Docket 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 PRESIDENTS AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY & COMPANY,

Defendant-Appellant.

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

PRINCIPAL BRIEF FOR PLAINTIFFS-APPELLEES ON REHEARING EN BANC

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October 5, 2009

CERTIFICATE OF INTEREST

Counsel for plaintiffs-appellees ARIAD Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and The President and Fellows of Harvard College certifies the following:

1. The full name of every party represented by me is:

ARIAD Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and The President and Fellows of Harvard College

2. The names of the real parties in interest represented by me are the same as the parties named in the caption.

3. No parent corporations and publicly held companies own 10 percent or more of the stock of the parties represented by me.

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

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STATEMENT OF RELATED CASES

No other appeals in or from this action have previously been before this or any other appellate court.

Amgen, Inc. et al. v. ARIAD Pharms., Inc. et al., Civ. No. 06-259, is currently pending in the United States District Court for the District of Delaware. That case involves the patent-in-suit here and includes, as parties:

- ARIAD Pharmaceuticals, Inc. and The Whitehead Institute for Biomedical Research, as defendants and counterclaim plaintiffs;
- The Presidents and Fellows of Harvard College and Massachusetts Institute of Technology, as additional counterclaim plaintiffs;
- Amgen, Inc., Immunex Corp., Amgen USA Inc., Amgen Manufacturing, Ltd. and Immunex Rhode Island Corp., as plaintiffs and counterclaim defendants; and
- Wyeth, as an additional counterclaim defendant. Wyeth was dismissed from this lawsuit without prejudice by stipulation of the parties on December 12, 2007.

That case may be affected by this appeal.

RESPONSE TO EN BANC QUESTIONS

This Court's en banc order posed the following two questions which Plaintiffs-Appellees briefly answer as follows:

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

Answer: No, § 112, ¶ 1 does not contain a written description requirement separate from an enablement requirement.

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

Answer: Since § 112, ¶ 1 does not contain a separate written description requirement, it cannot have any scope or purpose as a separate requirement. Properly interpreted, the statute requires the specification to describe (i) what the invention is, and (ii) how to make and use it. The purpose of this description is to enable any person skilled in the art to make and use the claimed invention, and the description suffices if it achieves this purpose.

ARGUMENT

I. 35 U.S.C. § 112, ¶ 1, DOES NOT CONTAIN A WRITTEN DESCRIPTION REQUIREMENT SEPARATE FROM AN ENABLEMENT REQUIREMENT.

A. The statutory language does not support a separate written description requirement as currently interpreted by this Court

The first paragraph of 35 U.S.C. § 112 states in its entirety:

> 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.

Under a plain reading of the statute, a patent specification must be in writing[1] and must contain a description (i) of the invention, and (ii) of the manner and process of making and using it. The legal adequacy of that written description is then judged by the standard set forth in the final prepositional phrase, which demands that the description be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to

[1] The statute requires the applicant to submit a "*Written Application*" that must include "a specification as prescribed by section 112 of this title." 35 U.S.C. § 111.

which it pertains, or with which it is most nearly connected, to make and use the same."[2]

This interpretation may be represented as follows:

> The specification shall contain
>
> [A] a written description
>
> [i] of the invention, and
>
> [ii] of the manner and process of making and using it,
>
> [B] 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 . . . .

Under this construction, clauses [i] and [ii] are components of [A]; they are both parts of the "written description." The final prepositional phrase [B] ("in such full . . . terms as to enable") modifies the noun [A], "a written description," and thereby provides the standard to assess the legal adequacy of the whole of the written description. This construction has the important benefit of following ordinary rules of English grammar. Prepositional

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[2] *See University of Rochester v. G.D. Searle & Co., denial of rehearing en banc*, 375 F.3d 1303, 1325 (Fed. Cir. 2004) [hereinafter, *Rochester Denial*] (Linn, J., dissenting) (§ 112, ¶ 1 "requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in paragraph 1 of that statute depends solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention."); *accord Enzo Biochem, Inc., v. Gen-Probe Inc.*, 323 F.3d 956, 988 (Fed. Cir. 2002) (Linn, J., dissenting from denial of rehearing en banc) (same).

phrases are used as modifiers; they modify by relating the object (or complement) of the preposition to some other word in the sentence. *See* Rodney Huddleston and Geoffrey K. Pullum, *The Cambridge Grammar of the English Language* 598 (2002) (setting forth the traditional definition that a preposition "governs, and normally precedes, a noun or pronoun" and "expresses the latter's relation to another word"); *see also* Mark Lester and Larry Beason, *The McGraw-Hill Handbook of English Grammar and Usage* 39 (2004). Under Plaintiffs-Appellees' reading, the prepositional phrase [B] modifies the word "description" and makes clear that "the written description" must be "in" such full, clear, concise, and exact terms so as to enable.

In *Enzo*, the United States took a similar position regarding the proper statutory construction of § 112, ¶ 1:

> A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention. The statute provides that the "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." 35 U.S.C. § 112 paragraph 1. Thus, an adequate written description assures that others can "make and use" the invention.

Brief for United States as Amicus Curiae at 5, *quoted in Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002).

This 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. Rather, this Court's written description cases tend to truncate the statutory language after the phrase "written description of the invention," and solely focus on only this one phrase, ignoring the remaining language in the paragraph. *See, e.g.*, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1370 (Fed. Cir. 2009); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991). Put another way, those cases interpret the phrase "written description of the invention" as though it were a stand alone requirement, independent from the remaining language of the paragraph. That approach seems to follow an alternate construction of the statute, which could be represented as follows:[3]

> The specification shall contain
>
> [A] a written description
>
> > [i] of the invention, and
> >
> > [ii] of the manner and process of making and using it,
> > [B] 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 . . . .

[3] The panel decision in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), appears to follow such a statutory analysis. *See id*. at 921.

Under this alternate construction, a "written description of the invention" is separate from the "written description . . . of the manner and process of making and using it," and the final prepositional phrase [B] modifies only the latter.

There are at least three significant problems with this construction. First, under this alternate construction, the statute provides no standard for testing the legal adequacy of the "written description of the invention." Under the proper construction of the statute, by contrast, the standard in prepositional clause [B] tests the sufficiency of the whole of the written description.

Second, this alternate construction of the statute does not make sense as a matter of grammar because, in the context of the sentence, the prepositional phrase [B] ("in such . . . terms") can only modify the word "description." A "description" may possess the quality of being created or written "in" certain "terms." By contrast, a "manner and process of making and using the invention" would be found in certain acts or steps, not "in" "terms."

Third, under the alternative reading of the statute, the addition of a comma between the phrases "the manner and process of making and using it" and "in such . . . terms" is inexplicable. Under Plaintiffs-Appellees'

construction of the statute, clause [ii] runs in parallel to clause [i], and therefore the entire parallel clause [ii] should be set off in commas, with one preceding, and one following, clause [ii] — just as the statute is written. Under the alternative view, prepositional phrase [B] is a part of, and modifies, clause [ii]. No reason exists for inserting a comma immediately before the [B].

Under § 112, ¶ 1, the invention is described for a reason, and the nature of that description would change if the reason were changed. For example, the description would say one thing if its purpose was to enable a person of ordinary skill to make and use the invention; something different if its purpose was to enable a layman to make and use the invention; and something different again if its purpose was to show why the invention was novel and non-obvious. Congress did not simply require an inventor to describe the invention in the abstract; rather it stated the reason for doing so: to enable a person of ordinary skill to make and use the invention. *See Enzo*, 323 F.3d at 976 (Rader, J., dissenting from denial of rehearing en banc) ("an adequate written description assures that others can 'make and use' the invention") (citation omitted).

B. Earlier versions of the Patent Act do not support a separate written description requirement as currently interpreted by this Court

A review of the major revisions of the patent laws – the Patent Acts of 1790, 1793, 1836, and 1870 – does not support a separate written description requirement as currently interpreted by this Court.[4]

1. The Patent Acts of 1790 and 1793

The first Patent Act, adopted in 1790, and its immediate successor, adopted in 1793, both required a written disclosure that accomplished two things: (i) to distinguish the invention from the prior art, and (ii) to enable any person skilled in the art to make and use the invention.

