

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

REPLY BRIEF FOR PLAINTIFFS-APPELLEES ON REHEARING EN BANC

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

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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TABLE OF CONTENTS

| | Page |
|---|------|
| CERTIFICATE OF INTEREST | i |
| TABLE OF AUTHORITIES | iv |
| ARGUMENT | 1 |
| I. THERE IS MUCH COMMON GROUND, BUT THE PARTIES AND AMICI DISAGREE ON THE STANDARD FOR MEASURING SUFFICIENCY OF WRITTEN DESCRIPTION | 1 |
| II. THE TEXT AND HISTORY OF THE PATENT STATUTE DO NOT SUPPORT LILLY’S CONSTRUCTION OF THE WRITTEN DESCRIPTION REQUIREMENT | 2 |
| III. SUPREME COURT PRECEDENT DOES NOT SUPPORT LILLY’S CONSTRUCTION OF THE WRITTEN DESCRIPTION REQUIREMENT | 7 |
| A. Pre-1836 Supreme Court Precedent | 7 |
| B. Post-1836 Supreme Court Precedent | 10 |
| 1. Sufficiency of the Written Description and the Inventor’s Contribution | 12 |
| 2. Timing of the Written Description and Priority | 18 |
| IV. THE DESCRIPTION REQUIREMENT OF SECTION 112 POLICES PRIORITY AND ENSURES THAT THE CLAIMS MATCH THE INVENTOR’S CONTRIBUTION | 21 |
| A. The Description Requirement of Section 112 Polices Priority of New or Amended Claims | 22 |
| B. The Description Requirement of Section 112 Ensures that the Claims Match the Inventor’s Contribution | 23 |
| C. The Facts of this Case Illustrate the Proper Operation of the Written Description Requirement | 25 |
| CONCLUSION | 31 |
| CERTIFICATE OF COMPLIANCE | |

TABLE OF AUTHORITIES

| | Page(s) |
|---|------------|
| CASES | |
| <i>Ariad Pharms., Inc. v. Eli Lilly & Co.</i> , 560 F.3d 1366 (Fed. Cir. 2009) | 12, 26, 30 |
| <i>Brooks v. Fiske</i> , 56 U.S. (15 How.) 212 (1853) | 9 |
| <i>Evans v. Eaton</i> , 20 U.S. (7 Wheat.) 356 (1822) | 7, 8, 9 |
| <i>Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002)..... | 4 |
| <i>Gill v. Wells</i> , 89 U.S. (22 Wall.) 1 (1874)..... | 18, 19 |
| <i>Holland Furniture Co. v. Perkins Glue Co.</i> , 277 U.S. 245 (1928)..... | 17, 18 |
| <i>In re Ruschig</i> , 379 F.2d 990 (CCPA 1967)..... | 23 |
| <i>Knight v. Comm’r of Internal Revenue</i> , 552 U.S. 181 (2008)..... | 2 |
| <i>Merrill v. Yeomans</i> , 94 U.S. 568 (1876)..... | 9 |
| <i>O’Reilly v. Morse</i> , 56 U.S. (15 How.) 62 (1854)..... | 12, 14, 24 |
| <i>Permutit Co. v. Graver Corp.</i> , 284 U.S. 52 (1931)..... | 18, 20 |
| <i>Pfaff v. Wells Elecs., Inc.</i> , 525 U.S. 55 (1998)..... | 24 |

| | |
|--|----------------|
| <i>Regents of the Univ. of California v. Eli Lilly & Co.</i> , 119 F.3d 1559 (Fed. Cir. 1997) | 2 |
| <i>Schriber-Schroth Co. v. Cleveland Trust Co.</i> , 305 U.S. 47 (1938)..... | 18, 20, 21, 23 |
| <i>Smith v. Snow</i> , 294 U.S. 1 (1935)..... | 17 |
| <i>The Corn-Planter Patent</i> , 90 U.S. (23 Wall.) 181 (1874)..... | 9 |
| <i>The Incandescent Lamp Patent</i> , 159 U.S. 465 (1895)..... | 16, 17 |
| <i>The Telephone Cases</i> , 126 U.S. 1 (1888) | 14, 15, 25 |
| <i>Tilghman v. Proctor</i> , 102 U.S. 707 (1880)..... | 14 |
| <i>United States v. Ron Pair Enters.</i> , 489 U.S. 235 (1989)..... | 7 |

STATUTES

| | |
|-----------------------------|---------|
| 35 U.S.C. § 112..... | passim |
| 35 U.S.C. §§ 120 & 132..... | 22 |
| Patent Act of 1793 | 5, 6, 7 |
| Patent Act of 1836 | 5, 6 |
| Patent Act of 1952 | 6 |

OTHER AUTHORITIES

| | |
|--|--------|
| 2 Robinson, <i>The Law of Patents for Useful Inventions</i> (1890) | 10, 11 |
| Phillips, <i>The Law of Patents for Inventions</i> (1837)..... | 10 |

