IN THE

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

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

v.

ELI LILLY AND COMPANY,
Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in case no. 02-CV-11280, Judge Rya W. Zobel.

PRINCIPAL BRIEF FOR DEFENDANT-APPELLANT ELI LILLY AND COMPANY ON REHEARING EN BANC

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November 9, 2009

CERTIFICATE OF INTEREST

Counsel for Defendant-Appellant Eli Lilly and Company certifies the following:

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

   Eli Lilly and Company.

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

   None.

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

   None.

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

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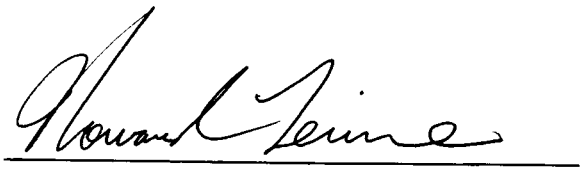

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"Lilly"	Defendant-Appellant Eli Lilly and Company
"Lilly Blue Br."	Brief of Defendant-Appellant Eli Lilly and Company, dated June 18, 2008
"Lilly Gray Br."	Reply Brief of Defendant-Appellant Eli Lilly and Company, dated November 12, 2008
"Ariad"	Plaintiffs-Appellees Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for BioMedical Research, and The President and Fellows of Harvard College
"Ariad Br."	Ariad's Principal Brief For Plaintiffs-Appellees on Rehearing *En Banc*, dated October 5, 2009
"NYIPLA Br."	Brief of New York Intellectual Property Law Association as Amicus Curiae on *En Banc* Rehearing in Support of Neither Party, dated October 15, 2009
"Novozymes Br."	Brief of Novozymes A/S as Amicus Curiae on *En Banc* Rehearing in Support of Neither Party, dated October 13, 2009
"C.C.P.A."	Court of Customs and Patent Appeals
"PTO"	U.S. Patent and Trademark Office
"the '516 patent"	U.S. Patent No. 6,410,516
A___, xx:yy	For a transcript, "A___" refers to appendix page of transcript, "xx" refers to particular page of minuscript, "yy" refers to line
Bold italicized text	All emphasis in this brief has been added unless otherwise noted.

STATEMENT OF RELATED CASES

No other appeal in or from the same civil action in the district court was previously before this or another appellate court.

There is a case between Ariad and Amgen Inc. (Civ. No. 06-259) in the United States District Court for the District of Delaware that involves the '516 patent and may be affected by this Court's decision.

In addition, there is an ongoing reexamination proceeding regarding the '516 patent, where all the claims asserted against Lilly have been finally rejected as being anticipated. (A24898-25009.) That issue is now on appeal before the PTO Board of Patent Appeals and Interferences. This appeal may affect the reexamination proceeding.

I. RESPONSE TO EN BANC QUESTIONS

This Court has requested answers to the following two questions: (1) whether 35 U.S.C. § 112, first paragraph, contains a written description requirement separate from an enablement requirement; and (2) if a separate written description is set forth in the statute, what is the scope and purpose of that requirement?

Lilly's answers are as follows: (1) Yes, there has always been a robust written description requirement separate from enablement that is supported by almost two hundred years of precedent; and (2) the written description applies to both original and amended claims and ensures that inventors have actually invented the subject matter claimed in their patents.

II. PRELIMINARY STATEMENT

In seeking to reverse long-standing precedent so as to allow the patenting of the hypothetical results of broad, prophetic research plans, Ariad and its supporting amici ignore half of the public policy underlying the U.S. patent system. The patent statutes are as important for what they say is ***not*** patentable as for what they say ***is*** patentable. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). The statutory scheme has always been a delicate balance between providing an incentive for innovation and protecting the public's right to use technology that does not qualify for the incentive. Thus, that which was old or

would have been obvious is excluded from the incentive, as are developments for which the applicant has failed to provide an enabling disclosure or disclosure of a known best mode. Also excluded from the incentive is subject matter that the patent application shows had not been invented by the applicant, i.e., was not within his possession, at the time the application was filed. This is the "written description" requirement currently embodied in § 112, first paragraph, the essence of which is that a patent applicant may not reap where he has not sown.

It has been forever thus, and for good reason. Even inventors as distinguished as Samuel Morse have fallen prey to the temptation to preempt the future before it has arrived. *See O'Reilly v. Morse*, 56 U.S. 62 (1853). Based on little more than an outline of the research program that would be required to make the invention, patent applicants have sought broad, dominating patent protection covering every means of attaining a desired result. When others later succeed in attaining the sought after result, it is alleged that the research plan was "enabling," confirming the validity of the preemptive claim. From at least as early as the nineteenth century, however, the courts have recognized that the patent statute requires something more.

The patent statute requires a description of the invention, beyond mere enablement, that ensures that what has been patented is a completed invention—the fruit of a full and complete conception. Conception, the mental part of the act

of invention, has always required "the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Mergenthaler v. Scudder*, 11 App. D.C. 264, 276 (D.C. Cir. 1897)(emphasis omitted). Providing a written description of the structures, materials, and acts that make up the process, machine, article of manufacture, or composition of matter sought to be patented is a trivial matter when there has been a complete conception—it is, however, virtually impossible when all that has been developed is a hoped for result and a research program to pursue it.