The 1790 Patent Act provided, in relevant part:

> SEC. 2. [T]he grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit of a model) of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular, and said models so exact, as 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, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the

[4] For the Court's convenience, a statutory addendum is annexed giving the full text of the cited sections of these earlier Patent Acts.

> patent term . . .

Act of Apr. 10, 1790, 1 Stat. 109, 110-11, ch. 7, § 2.

The 1793 Patent Act provided, in relevant part:

> SEC. 3. [E]very inventor, before he can receive a patent, shall . . . deliver a written description of his 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, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.

Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11, § 3. Thus, both the 1790 and 1793 Patent Acts required a written description that served two purposes: (i) to distinguish the invention from the prior art, and (ii) to enable those of ordinary skill in the art to make and use the invention. In explaining the "written description" requirement of the 1793 Act, the Supreme Court stated:

> "It is the business and duty of the inventor, then, at the time of applying for his patent, and before he can receive a patent, to deliver a 'written description of his *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 of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same*.'"

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 380-381 (1822) (emphasis in original); *accord Enzo*, 323 F.2d at 977 (Rader, J., dissenting from denial of rehearing en banc).

2. The Patent Acts of 1836 and 1870

From 1836 onwards, the function of defining the patented invention was assigned to claim(s), and the "written description" henceforth served a single purpose: enablement. A best mode requirement was also added.

The next significant revision of the patent laws was the Patent Act of 1836, which provided, in relevant part:

> SEC. 6. [B]efore any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.

Act of July 4, 1836, 5 Stat. 117, 119, ch. 357, § 6. In the 1836 Patent Act, the single purpose of the written description is to enable a person skilled in the art to make and use the invention. The 1836 Act eliminated the

requirement that this description distinguish the invention from the prior art, and added a separate requirement for claims by which the inventor must "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." Thus in the 1836 Act, the written description no longer served to distinguish the invention from prior art, and functioned solely for purposes of enablement. *See Enzo*, 323 F.2d at 977 (Rader, J., dissenting from denial of rehearing en banc).

The 1870 Patent Act provided, in relevant part:

> SEC. 26. [B]efore any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the commissioner, and shall file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions; and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery . . . .

Act of July 8, 1870, 16 Stat. 198, 201, ch. 230, § 26. The 1870 Act, like its predecessor, required that the inventor make an application "in writing" and provide an enabling description of the invention and a separate claim that distinguished the invention from the prior art. The 1870 Act further defined

the "best mode" requirement that is the forerunner of the similar requirement in the § 112, ¶ 1 of the present-day Patent Act.

In explaining both the (i) disclosure and (ii) claim requirement of § 26 of the 1870 Act, the Supreme Court stated:

> The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and 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.

Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 57 (1938) (quotation omitted).

Thus, § 26 of the 1870 Patent Act required a description of the invention that enabled others to make and use it, as well as the best mode the inventor contemplated for doing so. In addition, § 26 required claims that pointed out and distinctly claimed the invention. Section 26 did not contain a written description requirement separate from enablement as this Court's current interpretation of § 112, ¶ 1 requires.

In sum, a review of the major Patent Acts prior to 1952 – 1790, 1793, 1836 and 1870 – does not support the existence of a written description requirement separate from the enablement requirement. Rather, the history of the statutory text shows that the written description was simply a

description in writing, which initially (i.e., in the 1790 and 1793 Acts) had two purposes: (i) to enable persons of skill in the art to make and use the invention, and (ii) to distinguish the invention from the prior art. This latter "distinguishing" aspect was eventually (i.e., from 1836 onwards) eliminated from the written description requirement and transferred to claims at the end of the specification. And a best mode requirement was added.

Thus immediately prior to the 1952 Patent Act, the specification had to (i) disclose the invention and how to make and use it so as to enable any person of ordinary skill to make and use the invention, and (ii) set forth the best mode contemplated by the inventor for carrying out his invention. None of this history suggests, let alone supports, the existence of a written description requirement separate from enablement, as currently interpreted by the Court. *See University of Rochester v. G.D. Searle & Co., Inc.*, *denial of rehearing en banc*, 375 F.3d 1303, 1310-11 (Fed. Cir. 2004) [hereinafter, *Rochester Denial*] (Rader, J., dissenting) (analyzing the language of the written description requirements of the Patent Act since 1793).

C. The legislative history of § 112 of the 1952 Patent Act does not support a separate written description requirement as currently interpreted by this Court

In the Patent Act of 1952, the disclosure and claiming requirements were separated and placed in paragraphs 1 and 2 of 35 U.S.C. § 112. The

first paragraph of § 112 requires, in writing, a description of the invention and how to make and use it in such terms (full, clear, concise and exact) as to enable a person skilled in the art to make and use the invention. This language is quite similar to that of § 26 of the 1870 Patent Act. Section 112, first paragraph also requires the specification to include the "best mode contemplated by the inventor of carrying out his invention" – language that is likewise very similar to § 26 of the 1870 Patent Act.

The second paragraph of § 112 contains the requirement, previously found in § 26 of the 1870 Patent Act, for claims that define the scope of the patented invention. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("the claims made in the patent are the sole measure of the grant"); *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc) ("Consistent with its scope definition and notice functions, the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee's right to exclude.").

The House and Senate Committee Reports on the 1952 Act mention that "[t]he clause relating to the claim" from the pre-existing law was "made a separate paragraph to emphasize the distinction between the description

and the claim or definition." H.R. Rep. No. 82-1923, at 19 (1952); S. Rep. No. 82-1979, *reprinted in* 1952 U.S.C.C.A.N. 2394, 2412. While the congressional Reports provide no further elaboration as to why Congress wanted "to emphasize the distinction between the description and the claim," commentary by P. J. Federico (a leading Patent Office official and co-author of the Act) explains: "In the old statute the requirement for a claim pointing out what the applicant regarded as his invention appeared as a clause in the same sentence relating to the description, which led to some confounding of the nature of the two requirements in a few decisions." P.J. Federico, *Commentary on the New Patent Act*, *reprinted in* 75 J. Pat. & Trademark Off. Soc'y 161, 186 (1993). In the 1952 Act, paragraphs 1 and 2 were separated in order to eliminating such "confounding" of the claim and description. Modern case law creating a separate written description requirement appears to thwart this purpose, for it imports into § 112, paragraph 1 some sort of public notice function that is properly considered a matter for the claiming requirement under § 112, ¶ 2. *See Rochester Denial*, 375 F.3d at 1375 (Linn, J., dissenting).

D. Supreme Court precedent does not support a separate written description requirement as currently interpreted by this Court.

Supreme Court precedent does not support the existence of a separate written description requirement as construed by this Court's current precedent. Opinions of this Court primarily rely on a single Supreme Court decision, *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 380-381 (1822) to support a separate written description requirement. However, *Evans* interpreted the 1793 Patent Act which, as discussed in Section I.B.1 above, differs from the 1836 and subsequent Patent Acts in that the 1793 Act required the written description of the invention to serve two purposes.

The 1793 Act required that inventor must provide:

> [A] a written description
>
> > [i] of his invention, and
> >
> > [ii] of the manner of using, or process of compounding the same,
>
> [B] in such full, clear and exact terms, as
>
> > [i] to distinguish the same from all other things before known, and
> >
> > [ii] to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.

Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11, § 3. (enumeration and formatting added). Thus, the 1793 Act differs substantially from the current

§ 112, ¶ 1. In the 1793 Act, the prepositional phrase [B], which sets forth the legal standard for judging the sufficiency of the specification, had *two* requirements, not just one. In addition to the modern enablement standard, the 1793 Act required the written description [i] "to distinguish the [invention] from [the prior art]."

Thus, a historically accurate reading of *Evans* strongly supports Plaintiffs-Appellees' interpretation of the modern § 112. In concluding that the specification was required to have "two objects" under the then-existing statute, the *Evans* Court relied on the dual clauses present in the prepositional phrase [B] of the 1793 Act. In interpreting the 1793 Act, the Court explained the first object as follows:

> The specification, then, has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent.