ARGUMENT

I. THERE IS MUCH COMMON GROUND, BUT THE PARTIES AND AMICI DISAGREE ON THE STANDARD FOR MEASURING SUFFICIENCY OF WRITTEN DESCRIPTION

Lest it be obscured by rhetoric, it is important to note that there is much common ground amongst the parties and amici.¹ Specifically, they agree that:

1. The specification must provide a written description of the invention *and* of the manner and process of making and using it.
2. The description requirement of § 112 applies to all claims, whether they were originally present in the application or not.
3. The description requirement of § 112 polices an applicant's ability to add or amend claims during prosecution.
4. A patent may not claim an invention that is not described in the specification.
5. The description requirement of § 112 prevents claims that extend beyond the inventor's contribution as set forth in the specification;

¹ See, e.g., Amicus Brief for Federal Circuit Bar Association, filed Nov. 19, 2009, at 6-8 (“all parties agree with ‘the undisputed proposition that the claims must be directed to an invention that is identified in the specification.’”) (quoting Principal Brief of Plaintiffs-Appellees on Rehearing en Banc, filed October 5, 2009 (“ARIAD Br.”) at 23).

claims of broad applicability must correspond to an invention that is identified in the specification by a broadly applicable common principle.

The actual disagreement concerns whether § 112, first paragraph requires a written description of the invention that is *separate from enablement*. Specifically, is the entire written description required by § 112 (i.e., the description of the invention, and of the manner and process of making and using it) measured by the statutory duty to describe the invention in “such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same,” as Plaintiffs-appellants contend? Or, as urged by Lilly, does § 112 impose a written description requirement independent of the rest of the statute and measured by the judicially-created “possession” test of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) and its progeny?

This reply brief focuses on this important area of disagreement.

II. THE TEXT AND HISTORY OF THE PATENT STATUTE DO NOT SUPPORT LILLY’S CONSTRUCTION OF THE WRITTEN DESCRIPTION REQUIREMENT

While some of the briefs belittle a close analysis of the statutory text, “[w]e start, as always, with the language of the statute.” *Knight v. Comm’r of Internal Revenue*, 552 U.S. 181, 187 (2008).

The following table compares the competing statutory constructions proposed by plaintiffs-appellees and Lilly, and shows that Lilly has effectively rewritten the statute by adding the italicized words.²

| Plaintiffs-appellees | Defendant-appellant Eli Lilly & Co. |
|--|--|
| <p>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.</p> | <p>The specification shall contain a written description of the invention, and</p> <p><i>The specification shall contain a written description . . .</i> 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.</p> |

Plaintiffs-appellees explained why the actual text of the statute, following the ordinary rules of English grammar, supports their construction

² Compare ARIAD Br. at 3 with Principal Brief of Defendant-Appellant on Rehearing en Banc, filed November 9, 2009 (“Lilly Br.”) at 25-26 (emphasis added).

and not Lilly's. *See* ARIAD Br. at 2-7.³ Under Lilly's construction, the phrase "written description of the invention" is not modified by the subsequent words of that section. That construction severs the "written description of the invention" not only from the requirement to enable, but also from the requirement that it be in "full, clear, concise, and exact" terms. There is no reason for Congress to demand a written description of "the manner and process of making and using" the invention that is "full, clear, concise, and exact" while tolerating a "written description of the invention" that is incomplete, unclear, long-winded, and inexact.⁴ Under a proper construction of § 112, the entire written description "of the invention" and "of the manner and process of making and using [the invention]" must be "in

³ In addition, the word "shall" appears only twice in § 112, first paragraph, not three times (the specification "shall contain a written description" and "shall set forth the best mode"), consistent with the conclusion that this paragraph sets forth two statutory requirements, not three. Moreover, the term "invention" likewise appears only twice in § 112, first paragraph: once in relation to each occurrence of "shall," which is further evidence that this paragraph sets forth two requirements, not three. *See* Amicus Brief of Roberta J. Morris, Esq., filed Oct. 13, 2009, at 5-6.

⁴ Lilly wrongly believes that *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), supports its position. But *Festo* expressly recognized that the entirety of the written description requirement is modified by the prepositional phrase that begins "in such full, clear, concise, and exact terms . . ." *See id.* at 731 (noting that "the patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' 35 U.S.C. § 112").

full, clear, concise, and exact terms” and must enable one of ordinary skill to make and use the “same [invention]” that is described.⁵

The history of the Patent Act also shows that, since 1793, the requirement for a description of the invention has always been linked with the requirement to describe the manner of making and using the invention, and has been measured by the text that follows, i.e., clear, concise and exact, etc. In the 1793 Act, the written description was assigned two statutory tasks: (i) to define the claimed invention so as to distinguish it from the prior art, and (ii) to enable a person of ordinary skill in the art to make and use the invention. In the 1836 Act and thereafter, the distinguishing requirement was replaced with the claiming requirement, while enablement remained the responsibility of the written description.

