpretation, therefore, the Supreme Court construed the claim requirement adopted in the 1836 Act as an “addition” to — rather than a dilution of — the written-description requirement of the 1793 statute.

3. The 1870 Act, in turn, preserved these expanded disclosure rules, including separate requirements for a “written description of the [invention]” and a description “of the manner and process of making, constructing, compounding, and using it.” Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201.

In interpreting this provision, the Supreme Court repeatedly distinguished between the patentee’s obligation to describe his invention and his obligation to enable others to make and use it. In Gill v. Wells, 89 U.S. 1 (1874), for example, the

Court held invalid a reissue patent in which the patentee sought to claim a combination that he had failed to describe in the original specification. The Court emphasized that “the requirement of the Patent Act that the invention shall be fully and exactly described” served three “great ends,” of which enablement was only one: “(1.) That the government may know what they have granted and what will become public property when the term of the monopoly expires. (2.) That licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention. (3.) That other inventors may know what part of the field of invention is unoccupied.” Id. at 25-26. The reissue patent, the Court held, was invalid because the original specification failed to describe what the reissue patent claimed. See id. at 26.

Likewise, in Permutit Co. v. Graver Corp., 284 U.S. 52 (1931), the Court explicitly contrasted the description requirement with enablement. The patent at issue concerned an improved apparatus for softening water. The only asserted point of novelty in the claimed apparatus was the use of a “free” bed of zeolite (a type of hydrated silicate useful for softening water) rather than a “locked” bed; the “free” arrangement permitted improved water circulation among the zeolite material and, thus, more effective softening. Id. at 56. Although the drawings in the patent appeared to depict a “free” bed, neither the claims nor the specification described or referred to such a structure. The Court held this lack of disclosure fatal, regardless

whether the drawings would have enabled others to make and use the improved apparatus:

The statute requires the patentee *not only* to explain the principle of his apparatus and to describe it in such terms that any person skilled in the art to which it appertains may construct and use it after the expiration of the patent, *but also* to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

Id. at 60 (emphases added). The Court held that the patent was “void” because “the patentee has thus failed to give in the specification ‘a written description.’” Id. at 58.<sup>1</sup>

And in Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47 (1938), the Court invalidated a patent for a piston in an internal-combustion engine for lack of written description, turning aside an express objection that the disclosure was enabling. The original specification taught the use of an “extremely rigid” web around the piston, but when became clear from the marketplace that a flexible web was more advantageous, the patentee amended the patent to claim a flexible web instead. Id. at 55-56. The patentee argued that this amendment was “a permissible clarification” of his original specification in light of what would have been “well known to those skilled in the art.” Id. at 57-58. The Supreme Court rejected this reasoning and invalidated the patent. The Court did not question the patentee’s

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<sup>1</sup> The Court additionally held that the patentee had failed “particularly to point out and distinctly claim the free zeolite bed.” 284 U.S. at 58.

argument that the specification was enabling, but held the amended patent void for lack of adequate description:

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 [the patentee] described* by his references to an extremely rigid web.

Id. at 58-59 (emphasis added). The Court stressed: “If invention depends on emphasis of one quality over the other, \* \* \* the statute requires that emphasis to be revealed to the members of the public, who are entitled to know what invention is claimed.” Id. at 58.

4. It was against this backdrop that Congress recodified the patent laws in 1952. Although the 1952 Act divided the earlier provision into separate paragraphs “to emphasize the distinction between the description and the claim or definition,” H.R. Rep. No. 82-1923, at 19 (1952), Congress retained without change the venerable requirement that the applicant provide a “written description of the invention” distinct from enablement. 35 U.S.C. § 112, ¶ 1. Nothing in the new statute or its legislative history indicated that Congress intended to abrogate cases such as Scriber-Schroth, Permutit, and Gill, or to break from more than a century of accumulated decisions interpreting the disclosure requirements of the patent laws. To the contrary, “Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute

without change.” Forest Grove Sch. Dist. v. T.A., 129 S.Ct. 2484, 2492 (2009) (quoting Lorillard v. Pons, 434 U.S. 575, 580 (1978)). Petitioners have identified no basis for rebutting that presumption here.