20 U.S. (7 Wheat.) at 433-34. In other words, the first object of the specification was enablement. As to the second object, the Court explained:

> 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 anything 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. It is, therefore, for the purpose of warning an innocent purchaser or other person using a machine of his

> infringement of the patent; and at the same time of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification. Nothing can be more direct than the very words of the act. The specification must describe the invention "in such full, clear, and distinct terms, as to distinguish the same from, all other things before known."

Id. at 434. The Court emphasized that the second object – "to put the public in possession of what the party claims as his own invention" – was tied to the now repealed language in the 1793 statute that required the specification to "distinguish" the prior art. Since that language was repealed by Congress in 1836, the relevant language in the modern version of § 112 ¶ 1 now has only one object, which is to enable.

Supreme Court precedent interpreting the predecessors of § 112, ¶ 1 since 1836 has long held that a patent applicant is subject to but a single "written description" requirement, the measure of whose sufficiency is enablement: "the *quid pro quo* [for patent rights] is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired." *Universal Oil Prods. Co. v. Globe Oil & Refining Co*., 322 U.S. 471, 484 (1944). *See also Smith v. Snow*, 294 U.S. 1, 9 (1935) ("The patentee, obedient to the command of the statute (R.S. § 4888), gave such description of the manner

of using his discovery as would enable other skilled in the art to use it"); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933) ("the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it into use"); *Eibel Process Co. v. Minnesota & Ontario Paper* Co., 261 U.S. 45, 65-66 (1923) ("one versed in paper making could find in Eibel's specifications all he needed to know, to avail himself of the invention"); *The Telephone Cases*, 126 U.S. 1, 535-36 (1888) ("It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation") *quoted in Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 62 (1998).

Where, as in this case, subject matter claimed in a patent is novel and patentable, the "written description" requirement is satisfied by an enabling disclosure of the *claimed* subject matter; there is no requirement that a patentee describe *unclaimed* structures or materials whose use is unnecessary to the practice of a claimed invention. *See Deering v. Winona Harvester Works*, 155 U.S. 286, 302 (1894) ("If Steward were in fact the first to invent the pivotal extension to a butt-adjuster, he is entitled to a patent therefor, though the infringer may make use of other means than those

employeed by him to operate it."); *Tilghman v. Proctor,* 102 U.S. 707 (1881) ("The patentee showed one method in which the heat could be applied. That was all that was necessary for him to do.").

Deering and *Tilghman* reflect that compliance with the "written description" requirement depends importantly on "the nature of the invention." *In re Wands*, 858 F.3d 731, 737 (Fed. Cir. 1988). Where, as in *Tilghman* and *The Telephone Cases* (and the present case), a patent discloses a novel, useful, and non-obvious method for transforming matter from one state to another, the discoverer of such a method is entitled to patent the method as such. *See Diamond v. Diehr*, 450 U.S. 175, 182-83 (1981) ("That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed.") (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)). *The Telephone Cases*, 126 U.S. at 535-36 (emphasis added), the "written description" requirement is fully satisfied. *See also* Brief for Plaintiffs-Appellees filed Sept. 26, 2008, at 20-28.

E. CCPA precedent prior to 1967 does not support a separate written description requirement as currently interpreted by this Court

For at least the first fifteen years after adoption of the 1952 Patent Act, cases interpreting § 112, ¶ 1 "did not differentiate written description from enablement," *Enzo*, 323 F.3d at 977 (Rader, J., dissenting from denial

of rehearing en banc). Rather, those cases interpreted the statute as requiring a description that enables a person skilled in the art to make and use the invention.

For example, in *In re Gay*, 309 F.2d 769 (CCPA 1962), amended claims were rejected based on § 112, ¶ 1. In analyzing the statute, Judge Rich's opinion separated the first paragraph of 112 into two – and only two – sections, delineated as "A" and "B":

> [A] 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 it most nearly connected, to make and use the same, and shall
>
> [B] set forth the best mode contemplated by the inventor of carrying out his invention.

Id. at 772 (emphasis omitted). In analyzing section [A], Judge Rich explained:

> The essence of portion [A] is that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it.

Id.[5] Thus in *Gay* the CCPA did not treat written description and enablement as two separate requirements, as this Court's current precedent holds.

[5] "Separate and distinct from portion [A] is portion [B], the essence of which requires an inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out his invention." *Id*. at 772 (emphasis omitted).

Rather, the CCPA properly linked the description requirement of § 112, ¶ 1 with its statutory function: enablement. *Id*. at 774 (concluding that the specification enabled one skilled in the art to make and use the claimed invention without undue experimentation.)

To similar effect is *In re Wilke*, 314 F.2d 558 (CCPA 1963) where the CCPA explained that § 112, ¶ 1 had just two aspects – (i) to describe the invention so a person of ordinary skill can make and use it, and (ii) to describe the best mode contemplated by the inventor for carrying out the invention.

> The sufficiency of a specification must be tested in the light of this fact and judged by what it conveys to those who are skilled in the art. The judge's task is to decide whether from the disclosure the man skilled in the art can make the invention and use it. If he can, this part of the statute is complied with, subject to the one further requirement that the inventor describe the best mode contemplated by him of carrying out his invention.

314 F.2d at 564 (quotation omitted).

The panel decision in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) contended that three pre-1967 CCPA decisions recognized the existence of an "independent written description" requirement. *Id*. at 923-24 (citing *Jepson v. Coleman*, 314 F.2d 533 (CCPA 1963), *In re Moore*, 155 F.2d 379 (CCPA 1946) and *In re Sus*, 306 F.2d 494 (CCPA 1962)). However, those three cases merely tested whether the

specification *identified* the same invention that was defined by later-added or amended claims – which is an aspect of enablement – and did not interpret § 112, ¶ 1 as containing an independent description-possession requirement, as this Court's precedent currently provides.

In *Jepson*, the applicant's specification did not "disclose each and every limitation of the claims" that he sought to copy to provoke an interference, 314 F.2d at 536, and accordingly did not identify the invention to which the count was directed. In *Moore*, the application identified the invention "in its broadest aspect" as concerning the use of certain chemicals in gaseous form "as fumigants," 155 F.2d at 382, and accordingly did not support broader claims that encompassed the use of non-fumigant insecticides "such as solids and liquids." *Id*. at 381-82. In *Sus*, the specification identified the invention as novel, light-sensitive compounds having "*certain aryl radicals*" that made them useful in for photo-mechanical printing and accordingly did not support broader claims that included such chemicals with *any* aryl radicals. 306 F.2d at 504.

Thus, these three cases merely stand for the undisputed proposition that the claims must be directed to an invention that is identified in the specification. At no point prior to 1967 did the CCPA bifurcate this first

aspect of § 112, ¶ 1 into separate written description and enablement requirements.[6]

F. After 1967, the CCPA and this Court improperly interpreted § 112 as containing a separate written description requirement whose adequacy is measured by a non-statutory "possession" test

In re Ruschig, 379 F.2d 990 (CCPA 1967) is frequently cited as the leading case construing § 112, ¶ 1 as containing separate written description requirement separate from enablement. However, a careful reading of that decision demonstrates that *Ruschig* did not in fact so hold. *Ruschig* 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. It was only later cases that read *Ruschig* as discerning in § 112, ¶ 1 a written description requirement separate from enablement.

1. *Ruschig* did not interpret § 112, ¶ 1 as containing a written description requirement separate from enablement

Ruschig involved a claim, added during prosecution, to the specific chemical compound, chlorpropamide. The Court was faced with the

[6] Before 1967, the USPTO and the CCPA used a "new matter" rejection under Section 132 to police priority and test whether amended claims were adequately supported, and thus entitled to the benefit of the filing date of an earlier filed application. *See Enzo*, 323 F.3d at 977 (Rader, J., dissenting from denial of rehearing en banc).

question whether this newly-added claim was supported by an earlier filed application. The originally filed specification disclosed a large genus of compounds that was defined by a common structural formula with a number of variable elements. Each variable component of the structural formula permitted several options. Because of the permutations associated with the variable elements, the entire genus described in the application encompassed "something like half a million possible compounds." 379 F.2d at 993. Even the narrowest relevant subgenus in the originally filed application included more than 1000 species "excluding stereoisomerides." *Id*. at 994. The Patent Office rejected Ruschig's claim to the species chlorpropamide on the ground that the original disclosure did not provide sufficient "support" for the newly added claim.