The following table compares the relevant language from the Patent Acts of 1793, 1836, and 1952:

⁵ In supporting Lilly, the Government has significantly deviated from its prior position on this issue. See Amicus Brief for the United States in Support of En Banc Review, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), 2002 WL 32345618, at *5 (“A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough information for others to make and use the invention.”).

| 1793 Patent Act | 1836 Patent Act | 1952 Patent Act § 112, ¶ 1 |
|--|--|---|
| a written description of his invention, and of the manner of using, or process of compounding the same, | a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, | a written description of the invention, and of the manner and process of making and using it, |
| in such full, clear and exact terms, as | in such full, clear, and exact terms, avoiding unnecessary prolixity, as | in such full, clear, concise, 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 | 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 | 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 Lilly’s construction, the “written description of [the] invention” in the 1793 Act must also stand alone and is not required to enable or to “distinguish the [invention] from all other things before known,” and the task of distinguishing the invention would fall to the “[written description] of the manner of using, or process of compounding the same” That construction makes no sense, and Supreme Court precedent is to the

contrary. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 434 (1822) (testing whether the written description distinguished the invention from the prior art).

Lilly relegates its discussion of the statutory text to a secondary argument (*see* Lilly Br. at 25-31) and criticizes plaintiffs-appellees for undertaking “a fine grammatical parsing of the statute.” *Id.* at 26. *Contra United States v. Ron Pair Enters.*, 489 U.S. 235, 241 (1989) (relying on “the grammatical structure of the statute” to construe it). Lilly relies principally on “almost two hundred years of precedent” as purportedly supporting its interpretation of the statute, but mischaracterizes the Supreme Court decisions on which it relies.

III. SUPREME COURT PRECEDENT DOES NOT SUPPORT LILLY’S CONSTRUCTION OF THE WRITTEN DESCRIPTION REQUIREMENT

Supreme Court precedent both before 1836 and after 1836 provides no support for the view that the written description requirement is to be separated from its statutory standard for enablement, let alone that it be judged by this Court’s current “possession” test.

A. Pre-1836 Supreme Court Precedent

Lilly begins its discussion of Supreme Court precedent with *Evans*, which Lilly asserts “found that [section 3 of the Patent Act of 1793]

established two requirements: (1) enablement and (2) written description.” Lilly Br. at 5 (emphasis omitted). It is unclear where in the Court’s opinion Lilly finds this holding. Lilly cites pages 380-81 of the U.S. Reports for this proposition, but those pages set forth not the Court’s opinion but the report of arguments made by a “Mr. Sergeant” for the defendant. *Evans*, 20 U.S. 378 (beginning of Sergeant’s argument). Moreover, no other portion of the report of that case – and certainly not any portion of the Court’s opinion – supports Lilly’s simplistic and ahistorical characterization of the case.

As explained in plaintiffs-appellees’ opening brief, *Evans* relied on the plain language of the then-existing statute to conclude that “[t]he specification, then, has two objects.” *Id.* at 433. Those two objects were not, as Lilly asserts, enablement and written description. Rather the objects were (1) “to enable” the invention and (2) “to distinguish” the invention from all things previously known. *Id.* at 433-34. Lilly is simply incorrect in asserting that *Evans* constitutes support for a case law doctrine that requires something more than an enabling written description and distinct claims. Indeed, in *Evans* itself, the patent specification in question fully identified the claim’s subject matter. *Id.* at 434 (noting that the specification was “sufficiently exact and minute in the description”). The problem in *Evans*

was that the specification did not particularly point out and distinguish the subject matter that the applicant claimed to have invented.

The objective of distinguishing the invention has not vanished from modern patent specifications; it survives in the claims required under § 112, second paragraph. Indeed, in *Brooks v. Fiske*, 56 U.S. (15 How.) 212 (1853), the Court quoted the claiming requirement from the 1836 Patent Act and then explained its purpose by quoting directly from the portion of *Evans* that explained the importance of distinguishing the patentee's invention. *See id.* at 214-15 (quoting *Evans*, 20 U.S. (7 Wheat.) at 434). Later Supreme Court cases also describe the function of the claiming requirement as distinguishing between the old and the new – language which traces back directly to the *Evans* Court's interpretation of the then-existing requirement that the written description of the invention “distinguish” the invention. *See, e.g., The Corn-Planter Patent*, 90 U.S. (23 Wall.) 181, 224 (1874); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876).

An accurate assessment of the history also provides a complete answer to the Government's argument that, if the language of the modern statute is respected, the result would be somehow “to abrogate *Evans* or otherwise dilute the disclosure requirements of the patent laws.” Amicus Brief of the United States (“Gov't Br.”), filed Nov. 19, 2009, at 7. Not so.

It is the Government’s position – not plaintiffs-appellees’ – that would have the 1836 Patent Act abrogating *Evans*. Under plaintiffs-appellees’ construction, the specification, including the claims, still has the two functions articulated by *Evans*: to enable the person having skill in the art to make and use the invention (the function of the written description); and to distinguish with precision what the inventor claims as his own invention (the objective of the claims).⁶ Under the Government’s view, the statutory revision in 1836 somehow created three functions for the specification: the two recognized in *Evans* plus some additional “written description of the invention” that has an objective different from those recognized in *Evans*. That position has no basis in history or congressional intent, and the Government’s brief is not even clear what that third objective is.