**B. The Plain Language of the Statute Distinguishes Between Written Description and Enablement.**

Even aside from Congress’s consistent distinction between the “written description of the invention” and the description “of the manner and process of making and using it,” the plain terms of the statute contemplate a written description of the invention itself, entirely apart from enablement.

First, Congress specifically required a “written description of the *invention*.” 35 U.S.C. § 112, ¶ 1 (emphasis added). As the Supreme Court has observed, “[t]he word ‘invention’ must refer to a concept that is complete.” Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 66 (1998). Indeed, this Court has explained that the “touchstone” of invention is conception, which is “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) (citation omitted). It is this “complete and operative invention” that Section 112 requires the patent applicant to describe in writing — not merely enough of the invention to render the remainder obvious to others skilled in the art. See Lockwood v. American Airlines, Inc., 107 F.3d 1565,

1572 (Fed. Cir. 1997) (the statute requires “describing *the invention*, with all its claimed limitations, not that which makes it obvious” (emphasis in original)); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997); In re Barker, 559 F.2d at 593.

The first paragraph of Section 112 must also be construed in pari materia with the sixth paragraph, which contains the only other reference in Section 112 to the “descri[ption]” of the invention. Paragraph six was enacted in response to the Supreme Court’s decision in Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1 (1946), which held invalid a patent that claimed the crucial element of the invention in purely functional terms. See id. at 9-14. Congress responded by authorizing certain functional claims expressed in a means-plus-function format, but instructed that such claims “shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” 35 U.S.C. § 112, ¶ 6. This formulation is telling, for it reflects Congress’s expectation that the specification would in fact “describe[]” the “structure, material, or acts” that “correspond[]” to the claimed function, irrespective of whether the specification would otherwise enable those skilled in the art to make and use the invention. Congress in 1952 had every reason to regard that expectation as legitimate, given the settled historical understanding of the disclosure requirements of the patent laws.

Similarly, Section 112, ¶ 1 must be construed in light of 35 U.S.C. § 162, which was enacted in 1930 as part of the Plant Patent Act. As the Supreme Court observed in Diamond v. Chakrabarty, 447 U.S. 303 (1980), Congress passed the Plant Patent Act partly out of concern that plants were not amenable to the “written description requirement” of the patent laws “[b]ecause new plants may differ from old only in color or perfume” — qualities not easily captured in writing. Id. at 312. Congress accordingly “relaxed the written description requirement” for plant patents, ibid., by providing that the written description of a plant need only be “as complete as is reasonably possible.” 35 U.S.C. § 162. This provision — and its implicit comparison with the stricter requirements of Section 112, ¶ 1 — reflects Congress’s recognition in 1930 that a “complete” description of the claimed invention is a basic requirement of the patent laws, irrespective of enablement.

### **C. Petitioners’ Interpretation Is Unpersuasive.**

Petitioners argue that the grammatical structure of Section 112 creates a single description requirement whose sole measure is enablement.<sup>2</sup> Ariad Br. 2-7. But it is

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<sup>2</sup> Petitioners mistakenly contend that “the United States took a similar position regarding the proper statutory construction of § 112, ¶ 1” in its amicus brief supporting rehearing en banc in Enzo. Ariad Br. 4. In fact, as the government’s brief as a whole made clear, the United States took no position in that case regarding the correct interpretation of Section 112, but simply urged the Court to grant rehearing to “provide inventors, the public, and the USPTO with an authoritative interpretation of the provision.” USA Amicus Br., No. 01-1230, at 9. Four years later in Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006), the United

petitioners who overread the statutory text. Section 112 requires a “written description” and provides that the required description must “enable any person skilled in the art \* \* \* to make and use” the invention. But nothing in the statute requires petitioners’ additional inference that *any* description that enables the invention will suffice. That inference disregards two centuries of judicial and administrative interpretation and collapses Congress’s careful distinction in the statutory text between a “written description of the invention” and a description of the “manner and process of making and using the same” — a dichotomy that, as noted, Congress has preserved in every iteration of the patent laws since 1790.