The CCPA affirmed, explaining that "[s]pecific claims to single compounds require reasonably specific supporting disclosure . . . ." *Id*. The specification provided no guides or "blaze marks" that singled out the compound chlorpropamide, and accordingly did not support the later-added claim. *Id*. at 994-95. In so holding, the Court rejected Ruschig's argument that "one skilled in the art would be enabled by the specification to make chlorpropamide" as unfounded because it "presumes some motivation for wanting to make the compound in preference to others." *Id*. at 995.

The court reasoned that the Patent Office's rejection – if "truly based on section 112," which was "doubt[ful]," *id*. – turned on the requirement that "'[t]he specification shall contain a written description *of the invention* . . . .'" *Id*. at 995-96 (emphasis in original). Whether the specification did so turned on the question: "Does the specification convey clearly to those of skill in the art, to whom it is addressed, in any way, the information that the appellants invented that specific compound?" *Id*. at 996.

The claim in *Ruschig* was properly rejected for two reasons. First, the *Ruschig* court questioned whether the Patent Office rejection was based on § 112 at all. The species claim added by the applicants almost certainly violated the prohibition against adding "new matter" during prosecution. 35 U.S.C. § 132. Second, to the extent the rejection was based on § 112, Ruschig's argument that the specification enabled one of ordinary skill in the art to make and use chlorpropamide presupposed that the specification identified that compound to the skilled artisan as something to be made and used. The later-claimed compound was not "specifically named or mentioned in any manner" in Ruschig's application. *Ruschig*, 379 F.2d at 995. Rather, the skilled artisan "is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating

or directing that this particular selection should be made rather than any of the others which also could be made." *Id*. Accordingly, the specification failed to provide an enabling disclosure.

Thus, the court in *Ruschig* did not hold that § 112, ¶ 1 contains a written description requirement separate from enablement. Nor did *Ruschig* adopt "possession" as the test for measuring whether the specification provides a supporting description of the claimed invention.

2. Later cases misread *Ruschig* as recognizing a written description requirement separate from enablement

Although *Ruschig* did not hold that § 112, ¶ 1 contains a written description requirement separate from enablement, subsequent decisions have characterized *Ruschig* as recognizing that description and enablement are "severable." *See, e.g.*, *Vas-Cath Inc.*, 935 F.2d at 1561 ("the severability of [the] 'written description' provision [of § 112] from its enablement ('make and use') provision was recognized . . . as early as *In re Ruschig*").

Interpreting § 112 as containing separate written description and enablement requirements proved highly controversial, as is shown by the fractured opinion in *In re Barker*, 559 F.2d 588 (CCPA 1977), which was decided 2-1-2 and thus failed to produce a controlling opinion. In *Barker* the applicant urged essentially the same construction of § 112, ¶ 1 as Plaintiffs-Appellees do here: "that the 'enablement' requirement of the first

paragraph of 35 U.S.C. § 112 cannot be read separately from the 'description' requirement therein." *Id*. at 591. Judge Miller (joined by Judge Lane) rejected that argument, stating:

> This court has clearly recognized that there is a description of the invention requirement in 35 U.S.C. § 112, first paragraph, separate and distinct from the enablement requirement. A specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement.

Id. (citing *Ruschig*, among other cases, and tracing the history of successive Patent Acts since 1790).

Judge Rich concurred in the result, but not in the reasoning of the Miller/Lane opinion, and wrote separately, stating:

> The basic problem here is simple: new matter, in violation of 35 U.S.C. § 132, was inserted by amendment and the claim contains that new matter. It therefore lacks support and must be rejected. The decision is in accord with many of our prior interpretations of 35 U.S.C. § 112 and there is no need to justify it by extensive review of the evolution since 1790 of the language of Section 112, first paragraph.

Id. at 594 (concluding that "issues of the sufficiency of description and enablement" are "distinct though commingled requirements").

While Judge Baldwin dissented without opinion, Judge Markey "respectfully, but heartily dissent[ed]" and expressed views very much in accord with the position urged here by the Plaintiffs-Appellees:

> The attempt to create historical and current statutory support for a "separate description" requirement, which was solely a judicial (and unnecessary) response to chemical cases in which appellants were arguing that those skilled in the art "might" make and use a claimed invention, is mistaken.

Id. As Judge Markey read § 112:

> Congress *saved* words by specifying, in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall *both* be in "such full, clear, concise, and exact terms as to enable." Section 112, first paragraph, is a simple sentence with a comma after "it," making the phrase "in such full . . . the same" a modifier of both objects of the verb "contain." All before that comma prescribes *what* shall be described. The phrase following the comma prescribes *how* and for *whom* it shall be described.

Id. at 594-95 (emphasis in original). Judge Markey concluded with what has become the central disputed issue in this area of the law: "I cannot see how one may, in 'full, clear, concise and exact terms,' enable the skilled to practice an invention, and still have failed to 'describe' it." *Id*. at 595.[7]

Plaintiffs-Appellees are in complete agreement with Judge Markey's opinion in *Barker* and believe it should be adopted by this Court en banc. *See Rochester Denial*, 375 F.3d at 1326) (Linn, J., dissenting) (quoting with approval J. Markey's dissenting opinion in *Barker*). The description

[7] Thirty years after this salient observation, the court is still searching for, but has yet to find, a real case "where the patent can enable an invention that is not described by the specification." *Rochester Denial*, 375 F.3d at 1312 (Rader, J., dissenting).

requirement has two aspects, which are both necessary to show enablement. First, the specification must state *what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use. Second, the specification must explain to a person of skill in the art *how* to make and use the invention. This description requirement has a single purpose and is judged by a single standard, namely enablement.

The disagreement highlighted in *Barker* continued after the creation of this Court. *Compare In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984) ("The description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision.") *with Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421 (Fed. Cir. 1987) ("The purpose of the description requirement is to state what is needed to fulfill the enablement requirement. These requirements may be viewed separately, but they are intertwined."). In *Vas-Cath*, this Court attempted once again to put an end to this debate:

> [W]e hereby reaffirm that 35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is*

now claimed.

935 F.2d 1563-64 (emphasis in original).

It is important to note that, although *Vas-Cath* erred by separating written description from enablement, it recognized that this judicially-construed written description inquiry would only apply to later filed or amended claims that sought the benefit of the priority date of an earlier filed specification. Although amended claims can be introduced in different situations (e.g., amended in the same application, claims to priority via §§ 119 and 120, and in an interference), the Court determined that amended, non-original claims were the only claims that would receive this "separate written description" scrutiny. *See Vas-Cath*, 935 F.2d at 1560. During this time the purpose of the written description doctrine "did not change" – "§ 112 doctrine, like its corollary § 132, policed priority, nothing more." *Enzo*, 323 F.2d at 979 (Rader, J., dissenting from denial of rehearing en banc).[8] For the three decades following *Ruschig*, written description was used as a "metric" to determine if a subsequently filed claim was entitled to

[8] *See TurboCare Div. Of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date . . . the new claims or other added material must find support in the original specification.")

the benefit of the filing date of an earlier filed application. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003). At no time over the 30 year period between *Ruschig* and *Lilly* "did either the CCPA or the Federal Circuit purport to apply the equivalent new matter/written description rejections to original claims or other claims without priority problems." *Enzo*, 323 F.3d at 979 (Rader, J., dissenting from denial of rehearing en banc); s*ee also id*. at 988 (Linn, J., dissenting from denial of rehearing en banc) (the notion of written description "possession" test discussed in *Vas-Cath* and other cases was "a convenient way to measure or test entitlement of later filed claims to an earlier priority date. It was not and should not be a test for sufficiency of disclosure, per se. It should have no place in and does not aid in the disposition of cases where the claims in question are part of the original disclosure.")