B. Post-1836 Supreme Court Precedent

Since 1836, Supreme Court precedent has interpreted the statute as requiring that, at the time of filing the patent application, the applicant must

⁶ In early nineteenth century practice, the two objectives for the specification tended to be “run so much into each” that a prominent commentator suggested Congress should “arrange them in different sections.” Phillips, *The Law of Patents for Inventions* 237 (1837). Yet even before Congress separated the two objectives into different statutory paragraphs, the historical trend was to recognize that, because it had “these two objects to fulfill, a specification is naturally divided into two parts . . . the Description, and the Claim.” 2 Robinson, *The Law of Patents for Useful Inventions* § 482, at 71 (1890).

provide a written description of the invention, and of manner and process of making and using it. The Supreme Court cases decided under the written description requirement concern one of two issues: (1) whether the written description identified the invention at the time of filing; and (2) whether the written description of that identified invention is sufficient. The first issue concerns *timing*, and the Court has made clear that, consistent with the statutory language and structure, the written description of the invention must be complete as of the date of filing. The second issue involves *sufficiency*, and the Court has consistently judged sufficiency under a single standard, by testing whether the written description achieves its statutory goal – that it be in such full, clear, concise, and exact terms as to enable a person skilled in the art to make and use the same.⁷

All the post-1836 Supreme Court cases cited by Lilly fall into one of these two categories. What Lilly cannot produce is even one post-1836 Supreme Court opinion in which the description of an invention claimed or otherwise identified at the time of filing was found to be deficient under any standard other than the enablement standard. There is a reason Lilly cannot

⁷ Professor Robinson, whom the Government correctly cites as a leading authority, defines the sufficiency of the written description thus: “if [the inventor] affords to [those skilled in the art] such information as enables them to practise his invention, he satisfies all the requirements of the law.” Robinson, *supra*, § 488, at 80; *see also id.* § 491, at 85 (defining completeness of the description in terms of enablement).

find such a case. The Supreme Court cases have never decoupled the “written description of the invention” from rest of the statutory language and have never held that a written description of an invention sufficient to enable others to practice a claimed invention could nonetheless fail because the description somehow did not “establish that the applicant was in possession of the claimed invention.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1372 (Fed. Cir. 2009) (citations omitted).

- 1. Sufficiency of the Written Description and the Inventor’s Contribution**

Lilly begins its discussion of the post-1836 Supreme Court precedents with *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854), which Lilly wrongly characterizes as demonstrating that “there remained a separate written description requirement in the 1836 statute.” Lilly Br. at 7. In fact, *Morse* demonstrates that the sufficiency of the written description requirement was tested by enablement. Thus, for example, Lilly (*id* at. 8) quotes extensively from pages 120-21 of the opinion and repeatedly highlights the words “description” and “described.” It is of course common ground that an inventor may “lawfully claim only what he has invented and described,” *Morse*, 56 U.S. at 121, but the crucial question is how the sufficiency of the description is to be tested.

The *Morse* opinion provides a clear answer to that question in the very sentence before Lilly begins its block quote. The Court states that, under the statute, “the invention shall be so described, that a person skilled in the science to which it appertains, or with which it is most nearly connected, shall be able to construct the improvement from the description given by the inventor.” *Id.* at 120. Similarly, on the prior page, the Court recognized that the Patent Act could “be summed up in a few words”:

Whoever discovers that a certain useful result will be produced, in any art, machine, manufacture, or composition of matter, by the use of certain means, is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact, that anyone skilled in the science to which it appertains, can, by using the means he specifies, without any addition to, or subtraction from them, produce precisely the result he describes.

Id. at 119. Thus, the validity of a written description turns on whether “the means” of practicing the invention are articulated with sufficient fullness and exactitude so that others skilled in the art may use the same means to produce the desirable result. Since *Morse*’s eighth claim was on its face not limited to any particular means of achieving the desirable result (“I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims,” 56 U.S. at 112), the Court had no difficulty in invalidating it.

Tilghman v. Proctor, 102 U.S. 707 (1880), clarified precisely what constitutes a sufficient description of “the means” for practicing a process – an issue that *Morse* had left ambiguous. As the *Tilghman* Court recognized, “everything turns on the force and meaning of the word ‘means.’” *Id.* at 728 (quoting *Morse*, 56 U.S. (15 How.) at 119). The Court held that “means” may refer to a “process,” which the Court equated with “a conception of the mind, seen only by its effects when being executed or performed.” *Id.* The Court then defined the amount of description necessary to sustain a patent for a process, holding that “[i]f the mode of applying the process is not obvious, then a description of *a particular mode* by which it may be applied is sufficient. There is, then, *a description of the process and of one practical mode* in which it may be applied.” *Id.* (emphasis added). The Court expressly recognized that the process might be “susceptible of being applied in many modes and by the use of many forms of apparatus,” but expressly held that “[t]he inventor is not bound to describe them all in order to secure to himself the exclusive right to the process if he is really its inventor or discoverer.” *Id.* at 728-29.