Indeed, petitioners’ argument depends on the assumption that Congress meant nothing of significance by this distinction. Petitioners are explicit in their insistence that the phrase “written description of the invention” has no independent content: “a patent applicant is subject to but a single ‘written description’ requirement, the measure of whose sufficiency is enablement.” *Ariad Br.* 18. On this view, *any* description that enables others to make and use the invention is sufficient, whether or not it describes “the invention” itself. Thus, for example, if an applicant’s description

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States specifically endorsed the proposition that “[i]n addition to enabling the invention, the specification must contain a ‘written description of the invention,’ 35 U.S.C. 112, that conveys to a person skilled in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed.” *USA Amicus Br., LabCorp*, at 8 (alterations omitted).

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. Cf. In re Ruschig, 379 F.2d 990, 993-96 (CCPA 1967); In re DiLeone, 436 F.2d 1404, 1405 n.1 (CCPA 1971).

Likewise, under petitioners’ construction of the statute, any 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. Such abusive tactics — which allow opportunistic claimants to withdraw from the public domain entire fields of nascent scientific endeavor while setting down a priority stake for all future work in the field — cannot properly be attributed to the statutory design.<sup>3</sup> As the Supreme Court has

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<sup>3</sup> This point is well illustrated by University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004). Rochester’s specification described how to identify the COX-2 selective inhibitors encompassed by its claims, but failed to describe any specific molecules having that function. Researchers later learned, however, that there is a great deal of structural variability in COX-2 selective inhibitors. See Botting, Hla, & Simmons, Cyclooxygenase Isozymes: The Biology of Prostaglandin

stressed, “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Brenner v. Manson, 383 U.S. 519, 536 (1966); see also Eli Lilly, 119 F.3d at 1568; H. Ward Leonard, Inc. v. Maxwell Motor Sales Corp., 252 F. 584, 590 (2d Cir. 1918) (L. Hand, J.) (“A patent is the reward of a tested contribution to the art, not of a pregnant surmise or a promising hypothesis.”). By requiring a written description of the invention itself, Section 112 limits patent protection to those who actually perform the difficult work of “invention” — that is, conceive the complete and final invention, including all of its claimed limitations, and actually or constructively reduce it to practice — and disclose the fruits of that effort to the public. It is this sort of written description, and not merely any description that enables, that is “the *quid pro quo* of the right to exclude.” J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 142 (2001) (citation omitted).

Even petitioners flee from the consequences of their own interpretation of the statute. Petitioners argue that Section 112 requires not only a description of how to make and use the invention, but also a description of “*what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use.” Ariad Br. 30 (petitioners’ emphasis). On this basis, petitioners distinguish cases such as Jepson v. Coleman, 314 F.2d 533 (CCPA 1963), In re Sus, 306 F.2d 494 (CCPA

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Synthesis and Inhibition, 56 Pharm. Rev. 387, 407 (2004). Had Rochester’s claims been held valid, they would have covered these later-developed compounds.

1962), and In re Moore, 155 F.2d 379 (CCPA 1946), as “merely stand[ing] for the undisputed proposition that the claims must be directed to an invention that is identified in the specification.” Ariad Br. 23. Likewise, petitioners contend that In re Ruschig, widely recognized as one of the CCPA’s seminal cases on the written-description requirement, “was 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.” Ariad Br. 24.

These concessions give away the store. Whether an otherwise-enabled claim is directed to something actually “identified in the specification,” or “something that the applicant had invented,” is the essence of the written-description inquiry. Indeed, the similarity between the enablement test advocated by petitioners and this Court’s written-description jurisprudence is striking. Compare Ariad Br. 23-24 with, e.g., Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.” (citation omitted)); Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345-46 (Fed. Cir. 2000) (“The purpose of [the written-description requirement] is to ensure that the scope of the right to exclude \* \* \* does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.”). That petitioners prefer to characterize this inquiry as a component of enablement, rather than as a distinct written-description

requirement, is irrelevant — nothing turns on the doctrinal labels. The point is that the Patent Act requires, and always has required, more than bare enablement.

**II. A “WRITTEN DESCRIPTION OF THE INVENTION,” DISTINCT FROM ENABLEMENT, IS ESSENTIAL TO THE OPERATION OF THE PATENT SYSTEM.**

Even aside from the text and history of Section 112, the requirement for a “written description of the invention” states a practical necessity for the operation of the patent system. As this Court has noted, written description and enablement “usually rise and fall together.” LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). But in the unusual case in which an enabling description fails to describe the claimed invention, there should be no doubt regarding where the requirement of the statute lies.