3. *Lilly* and its progeny

In *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), the Court took the "separate written description" doctrine in a new direction and "for the first time applied the written description language of 35 U.S.C. § 112, ¶ 1 as a general disclosure requirement in place of enablement, rather than in its traditional role as a doctrine to prevent applicants from adding new inventions to an older disclosure." *Rochester*

Denial, 375 F.3d at 1307 (Rader, J., dissenting); *see also* Arti K. Rai, *Intellectual Property Rights in Biotechnology*: *Addressing New Technology*, 34 Wake Forest L. Rev. 827, 834 (1999) (in *Lilly* the court "broke new ground by applying the written description requirement not only to later-filed claims but also to claims filed in the *original* patent") (emphasis in original).

Lilly involved claims to a "plasmid" (a certain type of DNA well known in the prior art) that comprised a novel DNA, namely: a "cDNA" that encodes a *vertebrate* insulin. 119 F.3d at 1536.[9] Other claims were directed to plasmids comprising a cDNA that encodes a mammalian insulin, or that encodes human insulin. *Id*. However, the specification only disclosed the construction of a plasmid comprising a cDNA encoding *rat* insulin. Applying a description-possession test that "requires a precise definition" of the claimed invention "such as by structure, formula, chemical name, or physical properties," *id*. at 1566, the Court held invalid the claims to plasmids comprising cDNAs encoding vertebrate, mammalian, or human insulin "[w]hether or not [the patent] provides an enabling disclosure." *Id*. at 1657.

[9] A "cDNA" is a type of DNA that provides information needed by a cell to make a particular protein. *In re Deuel*, 51 F.3d 1552, 1554 (Fed. Cir. 1995).

In *Lilly*, the novel and non-obvious feature that distinguished the claimed plasmids from the prior art was that they comprised a cDNA encoding vertebrate (or mammalian or human) insulin. Under a proper interpretation of § 112, ¶ 1, the correct inquiry should have been whether the specification, as of its 1977 filing date, provided a description of *what* these recited cDNAs were, and *how* to make and use them, that enabled a person of ordinary skill in the art to make and use the invention as broadly as it was claimed.

Given that biotechnology, in 1977, was still new, and that the class of vertebrates ranges from fish to humans, the specification may well have failed to enable the claimed plasmids. *See Moba*, 325 F.3d at 1324 n.2 (Rader, J., concurring) ("Under a proper enablement analysis . . . the claims at issue [in *Lilly*] would have been found invalid for lack of enablement"); *Enzo*, 323 F.3d at 980 (Rader, J., dissenting from denial of rehearing en banc) (applying the *Wands* factors to the claims in *Lilly*, "the inventor certainly did not show one of skill in the art how to make human insulin cDNA," or vertebrate insulin cDNA). But even if the holding in *Lilly* was correct, its reasoning was not.

In subsequent cases, the Court has followed *Lilly* and has held claims invalid under the judicially-derived description-possession test, thereby

eschewing an inquiry into the statutory enablement requirement. For example, the claims at issue in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004), were directed to a method that required "administering a non-steroidal compound that selectively inhibits activity of [a particular enzyme] to a human host in need of such treatment." *Id*. at 918. It was "undisputed that the [patent-in-suit] does not disclose any compounds that can be used in its claimed methods. . . . No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known." *Id*. at 927. The Court held the claims invalid under the description-possession test without reaching the question of enablement. *Id*. at 929-930 ("In view of our [ruling] on the written description ground, we consider the enablement question to be moot and will not discuss it further.").

Under the facts identified in the opinion, the patent in *Rochester* may have been invalid for lack of enablement. *See The Telephone Cases*, 126 U.S. at 536 (the specification must disclose "some practicable way of putting [a claimed method] into operation."). Once again, even if the holding in *Rochester* was arguably correct, its reasoning was not.

G. Improperly interpreting § 112, ¶ 1 to require a written description doctrine separate from enablement has produced negative unintended consequences.

"By making written description a free-standing disclosure doctrine, this court produces numerous unintended and deleterious consequences." *Moba*, 325 F.3d at 1322 (Rader, J., concurring).

1. Courts will bypass the issue of enablement and decide cases based on the written description doctrine

Enablement is clearly provided for in the statute, whereas a separate written description doctrine requiring evidence of "possession" is not. Yet many patents challenged under § 112, first paragraph are resolved under the non-statutory written description doctrine rather than under statutory requirement of enablement. The present case is simply one such example.

The reason for this is simple. Once written description was de-linked from enablement, it was necessary to frame some other test for determining whether the judicially-construed "separate written description requirement" was satisfied. For this purpose, the Court created a new standard: "the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Ariad*, 560 F.3d at 1371-1372 (citations omitted). Under this doctrine, the written description must show "possession" by giving a "precise definition"

of the claimed invention "such as by structure, formula, chemical name, or physical properties." *Lilly*, 119 F.3d at 1566. However, this written description-possession test requires "far more specific disclosure than enablement." *Enzo*, 323 F.3d at 981-982 (Rader, J., dissenting from denial of rehearing en banc), and has been viewed as a "super-enablement" test. *Id*.; *Moba*, 325 F.3d at 1325 (Rader, J., concurring); *see also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1652-54 (2003) (In biotechnology, the written description "doctrine has been applied as a sort of 'super-enablement' requirement."); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 Wake Forest L. Rev. 827, 835 (1999) (describing the *Eli Lilly* doctrine as "a type of elevated enablement requirement"); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 617 (1998) (criticizing *Eli Lilly* as establishing "uniquely rigorous rules for the description of bio-technological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding."). The predictable consequence is that defendants will "have no need to invoke enablement, but will proceed directly to the more demanding

Lilly § 112, ¶ 1" written description requirement. *Enzo*, 323 F.3d at 982 (Rader, J., dissenting from denial of rehearing en banc).

Moreover, under the separate description-possession doctrine the patentee may not defend the validity of the patent based on the same body of evidence that may be used to show enablement. For example, evidence that, shortly after the filing date, other scientists successfully practiced the claimed methods is relevant to prove enablement. *See Amgen Inc. v. Hoechst Marion Roussell, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003). But that evidence, which is present in this case, was deemed legally irrelevant to the description-possession issue. *Ariad*, 560 F.3d at 1375-76. In other words, a patentee must defend the validity of the patent under a higher "super-enablement" standard, but with access to less evidence than can be used to demonstrate enablement. In view of this discrepancy (higher standard, less evidence), it is unsurprising that the non-statutory description-possession test is frequently invoked to challenge, and invalidate, patents rather than the statutory doctrine of enablement.

2. Research universities and small biotechnology companies are disadvantaged by the separate description-possession standard

This Court's separate written description-possession requirement is not only extraneous to the statute, but also has severe adverse consequences

for research universities and biotechnology companies. *See Rochester Denial*, 375 F.3d at 1313-14, 1325 (Rader, J., dissenting); *Moba*, 325 F.3d at 1325-26 (Rader, J., concurring). The Plaintiffs-Appellees here are three of the finest research institutions in the world – Harvard University, MIT, and the Whitehead Institution – and the biotechnology company that is the exclusive licensee of the patent (ARIAD). Similarly, the patents at issue in *Rochester* and *Lilly* both stemmed from research universities (University of Rochester and University of California, respectively). In all three cases, research university patents were held invalid under the "separate written description" doctrine at the behest of pharmaceutical companies whose commercial activities are downstream of, and benefit from, the type of discoveries that universities make.

The written description-possession rule "prejudices university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention to extract its nucleotide sequence." *Enzo*, 323 F.3d at 983 (Rader, J., dissenting from denial of rehearing en banc) (citing Mueller, 13 Berkeley Tech. L.J. at 617 ("*Lilly* . . . will likely chill development."); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233,

1262 (2000) ("The primary argument against the Federal Circuit's heightened written description requirement for biotechnological invention is that . . . it also 'reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research.'").