Tilghman thus provides very clear guidance from the Supreme Court concerning the amount of written description sufficient to sustain a process patent. Further guidance was given in *The Telephone Cases*, 126

U.S. 1 (1888). There, the Court made clear that Bell’s broadest claim would be sustained “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.” *Id.* at 536 (emphasis added). This articulation of the standard tracks the enablement test, which requires enough information so that the person skilled in the art can understand the invention to such a degree as to make it and also to use or operate it.

In one significant passage in its brief, Lilly departs from an accurate rendering of the facts in *The Telephone Cases*. Lilly asserts that “Bell taught two ways of transmitting speech telegraphically.” Lilly Br. at 16. That is not so. Bell “*pointed out* two ways in which [his process] might be done.” 126 U.S. at 536 (emphasis added). But of those two possible ways in which the method might be practiced, the magneto and the variable resistance methods, Bell taught – i.e., provided an enabling description of – only one of them (the magneto method). The Court expressly held that Bell had not enabled an apparatus that worked under the variable resistance method, and thus could not claim that apparatus even though he could claim the generic process. *Id.* at 538.

Along with *Morse*, *Tilghman* and *The Telephone Cases*, *The Incandescent Lamp Patent*, 159 U.S. 465 (1895), rounds out the major nineteenth century Supreme Court cases defining the sufficiency of an enabling written description. The inventors there, Sawyer and Man, “supposed they had discovered in carbonized paper the best material for an incandescent conductor.” *Id.* at 472. Yet, “[i]nstead of confining themselves to carbonized paper, as they might properly have done, . . . they made a broad claim for every fibrous or textile material” *Id.* If there were a separate “written description” requirement of the sort articulated in recent opinions by this Court, this type of case would be the classic situation in which it should have been applied. But the Supreme Court quoted and applied the entirety of the statutory written description requirement, with the sufficiency of the written description tested by enablement.

Moreover, *The Incandescent Lamp Patent* case provides clear instruction as to when an inventor *may claim* broadly – where the inventor has discovered some “general quality” running through the whole of the claimed subject matter that distinguished it and gave it a “peculiar fitness” for the purpose to which the invention was directed. *Id.* at 475. That approach reconciles why inventors such as Sawyer and Man were not entitled to a broad patent, but an inventor such as Bell was. A common

quality – the use of undulating current to transport speech – united the subject matter in Bell’s process claim. In the Supreme Court’s words, “[t]his was his art,” 126 U.S. at 532 – his contribution taught to the field – and he was therefore entitled to a claim of corresponding breadth even though he had not yet made the process work himself and had an enabling disclosure of only one mode of practicing the process.⁸

The doctrine as a whole was well summarized in *Smith v. Snow*, 294 U.S. 1 (1935): “[I]t is not necessary to embrace in the claims or describe in the specifications all possible forms in which the claimed principle may be reduced to practice. It is enough that the principle claimed is exemplified by a written description of it and of the manner of using it ‘in such full, clear, concise, and exact terms’ as will enable one ‘skilled in the art to make, construct, compound and use the same.’” *Id.* at 11.

Though Lilly (Lilly Br. at 9-10) relies on *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), this case, too, shows that the written

⁸ Edison’s pioneering patent also claimed broadly: “An electric lamp for giving light by incandescence, consisting of a filament of carbon of high resistance, made as described, and secured to metallic wires, as set forth.” U.S. Patent No. 223,898 (issued Jan. 27, 1880) (claim 1). Though that claim was at least as broad as the invalidated claims of Sawyer and Man, the claimed subject matter was united by the common quality of high resistance. That approach marked a break with prior inventors, who had used low resistance filaments and had been striving to decrease the resistance further. *Id.* at ll.32-59. Because high resistance filaments were Edison’s contribution to the art, he was entitled to a correspondingly broad claim.

description requirement is not at all separate from enablement principles. *Holland Furniture* applied *The Incandescent Lamp Patent* and other enablement cases to determine what was “the real contribution [the inventor] made to the art.” *Id.* at 255. That contribution was the discovery that a good glue – one as good as animal glue – could be made from a starch ingredient having a particular “range of water absorptivity.” *Id.* The Court stated that the inventor “was entitled to the protection of a patent” for that contribution. *Id.* In certain claims, however, the patentee characterized his invention as a starch-based glue containing any starch that would make it “as good as animal glue.” *Id.* at 256. That claim clearly went beyond the inventor’s contribution because starch-based glues were previously known, and prior art starch glues were known not to work as well as animal glue. *See id.* at 248.