In the practical experience of the USPTO, which applies the requirements of Section 112, ¶ 1 to more than 400,000 patent applications each year, the written-description requirement serves an indispensable role in the administration of the patent system that, at least as presently interpreted, no other provision of Section 112 adequately serves. USPTO’s examination guidelines set out clearly what is necessary to satisfy the written-description requirement. See 66 Fed. Reg. 1099 (Jan. 5, 2001). Those guidelines make clear that, contrary to the claims of amici and others, there is no mechanical requirement for a recitation of complete DNA sequences or chemical structures, nor is there any requirement to identify every species in a genus. See, e.g.,

id. at 1106. What is required is a description of the invention itself, in sufficient detail to convey to others skilled in the art that the applicant in fact invented what is claimed. This simple requirement — that applicants must describe the invention they claim — remains as fundamental to the operation of the patent system now as it was in 1790.

**A. A Written Description of the Invention Is Necessary To Permit USPTO To Perform Its Basic Examination Function.**

A complete description of the claimed invention is necessary for USPTO to perform its examination function under 35 U.S.C. § 131. As the Supreme Court explained in Hogg v. Emerson, 47 U.S. 437 (1848), the Act requires a written description of the invention so that “the officers of the government might at the outset have before them full means to examine and understand the claim to an invention better, and decide more judiciously whether to grant a patent or not.” Id. at 479-80; see also Gill, 89 U.S. at 25 (one of the “great ends” of the description requirement is that “the government may know what they have granted”). Where an applicant fails to provide a concrete written description of the actual thing or process claimed, USPTO lacks any reliable means “to judge correctly whether the matter claimed is new or too broad.” Hogg, 47 U.S. at 484; see 1 Schlicher, Patent Law, Legal and Economic Principles, § 7:45, at 7-138 (2d ed. 2008) (USPTO “needs an

accurate, written description of the invention and the rights asserted to determine whether a patent should be issued and what the scope of the rights should be”).

This problem is especially acute when inventions are claimed in functional terms, as when a biological or chemical molecule is claimed solely by reference to its function or effect. See 66 Fed. Reg. at 1105-1106. Though such claims may be enabled, 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. By insisting that each applicant provide a full and exact “written description of the invention” as part of the specification, Congress protected the ability of USPTO to perform its essential function of distinguishing patentable inventions from the prior art. Indeed, this is one of the original and enduring purposes of the written description requirement: to “distinguish the invention or discovery from other things before known and used.” Act of 1790, ch. 7, § 2; accord Eli Lilly, 119 F.3d at 1568 (written description must be “sufficient to distinguish” the claimed invention “from other materials”).

Likewise, the written-description requirement of Section 112 permits both USPTO and the courts to police the myriad rules of priority on which the orderly administration of the patent laws depends. See 35 U.S.C. §§ 102(b), 102(g), 119, 120, 365. Priority is one of the organizing principles of the patent system; the

resolution of priority questions commonly determines patentability. The written-description requirement permits USPTO and the courts to resolve priority disputes in an expedient and judicially reviewable fashion by comparing the specifications of the patents or applications in question. Similarly, “[e]very patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office.” Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 977 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing); see 35 U.S.C. § 132. “Adequate description of the invention guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.” Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991) (citation omitted).

The “written description of the invention” required by Section 112 is also crucial to the patent system after the patent issues. The first step in any infringement analysis is to construe the claims, and “[t]he claims of a patent are always to be read or interpreted in the light of its specifications.” Schriber-Schroth v. Cleveland Trust Co., 311 U.S. 211 (1940); see generally Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). The public is entitled to assume that the invention defined by the claims is described in the specification, and to organize its conduct accordingly. A specification that enables but fails to describe the claimed invention impedes the

ability of the public and the courts, including this Court, to “evaluate whether the Patent and Trademark Office correctly issued the patent.” 1 Schlicher, Patent Law, § 7:45, at 7-138.