3. The separate written description-possession test has proved unpredictable and inconsistent

Judges of this Court and legal commentators alike have expressed concern that the Court has never clearly articulated what is necessary to satisfy the written description-possession test. *See Rochester Denial*, 375 F.3d at 1327 (Dyk, J., concurring) (the Court has "yet to articulate satisfactory standards [for the written description doctrine] that can be applied to all technologies"); *accord Conflicts in Federal Circuit Patent Law Decisions*, 11 Fed. Cir. 723, 725 (2001-2002) ("[T]he Federal Circuit has not provided clear and consistent rules for determining precisely what type of disclosure is sufficient to comply with the § 112 written description requirement."). Others have noted the "confusion" the written description doctrine has caused, and in particular to district courts and the trial process. *Ariad*, 560 F.3d 1366, 1381 (Linn, J., concurring) ("The court's invention of a separate written description requirement has 'created confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude,' causing uncertainty 'in how inventions are

protected, in how the Patent & Trademark Office discharges its responsibilities, and in how business is conducted in emerging fields of law.'") (citing *Rochester Denial*, 375 F.3d at 1326, 1327); *Rochester Denial*, 375 F.3d at 1309 (Rader, J., dissenting) ("by any measure, the *Eli Lilly* doctrine has engendered confusion"); *see also Vas-Cath*, 935 F.2d at 1560 (quoting the district courts remark that "unfortunately it is not so easy to tell what the law of the Federal Circuit is" on written description) (citation omitted).

For example, in *Lilly* the Court explained how one must satisfy the written description-possession test: written description "'requires a precise definition, such as by structure, formula, chemical name, or physical properties.'" *Lilly*, 119 F.3d 1566 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).) Yet only five years later, the application of this test caused the court to "flip-flop" in its decision in *Enzo*. *Rochester Denial*, 375 F.3d at 1308 (Rader, J., dissenting).

In sum, the written description doctrine has essentially taken on a life of its own, far from the statutory purpose of the description which is enablement, and far from the original focus on the phrase in policing priority of amended claims in *Ruschig* and its progeny. *See Enzo*, 323 F.3d at 983 (Rader, J., dissenting from denial of rehearing en banc); *see also* Mark D.

Janis, *On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 Wash. U.J.L. & Pol'y 55, 60 (2000) ([t]oday . . . the written description requirement enjoys a prominence wholly out of proportion to its humble origins.").

This case presents a long-sought opportunity for this Court to clarify and correct the law regarding the disclosure requirement of § 112, ¶ 1. As Judge Bryson aptly stated in his concurrence in *Moba*:

> Perhaps the entire line of cases stemming from *Ruschig* is wrong, and perhaps we should at some point address that question en banc. I take no position on that issue at this juncture. I think it is worth pointing out, however, that the real question raised by Judge Rader's statutory analysis is not whether *Lilly* was an unwarranted departure from the *Ruschig* line of cases, but whether that entire line of cases is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1.

Moba, 325 F.3d at 1328 (Bryson, J., concurring); *see also id*. at 1327 (Rader, J., concurring) ("as indicated in Judge Bryson's concurring opinion, the problem in this area of the law may lie in the line of cases stemming from the *Ruschig* case").

II. SECTION 112, ¶ 1 CONTAINS A SINGLE WRITTEN DESCRIPTION REQUIREMENT, WHOSE MEASURE IS ENABLEMENT

A. Section 112, first paragraph requires a written description that enables one of ordinary skill in the art to make and use the invention by identifying what the invention is and teaching how to make and use it

For the reasons set forth in Section I, above, § 112, ¶ 1, does not contain a written description requirement separate from an enablement requirement, and Plaintiffs-Appellees accordingly answer the Court's first en banc question in the negative. To respond to the Court's second en banc question, it necessarily follows that the statute provides no scope or purpose for a separate written description requirement.

Properly interpreted, the written description requirement of § 112, ¶ 1 requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention. The sufficiency of this written description is judged by a single standard: whether it enables any person skilled in the art to make and use the claimed invention.

Identifying the invention is necessary for enablement, since a specification that does not teach one of ordinary skill *what* to make and use does not enable the skilled artisan to make and use the unidentified subject matter. This requirement plays an important role in policing priority.

However, original claims necessarily identify the subject matter that they define; since they are part of the disclosure at the time of filing and "constitute their own description." *In re Koller*, 613 F.2d 819, 823 (CCPA 1980) (citing *In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973)).[10]

The description requirement also requires the specification to teach one of ordinary skill in the art *how* to make use the claimed invention. Enablement is "not precluded by the necessity for some experimentation such as routine screening" provided that "undue experimentation" is not required. *In re Wands*, 858 F.2d 731, 736-77 (Fed. Cir. 1988). Whether a disclosure requires "undue experimentation" is not a "merely quantitative" inquiry, but rather requires "the application of a standard of reasonableness" to reach a legal conclusion based on "weighing many factual considerations" such as:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737.

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[10] Original claims may nevertheless fail to satisfy the § 112, ¶ 1 written description requirement, since the specification may properly identify the claimed invention, yet fail to enable the skilled artisan to make and use it.

Properly construed, the enabling description requirement of § 112, first paragraph differs in several important respects from the Court's current separate description-possession requirement:

(i) *Contribution vs. possession*. First and foremost, under this Court's current precedent the test for adequacy of description is "possession" and requires a precise definition of the claimed invention "such as by structure, formula, chemical name, or physical properties." *Lilly*, 119 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1171). This is incorrect: the proper test for adequacy of description is whether the description enables any person skilled in the art to make and use the claimed invention. That test is well illustrated in the Supreme Court cases, which focus on whether the claimed scope matches the inventor's contribution.

(ii) *Objective vs. subjective*. The statutory enabling-description requirement is focused objectively on what the specification conveys to *others*, namely those of ordinary skill in the art. This Court's description-possession requirement, by contrast, attempts to discern the applicants subjective state of mind by asking whether, as judged by one or ordinary skill in the art, the specification shows that the claimed subject matter was in the inventor's conceptual possession. This state-of-mind criterion is not

only harder to satisfy, but is also unfamiliar and confusing to the skilled artisans through whose testimony it must be proven at trial.

(iii) *Different bodies of evidence*. Post-filing publications may be used to show that the specification was enabling in view of the state of the art at the time of filing, whereas this Court deems post-filing publications to be "legally irrelevant" to the description-possession issue. *Compare Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003) *with Ariad*, 560 F.3d at 1373-74. The use of different bodies of evidence to decide questions that are inextricably intertwined is confusing not only to juries but, frequently, also to courts.

(iv) *Law vs. fact*. Enablement is a question of law based on underlying factual determinations, whereas the Court has held that the "separate written description" requirement is a question of fact. *Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006); *Singh v. Brake*, 317 F.3d 1334, 1343, 1345 (Fed. Cir. 2003). This Court has never identified a statutory basis for this distinction.

B. Supreme Court Precedent Illustrates the Proper Approach to Determining Whether the Specification Provides an Enabling Disclosure

The proper approach to the enabling-description requirement of § 112 ¶ 1 is well illustrated by the leading Supreme Court precedents – *O'Reilly v.*

Morse, 56 U.S. 62 (1853), *The Telephone Cases*, 126 U.S. 1 (1888), and *The Incandescent Lamp Patent*, 159 U.S. 465 (1895) – and focuses on whether or not the claims of the patent encompass more than the inventor's contribution as set forth in the specification.

Morse and *The Telephone Cases* help illustrate the opposite sides of this line. In both cases, prior researchers had recognized the desirability of using electrical currents to communicate information (*Morse*) and to transmit speech (*Telephone Cases*). In both cases, the inventors had made important and meritorious advances in technology. And in both cases, the inventors included in their patents claims that were challenged as excessively broad. Yet the Supreme Court sustained the broadest claim in *The Telephone Cases* and invalidated the one in *Morse*. The difference in results between the two cases can be succinctly summarized: Bell's claim, though broad, was directed specifically to his contribution to the field. By contrast, Morse was attempting to go beyond his contribution.

In *The Telephone Cases*, the Court recognized that, prior to Bell's discovery, "[i]t had long been believed that if the vibrations of air caused by the voice in speaking could be reproduced at a distance by means of electricity, the speech itself would be reproduced and understood. *How to do it was the question*." *Id*. at 532 (emphasis added). Bell's contribution—

"his art," to use the Court's words—was the discovery that speech could be conveyed electrically by using "undulations" in continuous current, i.e., "by gradually changing the intensity of a continuous electric current so as to make it correspond exactly to the changes in the density of the air caused by the sound of the voice." *Id*. That technique was in contrast to the prior art, which had been trying to transport sound with an "intermittent or pulsatory current." *Id*. at 531. Because Bell's broadest claim was directed to that insight, the Court sustained it.