2. **Timing of the Written Description and Priority**

In contrast to *Morse*, *Tilghman*, *The Telephone Cases*, *The Incandescent Lamp Patent*, and *Holland Furniture*, cases such as *Gill v. Wells*, 89 U.S. (22 Wall.) 1 (1874), *Permutit Co. v. Graver Corp.*, 284 U.S. 52 (1931), and *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), concern the timing of the written description. These cases stand for the unremarkable point that the written description must be complete at the

time of filing, and the description cannot be supplemented by information added thereafter.

Gill concerned a reissued patent in which the specification had been amended to re-describe an alleged invention with different combinations of elements than those originally set forth. The Court noted that “that the description of the other combinations, beside the first [that originally set forth], would constitute a new matter, the introduction of which into the specification of a reissued patent is expressly forbidden by [the Patent Act].” 89 U.S. (22 Wall.) at 25. The Court then conducted a “[p]atient search” through the original description, but could not find “any trace of the description of any other invention” than that originally claimed. *Id.* at 26. The Court then held that the reissued patent was invalid as not being for the same invention originally patented.

Permutit demonstrates that elements necessary to patent validity also cannot be added after filing by unsupported claim construction. *Permutit* involved a patent on an allegedly improved water softening device “closely resembl[ing]” prior art devices. 284 U.S. at 56. The only invention alleged for the improved version (i.e., the only change not anticipated or obvious) was “the substitution of a ‘free’ for a ‘locked’ zeolite bed - a matter which [was] not referred to either in the specification or in the claim.” *Id.* The

only place in the patent containing even a hint of a “free” zeolite bed was in the patent’s one drawing, which illustrated an embodiment having an open space above the zeolite bed (thus, freeing the zeolites in the bed). But as the Supreme Court reasoned, “the absence in the claims of [a confining structure] placed above the zeolite bed does not imply that the zeolite bed is to be unconfined. The only normal inference from such silence is either that it was deemed immaterial whether the zeolite bed be locked or free, or that if a free bed is preferable, it was not claimed because it lacked novelty.” *Id.* at 59. Once interpreted not to require a free zeolite bed, the claims were conceded to cover nothing inventive.

Schriber-Schroth also demonstrates that the written description cannot be supplemented by amendments that would redefine the invention. Years after the filing of his patent application, the inventor in the case (Gulick) amended his claims and specification to introduce a concept – the flexibility or yieldability of a “web” used to connect an engine piston head to the piston “skirt” – that had not been described at all in the original application. Indeed, as the Court noted, the amendment was made *after a competing piston assembly with flexible webs was introduced into the market.* *Id.* at 55-56. The Court held that such “new matter” cannot be inserted into the description and claims after the filing of the application. *Id.* at 58. In

justifying that ruling, the Court noted that the flexibility of the web was an “essential element” needed to sustain the validity of the claim. *Id.* at 60. Moreover, the inventor had originally emphasized the rigidity, not flexibility, of the webs. In those circumstances, the Court concluded:

If invention depends on emphasis of one quality over the other, . . . the statute requires that emphasis to be revealed to the members of the public, who are entitled to know what invention is claimed. That is not accomplished either by naming a member having inherent antithetical properties or by ascribing to it one property when the other is meant.

Id. at 58.

Schriber-Schroth thus stands for the unremarkable proposition that amended claims cannot introduce elements nowhere mentioned in an application’s original disclosure. Nothing in *Schriber-Schroth* in any way hints that a claim could be viewed as failing the statutory disclosure requirement if the claimed subject matter is disclosed in the original specification “in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.”

IV. THE DESCRIPTION REQUIREMENT OF SECTION 112 POLICES PRIORITY AND ENSURES THAT THE CLAIMS MATCH THE INVENTOR’S CONTRIBUTION

When § 112, first paragraph is correctly interpreted in accordance with the statutory text and Supreme Court precedent, the requirement for an

enabling written description of the invention, and the manner and process of making and using it, ensures that the claims are directed to the same invention that is described in the specification, and that they match the inventor's contribution to the art. The description requirement of § 112, interpreted as proposed by plaintiffs-appellees, applies to all claims and accommodates the two principal concerns raised by the Government: (a) policing priority, and (b) cabining overbroad claims (*see* Gov't Br. at 21-24) which are addressed in turn below.

A. The Description Requirement of Section 112 Polices Priority of New or Amended Claims

The description requirement of § 112, properly construed, prevents patent applicants from introducing new or amended claims directed to a different invention than is described in an earlier-filed specification.

When continuing applications are filed, or when amendments are submitted in the course of patent prosecution, the description requirement of § 112, first paragraph (in conjunction with 35 U.S.C. §§ 120 & 132) plays an important role in policing claims to priority of earlier-filed applications and the propriety of amended or newly added claims. For example, a specification that discloses a new class of compounds, but does not specifically name or otherwise identify a particular compound within that class, does not support later-introduced claims to that unidentified

compound. *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967) (rejecting the argument that “one skilled in the art would be enabled by the specification to make [the later-claimed compound]” because that argument “presumes some motivation for wanting to make the compound in preference to others”). Similarly, a specification that describes the invention as a piston assembly comprising a *rigid* web structure will not support claims directed to a piston assembly comprising a *flexible* web structure. *Schriber-Schroth*, 305 U.S. at 59 (“that was not the invention which [the applicant] described by his references to an extremely rigid web.”).