**B. The Written-Description Doctrine Provides a Critical Tool for Cabining Overbroad Claims.**

The written-description requirement also provides a critical tool for USPTO and the courts to cabin overbroad claims. Claims with limitations expressed in functional terms (often called “functional claims”), for example, define an invention in terms of “what the invention does, rather than what the invention is.” In re Swinehart, 439 F.2d 210, 213 (CCPA 1971). Functional claims are not categorically impermissible. See, e.g., 35 U.S.C. § 112, ¶ 6. Where the protections of paragraph six do not apply, however, functional claims may embrace “any and all embodiments which perform the recited function.” Swinehart, 439 F.2d at 213. Even where the terms of the claim are definite and the known embodiments are enabled, such claims can deprive the public of fair notice regarding the scope of the patentee’s rights because it is frequently impossible to determine what other potential compounds or molecules (for example) may share the recited function. See General Elec. Co. v. Wabash Appliance Co., 304 U.S. 364, 371-75 (1938); Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245, 256-257 (1928).

Similar problems can occur when applicants seek to claim vast genera of chemical or biological compounds or other subject matter based on the disclosure of a few isolated species. In such circumstances neither USPTO nor the public may have any practical means for ascertaining the features common to all members of the genus — and, thus, the boundaries of the claimed invention. See 66 Fed. Reg. at 1106. If granted, moreover, such claims may effectively foreclose others from pursuing “efforts to discover a better specimen of [the] class” than the applicant has actually invented and described. Consol. Elec. Light Co. v. McKeesport Light Co. (The Incandescent Lamp Patent), 159 U.S. 465, 476 (1895).

Although USPTO and the courts have addressed overbroad claims under a variety of rubrics, the fundamental problem with such claims is that they sweep beyond what is described in the specification. The requirement in Section 112 for a “written description of the invention” provides an explicit statutory basis for rejecting such claims and thereby ensuring that “the scope of the right to exclude \* \* \* does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” Reiffin, 214 F.3d at 1345-46.

### **C. The Written-Description Requirement Applies To Original Claims**

As the foregoing discussion suggests, the vital ends served by the written description doctrine are not limited to policing priority disputes. Nor is there any textual basis for limiting the doctrine in this fashion. Rochester, 358 F.3d at 924;

Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1328 (Fed. Cir. 2003) (Bryson, J., concurring); see Lilly Br. 33-35. Because original claims usually describe themselves, questions of sufficiency of description have tended to arise in the context of amended claims. But original claims are not uniquely immune from failures of description, especially when the claims are framed solely in functional terms. See 66 Fed. Reg. at 1105. “The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy” the statutory requirement to describe the invention that is claimed. Enzo, 323 F.3d at 968.

Nor, contrary to petitioners’ argument, is this principle of recent vintage. The Supreme Court in the Morse case, for example, specifically rejected the contention that Morse’s eighth claim described itself. O’Reilly v. Morse, 56 U.S. 62, 119-20 (1853). Both the Supreme Court and the CCPA, moreover, applied written-description principles to invalidate original claims long before this Court’s decision in Lilly. See, e.g., Permutit, 284 U.S. at 58; In re Sus, 306 F.2d 494 (CCPA 1962); In re Moore, 155 F.2d 379 (CCPA 1946).

**D. Written-Description Principles Are Firmly Embedded in the Operation of the Patent System.**

Finally, even if Section 112 could have been construed to require enablement only, the plain fact is that it has not been. The patent laws have been understood to require more than bare enablement since the inception of the patent system. This

Court alone, by the government’s count, has issued at least twenty precedential decisions distinguishing between written-description and enablement. When CCPA cases drawing the same distinction are included, the total rises to at least thirty-five published decisions issued over fifty years — an average of more than one precedential decision every two years under the 1952 Patent Act. That total, moreover, does not include the Supreme Court and CCPA cases predating the 1952 Act. When the Supreme Court recently reiterated that “the patent application must *describe*, enable, and set forth the best mode of carrying out the invention,” and cautioned that “[w]hat is claimed by the patent application must be the same as what is disclosed in the specification,” Festo Corp., 535 U.S. at 736 (emphasis added), it was recounting not merely the requirements of Section 112, but the uniform judicial and administrative interpretation of that statute and its predecessor provisions over the history of our patent system.