In *Morse*, the Court also expressly recognized that, in the years before Morse's invention, "it was believed by men of science that this newly discovered power [of electromagnetism] might be used to communicate intelligence to distant places." 56 U.S. at 107. "The great difficulty" for creating a practical telegraph "was the fact that the galvanic current, however strong in the beginning, became gradually weaker as it advanced on the wire, and was not strong enough to produce a mechanical effect after a certain distance had been traversed." *Id*. Morse's key advance was to create a cascade of circuits—i.e., to "combin[e] two or more electric or galvanic circuits, with independent batteries for the purpose of overcoming the diminished force of electro-magnetism in long circuits." The Court *allowed* Morse to claim that contribution, which was articulated in his fourth claim.

See id. at 86 (setting forth the claim), 112 (sustaining the claim). Morse overclaimed only when he attempted to patent all possible electrical telegraphs because that broad class went beyond his contribution to the field. As the Court explained, Morse's broadest claim (which attempted to cover any electrical telegraph for printing characters at a distance) was invalid because it purported to cover "a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent." 56 U.S. at 113.

The line drawn by *Morse* and *The Telephone Cases* is also evident in the *Incandescent Lamp Patent* case. There, two early light bulb researchers, Sawyer and Man, created a new filament of carbonized paper that may have somewhat better than pre-existing carbonized filaments. In their broadest claims, however, they attempted to claim any filament "of a carbonized fibrous or textile material, and of an arch or horseshoe shape, substantially as hereinbefore set forth." 159 U.S. at 468. The Supreme Court did not hold that such a broad claim was *necessarily* impermissible because, at the time of patenting, Sawyer and Man had enabled only *one embodiment* of such a filament (carbonized paper). Indeed, the Court noted that, "[i]f the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials such as

minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad." *Id*. at 472. Rather, the Court considered the contribution made by Sawyer and Man and found that their "imperfect experiments" had at most found carbonized paper to be somewhat better as a filament than the prior art. *Id*. at 474-75.

III. THE WRITTEN DESCRIPTION REQUIREMENT OF § 112, ¶ 1, PROPERLY CONSTRUED, IS SATISFIED BY THE HARVARD/MIT/WHITEHEAD SPECIFICATION

A. The technological background of the claimed invention

The claims on appeal are directed to methods for interfering with a particular biological pathway inside cells to achieve medically useful results.

Living cells can respond to external stimuli by activating sets of genes to produce the corresponding proteins. For example, immune cells can respond to a bacterial substance called "lipopolysaccharide" (LPS) by activating genes that encode "cytokines" – proteins that signal other immune cells to combat the infection. While this cytokine response is normally beneficial, it can be harmful in excess. (A449, A10083).

The Harvard/MIT/Whitehead inventors discovered a particular intracellular pathway (out of thousands of pathways) that controls how immune cells respond to external stimuli. (A10076) In this pathway, a particular protein in the cell (which these inventors name "NF-κB") is

released in response to the stimulus. Upon release, the "NF-κB" binds to particular DNA sequences ("NF-κB" recognition sites") in certain genes and activates them. (A10064-65) Using the LPS/cytokine response as an example, this pathway can be simply represented as follows:

LPS → cell → release NF-κB → activate genes → make cytokines

These inventors discovered the existence of the protein that they named "NF- κB"; determined its biochemical characteristics; and showed that it plays a key role in the cell's response to an external stimulus. The discovery of NF-κB was especially noteworthy because the biological activity of this protein is normally masked in cells by a natural inhibitor, making it much more difficult to detect than convential proteins (like insulin) whose biological activities are readily apparent. The 1989 application provides a detailed description of the NF-κB pathway, including how NF-κB is activated in response to external stimuli, moves to and enters the cell's nucleus, and activates particular genes that permit the cell to respond to the extenral stimulus.

B. The claims involved in this appeal

The inventors determined that by increasing or decreasing the naturally-occurring activity of NF-κB they could increase or decrease the amount of response proteins (e.g. cytokines) produced. (A16942-43). The

claims on appeal are drawn to methods for altering a cell's response to an external stimulus by reducing the activity of NF-κB in the cell, thereby reducing the production ("expression") of responsive proteins. Claim 95 (which depends from claim 9) and claim 144 (which depends from claim 14) are representative of the claims at issue in this case. Re-written in independent form, they recite:

> 95. A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-κB-mediated intracellular signaling, the method comprising reducing NF-κB activity in the cells such that expression of said genes is reduced . . . carried out on human cells
>
> 144. A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-κB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells . . . wherein reducing NF-κB activity comprises reducing binding of NF-κB to NF-κB recognition sites on genes which are transcriptionally regulated by NF-κB.

(A489; A491-92). Thus, claims 95 and 144 are directed to a method of altering a particular cellular response (e.g., "expression of cytokines") to a particular stimulus (e.g., "bacterial lipopolysaccharide") by interfering with one pathway ("reducing NF-κB activity in the cells") out of hundreds of different pathways in cells. Moreover, claim 144 further requires that

"reducing NF-κB activity" must comprise "reducing binding of NF-κB to NF-κB recognition sites" on genes in the cell.

Thus, the claims on appeal are not directed to "methods for reducing NF-κB activity," as Lilly has incorrectly contended and as the panel accepted. *See Ariad*, 560 F.3d at 1374. On the contrary, the claims recite "reducing NF-κB activity" as one particular *way* to achieve useful results, such as "reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells."

C. The disclosure of the 1989 application

The priority application, filed April 21, 1989, provides a detailed description of the NF-κB pathway, its role in cellular responses to external stimuli such as LPS, and how those responses can be modified by artificially interfering with NF-κB. (A16942-43, A16960-67). In the section entitled "Summary of the invention," the disclosure identifies the invention as follows (A16942-43):

> The present invention relates to a method of regulating or influencing transduction, by NF-κB, of extracellular signals into specific patterns of gene expression in the cells and systems in which it occurs. In particular, the present invention relates to a method of regulating (enhancing or diminishing) the activity of NF-κB in cells in which it is present and capable of acting as an intracellular messenger, as well as substances or composition useful in such a method. . . . The expression of a gene having a NF-κB binding recognition sequence

> can be regulated, either positively or negatively, to provide for increased or decreased production of the protein whose expression is mediated by the gene.

The 1989 specification teaches that NF-κB activity can be reduced using "decoy molecules" – artificial pieces of DNA that contain an NF-κB recognition sequence: "[N]egative regulation can be effected using 'decoy' molecules, which are designed to mimic a region of the gene whose expression should normally be induced by NF-κB. In this case, NF-κB would bind to the decoy and, thus, not be available to bind to its natural target." (A16966). The 1989 specification includes a table that lists 10 different NF-κB recognition sequences suitable for use in decoy molecules. (A16965). This table, which also appears at column 37 of the patent-in-suit, is reproduced below:

TABLE 2

Sequences recognized by NF-κB.

Gene	Sequence
Ig κ enhancer - mouse SV40 enhancer HIV-1 (-91) CMV (4)[1,2]	GGGGACTTTCC
HIV-1 (-105) HIV-2 CMV (1)[1] β2-microglobulin serum amyloid A -g9	AGGGACTTTCC
Ig κ enhancer - human CMV (3)[1]	GGGGATTTCC
Interferon-β- PRDII	GGGAAATTCC
CMV(2)[1]	GGGACTTTCC
MHC class II-E_α^d	GGGACTTCCC
IL-2 lymphokine	GGGATTTCAC
mouse IL-2Rα	GGGGATTCCT
human IL-2Rα	GGGAATCTCC
MHC class I - H2 - K^b HLA - A2, A11, B7 B27, B51	GGGATTCCCC
CONSENSUS[3]:	GGGRATYYAC (C/T, C/T)

[1]In this particular element, the sequence has not been tested in a binding assay. All others have been proven by direct binding and usually by inhibition of binding to the Ig κ sequence.
[2]Since there are four putative NF-KB recognition sites in the cytomegalovirus enhancer, these have been numbered 1-4 as they are found from 5' to 3' on the coding strand.
[3]Consensus is based on all sequences though the assignments of the sixth and tenth positions ignore one deviant.