Thus, the identification aspect of the description requirement ensures that the claims are directed to the same invention that is described in the specification.

B. The Description Requirement of Section 112 Ensures that the Claims Match the Inventor’s Contribution

The description requirement of § 112 also ensures that the claims – whether original or amended – match the inventor’s contribution to the art. In order to support claims that encompass more than the particular embodiment(s) set forth in the specification, an applicant must identify the common principle that defines the invention and distinguishes it from the

prior art.⁹ This common principle must be present in all the claimed embodiments, or else the claims will be invalid as encompassing more than the invention that the applicant described. Just as specific claims require a specific disclosure, generic claims require generic disclosure.

For example, in *Morse*, the specification described an improvement in telegraphy that solved the problem of signal attenuation by “combining two or more electric or galvanic circuits, with independent batteries for the purpose of overcoming the diminished force of electro-magnetism in long circuits” 56 U.S. at 109. Morse was thus entitled to claims that were directed to that principle. *Id.* at 86 (setting forth Morse’s fourth claim), 112 (sustaining that claim). However, Morse’s eighth claim, which expressly extended beyond the principle described in his specification, was invalid because it encompassed more than his invention.

By contrast, in *The Telephone Cases*, Bell’s claimed method did not extend beyond his invention. Bell’s invention consisted in transmitting speech by employing a continuous “undulating” electrical current whose variation in amplitude reproduced the vibrations of speech. The Supreme Court upheld Bell’s method claim because it was limited to methods that

⁹ As the Supreme Court explained: “The primary meaning of the word ‘invention’ in the Patent Act unquestionably refers to the inventor’s conception rather than to a physical embodiment of that idea.” In *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998).

used this principle, even though it encompassed the use of a “variable resistance” apparatus that Bell had “not described” so as to enable its construction. *Id.* at 538. The Court held that Bell’s method “was not to be confined to the mere means he devised to prove the reality of his conception.” *Id.* at 539. Had Bell sought to claim all methods of telephony – whether or not they used an “undulating current” – such claims would have extended beyond his invention and would have been invalid for the same reasons as Morse’s eighth claim.

Thus, the description requirement of § 112 prevents applicants from claiming more than their contribution to the art, as set forth in the specification.

C. The Facts of this Case Illustrate the Proper Operation of the Written Description Requirement

The claims at issue in this appeal satisfy the description requirement of § 112, properly construed.

First, there is no question that the claims on appeal are directed to the same invention that is identified in the relevant priority application. The 1989 application included a “Summary of the invention” that described the invention as including methods for modulating a cell’s response to an external stimulus by reducing NF- κ B activity in the cell so as to reduce the cell’s expression of genes that are activated by NF- κ B. *See* ARIAD Br. at

50-54. This is, thus, not a case in which amended or later-added claims are directed to different subject matter than is identified in the specification.

Second, the claims on appeal are directed to a method defined by a common principle that is identified in the specification: reducing NF- κ B activity in a cell as one particular way of altering the cell's response to an external stimulus. The Panel correctly recognized that it was the inventors of the '516 Patent-in-suit who discovered the existence of NF- κ B activity and its role in mediating a cell's response to external stimuli, and who taught that reducing NF- κ B activity in cells was one way, out of hundreds of possible ways, to modify a cell's response to an external stimulus.

As the Panel correctly stated, "There are hundreds of different transcription factors that perform in concert with other molecules in the cell to control cellular behavior." *Ariad*, 560 F.3d at 1369. It is undisputed and uncontroverted that: "In the mid-1980s, the inventors of the '516 Patent discovered an important transcription factor that they named NF- κ B." *Id.* The inventors of the '516 Patent further realized that artificially reducing NF- κ B activity in the cell would ameliorate the harmful symptoms of diseases that trigger NF- κ B activation. *See id.* at 1370.

It was for the disclosure of that novel, non-obvious, and fundamental process – not some mere agent or compound designed to target a previously

known process – that the ‘516 Patent was granted. And when measured against the statutory standard of sufficiency, i.e., “such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same,” substantial evidence clearly supports the district court’s rejection of Lilly’s defense of alleged lack of enablement.

Lilly argues that upholding the asserted claims of the ‘516 Patent “would have preempted the entire field of NF- κ B inhibition” (Lilly Br. at 43), an argument that presupposes the existence of such a “field.” It is undisputed, however, that before the ‘516 Patent applicants discovered and named NF- κ B and disclosed that artificial reduction of NF-kB activity in cells was a novel way to regulate cellular responses to harmful extracellular influences such as lipopolysaccharide (“LPS”), there was no such “field” as the “field of NF-kB inhibition.” Thus, it is no more valid to argue that the claims on appeal preempt the “field of NF-kB inhibition” than to object that Bell’s method claim preempted the field of undulating current telephony. *See The Telephone Cases*, 126 U.S. at 535.