It is rare that a federal court contemplates upsetting statutory interpretations as settled as this, and only the most extraordinary justification could warrant doing so. As the Supreme Court has repeatedly emphasized, principles of stare decisis have “special force” in statutory interpretation because it is always within Congress’s authority to correct any error of judicial construction. See, e.g., John R. Sand & Gravel Co. v. United States, 552 U.S. 130, 139 (2008); Watson v. United States, 552 U.S. 74, 82-83 (2007). Absent legislative intervention, when the federal courts resolve

a question of statutory interpretation finally and in precedential fashion, the public is entitled to rely on that interpretation without fear that the rules will shift later when different judges happen to see the matter differently.

Petitioners thus fail to appreciate the significance of their embrace of Judge Markey's 1977 dissenting opinion in In re Barker. See Ariad Br. 29 (urging that Judge Markey's dissent "should be adopted by this Court en banc"). As this contention underscores, petitioners' arguments were fully aired and resolved more than thirty years ago. In the subsequent decades, this Court has repeatedly reaffirmed the holding in Barker, the USPTO has examined millions of patent applications under the principles established by this Court's precedents, and Congress has not intervened to change the law. Even if petitioners were correct that Judge Markey's view should have carried the day in 1977, that would not warrant reopening the question now.

### **III. IF PETITIONERS' ARGUMENTS ARE ACCEPTED, THE COURT MUST RECONSIDER ITS ENTIRE JURISPRUDENCE UNDER SECTION 112.**

If, notwithstanding the considerations above, the Court accepts petitioners' invitation to abolish the written-description doctrine, it is essential that the Court provide patent owners, prospective inventors, the public, and USPTO with clear guidance regarding the principles that will govern disputes over the sufficiency of a patent's written disclosure. The worst outcome of this proceeding would be to tear

down part of the longstanding doctrinal edifice of Section 112, ¶ 1, without a blueprint for repairing the gap.

Other doctrines in Section 112 could, if necessary, be interpreted to serve many of the functions now assigned to the written-description doctrine. Indeed, if petitioners are correct that written-description principles have become more prominent in recent decades, that is at least partly because this Court has limited other doctrines under Section 112 in ways that are, at a minimum, not compelled by the text of the Patent Act. The “undue experimentation” test for enablement, for example, is not required by the statutory text and is arguably in tension with Congress’s instruction that the invention be described in “full, clear, concise, and exact terms.” See, e.g., Morse, 56 U.S. at 119 (enablement satisfied if one skilled in the art “can, by using the means [the inventor] specifies, without any addition to, or subtraction from them, produce precisely the result he describes”); Wood v. Underhill, 46 U.S. 1, 5 (1847) (“without making any experiments of his own”). Likewise, although the statute demands that the claims “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention,” the Court has construed this requirement to require little more than that the claims not be “insolubly ambiguous.” Exxon Research & Eng’g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Cf. United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942) (interpreting same language under the 1870 Act to require that the

claims “clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise”). And notwithstanding the express injunction in 35 U.S.C. § 132 against “new matter,” the Court has held that Section 112 is the exclusive basis on which USPTO must reject claims amended to recite elements not supported by the disclosure. In re Rasumussen, 650 F.2d 1212, 1214-15 (CCPA 1981).

The United States takes no position here regarding whether these limitations on the scope of Section 112 are correct. If the written-description doctrine is abolished, however, reconsideration of one or more of these parallel doctrines may be necessary to ensure that the *quid pro quo* of the patent laws continues to function as Congress intended.

**CONCLUSION**

The United States respectfully urges the Court to reject petitioners’ challenge to the written-description doctrine.

Respectfully submitted,

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November 19, 2009

**CERTIFICATE OF COMPLIANCE WITH  
FEDERAL RULES OF APPELLATE PROCEDURE 29(d) AND 32(a)(7)(B)**

I hereby certify that this amicus brief complies with the type-face and volume limitations set forth in Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B) because the type face is Garamond, proportionally spaced, fourteen-point font, and the number of words in this brief is 6,957, according to the count of Corel WordPerfect 14.

s/ Mark R. Freeman

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## CERTIFICATE OF SERVICE

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