The 1989 specification identifies two further ways of reducing NF-κB activity: by using "dominantly interfering molecules" (A16967) or specific inhibitors such as "IκB" (A16966). The 1989 specification also provides two screening assays for identifying additional specific inhibitors. (A10475-

76; A10485-86; A16943-45; A16971 A10485-86); *see also* Brief for Plaintiffs-Appellees, filed Sept. 26, 2009 at 27.

D. The 1989 application describes the claimed invention in terms that enable persons skilled in the art to make and use it

As shown above, the 1989 application describes (i.e., identifies) the same invention that is defined by the claims on appeal: namely, methods for altering a cell's response to an external stimulus (e.g. LPS) by reducing NF-κB activity in the cell so as to reduce the expression of proteins (e.g. cytokines) from genes controlled by NF-κB.

In addition, the jury was correctly charged on the issue of enablement, *see* A10545-46 (charging the jury on the *Wands* factors) and its verdict that the claims are enabled is supported by substantial expert and other testimony. Plaintiffs-Appellees' experts testified that the 1989 specification enabled the use of decoy molecules for carrying out the claimed methods (A10087-88) and that as of April 29, 1989, techniques and machines were known for preparing stable DNA that "resists nucleases that chop it up" and accordingly are suitable for use as decoys. (A10483).

Moreover, a 1990 publication, in evidence before the jury, shows that scientists at the University of Michigan – using decoy molecules having a NF-κB recognition sequence taught in the 1989 specification – reduced NF-

κB activity in cells. (A16064-67). The authors of this publication specifically cited and acknowledged scientific publications by the inventors of the patent-in-suit that had disclosed to them, and others, the existence of NF-κB and the identity of the NF-κB recognition sequence. The patentees' disclosures, combined with prior art methods and commercially available machines for "routinely synthesiz[ing] in large amounts" nuclease-resistant DNA containing a desired sequence, enabled the Michigan scientists to make decoys molecules and use them for reducing NF-κB activity in cells. (A16064).

That other scientists promptly succeeded in reducing intracellular NF-κB activity by using the decoy molecules taught in the 1989 specification constitutes powerful evidence of enablement. The jury's verdict on enablement was also supported by expert testimony showing that other scientists successfully used dominantly interfering molecules soon after the 1989 application was filed (A10484-85); that known purification and recombinant techniques enabled the use of IκB as a specific inhibitor (A10477-78; A10485); and that the disclosed screening assays enabled the use of additional inhibitors to reduce NF-κB activity. (A10485-86).

Put simply, the inventors of the patent-in-suit discovered a previously unknown protein in cells, NF-κB, that plays a crucial role in regulating the

immune response to inflammatory stimuli. They realized the important benefits that would flow from reducing NF-κB activity in cells and promptly published their discoveries both in the scientific literature and in patent applications that described how to achieve such reduction. Other scientists promptly practiced these teachings and expressly cited and referred to the publications of the present inventors as the basis for their own results. Without the present inventors' discoveries and disclosures, no one would that NF-κB activity even existed in cells, nor even that reducing that activity was possible or desirable.

By making and disclosing their invention, these Nobel laureates provided their fellow scientists and the public with entirely new methods of broad applicability, and thus they were entitled to claims directed to the novel methods they had described, and not merely to the particular compounds by which they exemplified their invention. "What were once referred to as 'basic inventions' have led to 'basic patents,' which amounted to real incentives, not only to invention and its disclosure, but to its prompt, early disclosure." *In re Hogan*, 559 F.2d 595, 606 (CCPA 1977). As this Court has explained: "[T]he enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quotation marks

omitted); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (finding the "patent bargain" satisfied where the specification "fully teaches a mode of making the claimed invention"); *accord In re Rasmussen*, 650 F.2d 1212, 1215 n.17 (CCPA 1981) (requiring "disclosure of only one mode of practicing the invention").[11]

The Harvard/MIT/Whitehead inventors contributed far more than discovering the existence of yet one more previously unknown protein. They described the components and the mechanism of a very important celluar pathway (the NF-κB pathway) and its role in the cell's response to external stimuli; described a method of altering a cell's rsponse to such a stimulus by reducing NF-κB acvitity; and described compounds (including decoy molecules) suitable for performing that method, as well as screening assays for identifying yet further suitable compounds. The claimed methods encompass no more than the important contribution that these inventor described in the 1989 priority application.

[11] *See* Brief for Plaintiffs-Appellees, filed Sept. 26, 2008, at 20-28 (explaining why the 1989 application enabled the presently claimed methods).

CONCLUSION

For the reasons set forth above, the judgment of the District Court should be affirmed in its entirety.

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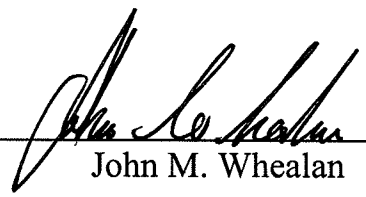
By 
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STATUTORY ADDENDUM

Statutory Addendum

THE PATENT ACT OF 1790[1]

SEC. 2. *And be it further enacted*, That the grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit of a model) of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular, and said models so exact, as 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, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term; which specification shall be filed in the office of the said Secretary, and certified copies thereof, shall be competent evidence in all courts and before all jurisdictions, where any matter or thing, touching or concerning such patent, right, or privilege, shall come in question.

THE PATENT ACT OF 1793[2]

SEC. 3. *And be it further enacted*, That every inventor, before he can receive a patent, shall swear or affirm, that he does verily believe, that he is the true inventor or discoverer of the art, machine, or improvement, for which he solicits a patent, which oath or affirmation may be made before any person authorized to administer oaths, and shall deliver a written description of his 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, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same. And in the case of any machine, he shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions; and he shall accompany the whole with drawings and written references, where the nature of the case admits of drawings, or with specimens of the ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where

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[1] Act of Apr. 10, 1790, 1 Stat. 109, 110-11, ch. 7.

[2] Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11.

the invention is of a composition of matter; which description, signed by himself and attested by two witnesses, shall be filed in the office of the Secretary of State, and certified copies thereof shall be competent evidence, in all courts, where any matter or thing, touching such patent-right, shall come in question. And such inventor shall, moreover, deliver a model of his machine, provided, the secretary shall deem such model to be necessary.

THE PATENT ACT OF 1836[3]

SEC. 6. *And be it further enacted*, That any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others before his or their discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer; and shall desire to obtain an exclusive property therein, may make application in writing to the Commissioner of Patents, expressing such desire, and the Commissioner, on due proceedings had, may grant a patent therefor. But before any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery. He shall, furthermore, accompany the whole with a drawing, or drawings, and written references, where the nature of the case admits of drawings, or with specimens of ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention or discovery is of a composition of matter; which descriptions and drawings, signed by the inventor and attested by two witnesses, shall be filed in the Patent Office; and he shall moreover furnish a model of his invention, in all cases which admit of a representation by model, of a convenient size to exhibit advantageously its several parts. The applicant shall also make oath or affirmation that he does verily believe

[3] Act of July 4, 1836, 5 Stat. 117, 119, ch. 357.

that he is the original and first inventor or discoverer of the art, machine, composition, or improvement, for which he solicits a patent, and that he does not know or believe that the same was ever before known or used; and also of what country he is a citizen; which oath or affirmation may be made before any person authorized by law to administer oaths.

THE PATENT ACT OF 1870[4]

SEC. 26. *And be it further enacted*, That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the commissioner, and shall file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions; and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery; and said specification and claim shall be signed by the inventor and attested by two witnesses.

[4] Act of July 8, 1870, 16 Stat. 198, 201, ch. 230, §26.

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Sworn to before me on October 5, 2009

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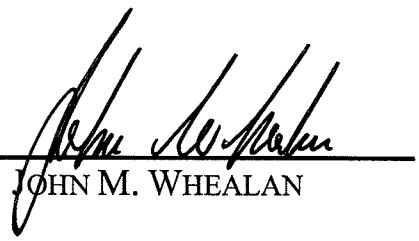
By 

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