Lilly repeatedly mischaracterizes the claimed inventions of the ‘516 Patent as being directed to “methods of inhibiting NF-kB activity in a cell” (Lilly Br. at 4); “methods of reducing NF-kB in a cell” (*id.* at 42); “any method of reducing NF-kB activity” (*id.* at 45); any conceivable method for

reducing NF-kB activity” (*id.* at 53); “all methods of reducing NF-kB activity” (*id.* at 54); and “all methods of inhibiting NF-kB activity” (*id.* at 55). Like its erroneous reliance on a purported “field of NF-kB inhibition” (*id.* at 43), Lilly’s opposition repeatedly and falsely assumes that “reducing NF-kB activity” was for some reason an unpatentable conception irrespective of whether it constituted a novel, useful, and non-obvious process within the meaning of 35 U.S.C. §§ 101-103, and irrespective of whether the applicants disclosed and enabled a mode for carrying out the claimed process.

It is only by ignoring the technological contribution that the ‘516 Patent applicants actually made that Lilly can characterize the disclosure of that patent as constituting nothing more than “prophetic research plans” (Lilly Br. at 1), a “research program” (*id.* at 2), or similar characterizations drawn from prior opinions of this Court. Nor is there any justification for Lilly’s characterization of the ‘516 Patent applicants as “overreaching inventors” (*id.* at 40) who are to be distinguished from “true innovators” (*id.* at 47) who make “real contributions” (*id.*). Such mischaracterizations serve only to obfuscate the actual dispute that gives rise to the controversy before this Court, which is: whether the methods disclosed and claimed in the ‘516 Patent are worthy of legal protection (as Plaintiffs-Appellees contend), or

fall completely outside of the patent system and can be exploited for free by downstream pharmaceutical manufacturers, as Lilly contends.

Under Lilly's view, even though the claims-in-suit might be directed to novel, useful, non-obvious, and statutory methods, and even though the '516 patent applicants might have complied with their statutory duty to provide a written description of their invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same," the asserted claims are nevertheless worthless and void because the '516 patent applicants purportedly did not comply with a "separate", non-statutory, judicially-devised duty to describe their invention in terms that a court or jury might deem sufficient to prove that the '516 patent applicants had "possession" of the claimed methods to a legally sufficient degree.

The discoverer of a new and non-obvious process, whose use is not tied to particular materials or machines, has never been restricted in his or her patent protection to the details of particular instrumentalities that were then the best-known ways of carrying out the process. Lilly's "written description" arguments are aimed at denying patent protection to upstream researchers who discover and disclose generally applicable methods that

Lilly would then subsequently exploit.¹⁰ As the panel in this case noted, the discovery of the claimed inventions in this case “required years of hard work, great skill, and extraordinary creativity – so much so that the inventors first needed to discover, give names to, and describe previously unknown cellular components as a necessary predicate for their inventions.” *Ariad*, 560 F.3d at 1372. As the Court stated in *The Telephone Cases*, 126 U.S. at 539, “[s]urely a patent for such a discovery is not to be confined to the mere means [the inventor] improvised to prove the reality of his conception.”

¹⁰ See Amicus Brief of Regents of Univ. of Cal. et al., filed Oct. 15, 2009, at 16-19.

CONCLUSION

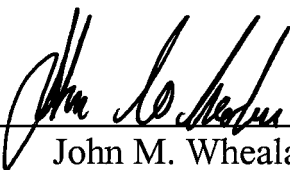
For the reasons set forth above, the judgment of the District Court should be affirmed in its entirety.

Dated: New York, New York
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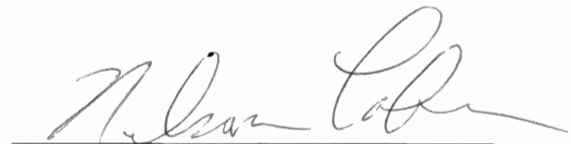
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the address(es) designated by said attorney(s) for that purpose by depositing **2** true copy(ies) of same, enclosed in a properly addressed wrapper in an Overnight Next Day Air Federal Express Official Depository, under the exclusive custody and care of Federal Express, within the State of New York. Twelve copies of the foregoing brief were filed on this date via overnight delivery, on September 26, 2008, addressed to the Clerk's Office, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place N.W., Washington, D.C. 20439.

Sworn to before me on November 30, 2009


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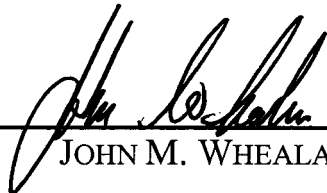


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I certify that this appeal brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B) and Fed. Cir. R. 32(b). Relying on the word count function in the word processing application used to prepare the brief, I certify that the total number of words in the brief is 6,975, excluding those certifications and other portions of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

I certify in addition that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). This brief has been prepared using Microsoft Word 2000 in Times New Roman, a proportionally spaced typeface including serifs, in 14 point font.

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