This principle has been articulated by many courts in many ways. The Supreme Court has noted that "a patent is not a hunting license[;] [i]t is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). This Court has observed that identification of a function to be performed or a research plan for achieving it is not a conception but an attempt to preempt the future before it has arrived. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). The self-evident corollary, that a patent applicant cannot describe what has not been conceived, has also been noted by this Court. *Id.*

Accordingly, there is and always has been a written description requirement separate from enablement, and Ariad's arguments to the contrary are simply

wrong. (*See* §§ III.C-D., *infra*.) The statute itself says so, requiring a description of the invention ***and*** of the manner of making and using it, and no amount of parsing can read that conjunction out of the statute. (*See* § III.B., *infra*.) Prior decisions of the Supreme Court, this Court's predecessor (the C.C.P.A.), and this Court say so. (*See* § III.A., *infra*.) The existing statutory language was codified by Congress in 1952 with a full and complete understanding of how that language had been interpreted for more than a century. Any disruption of such well-settled expectations of the intellectual property community should be effected, if at all, by Congress, not the courts. (*See* § III.E., *infra*.) Most importantly, this requirement is necessary for a healthy and functional patent system. (*See* § III.F., *infra*.) It prevents the preemption of great swaths of fertile research ground by those whose ideas have not yet advanced to the point of a full and complete conception. Here, Ariad sought to reap where it had not sown, contending that it was entitled to claim all methods of inhibiting NF-κB activity in a cell when it had not actually invented any means of doing so. (*See* §§ III.F.1 & G., *infra*.) The application of the written description requirement by the panel in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1376 (Fed. Cir. 2009), was correct and prevented that unjust result.

III. ARGUMENT

A. Almost Two Hundred Years of Precedent Support the Existence of a Separate Written Description Requirement

The statutory language defining the written description requirement is of ancient lineage. The language was reenacted in 1952, essentially unchanged, with full knowledge of the applicable prior judicial precedents construing it. More than sixty years of consistent additional construction has followed the 1952 Patent Act. Because this Court's interpretation of the statute is in accord with such long-established precedent, this authority is reviewed here before turning to the text of the modern statute.

1. The Precedent of the United States Supreme Court

The Supreme Court acknowledged a separate written description requirement as early as *Evans v. Eaton*, 20 U.S. 356, 433-34 (1822). There, the Supreme Court examined the Patent Act of February 21, 1793, which required that the patentee 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 . . . to make, compound, and use the same." *Id.* at 380-81 (emphasis omitted). The Supreme Court found that this portion of the Patent Act established two requirements: (1) enablement ***and*** (2) written description. *Id.* In discussing the separate written description requirement, the

Supreme Court explained that the written description requirement protects the public from an inventor who may "pretend[] that his invention is more than what it really is." *Id.* at 434.

Ariad concedes that a separate written description requirement existed in *Evans*, but argues that when Congress amended the patent statute in 1836 to add the requirement of claims, it eliminated the separate written description requirement. (Ariad Br. 18.) But, neither the language of the statute nor its legislative history supports Ariad's position. While Congress removed the language "as to distinguish the same from all other things before known" from the 1793 act, it did not remove the language that the patentee "shall deliver a written description of [1] his invention or discovery, ***and*** [2] 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 . . . to make, construct, compound, and use the same." Act of July 4, 1836, ch. 357, 5 Stat. 117, 119 (enumeration added). In other words, there remained two separate requirements.

If Congress wanted to remove the separate written description requirement, it could have removed the clause "***and*** of the manner and process of making, constructing, using, and compounding the same." *See In re Barker*, 559 F.2d 588, 591-92 (C.C.P.A. 1977). The statute would have thus read as follows: the patentee

"shall deliver a written description of his invention or discovery, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art . . . to make, construct, compound, and use the same." Congress, however, did not make such a change, but instead kept the two separate requirements in the statute. And these two separate requirements have remained to this day.

The Supreme Court confirmed that there remained a separate written description requirement in the 1836 statute in *Morse*. There, Samuel B. Morse, the famed inventor of the telegraph, discovered a way to transmit a message by using electromagnetism, generated from an electric current, to cause a telegraph to print characters. The patent at issue contained eight claims, and seven of the eight recited the specific instrumentalities Morse developed. The Supreme Court upheld the validity of each of these seven claims. *Morse*, 56 U.S. at 112. However, Morse's eighth claim—like the broad claims of Ariad's '516 patent—attempted to claim every conceivable way of performing the desired function. It was directed to the use of an electric current—however developed—for printing intelligible characters at a distance. *Id.* The Court struck down this claim, explaining that Morse claimed "an exclusive right to use a manner and process which he has not ***described and indeed had not invented***, and therefore could not ***describe*** when he obtained his patent. The court is of [the] opinion that the claim is too broad, and not warranted by law." *Id.* at 113.

The Court, after discussing case law from the United Kingdom and other U.S. precedent, turned specifically to the 1836 act for a legal justification for its holding. The Court specifically held:

> Now, in this case, there is no ***description*** but one, of a process by which signs or letters may be printed at a distance. And yet [Morse] claims the exclusive right to any other mode and any other process, although not ***described*** by him, by which the end can be accomplished, if electro-magnetism is used as the motive power. That is to say-he claims a patent, for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it. The words of the acts of Congress above quoted show that no patent can lawfully issue upon such a claim. For he claims what ***he has not described*** in the manner required by law. And a patent for such a claim is as strongly forbidden by the act of Congress, as if some other person had invented it before him. . . . The evil is the same ***if he claims more than he has invented***, although no other person has invented it before him. He prevents others from attempting to improve upon the manner and process which he has ***described in his specification***-and may deter the public from using, it, even if discovered. ***He can lawfully claim only what he has invented and described,*** and if he claims more his patent is void.
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> ***
>
> ***Whether, therefore, the patent is illegal in part because he claims more than he has sufficiently described, or more than he invented***, he must in either case disclaim, in order to save the portion to which he is entitled; and he is allowed to do so when the error was committed by mistake.

Id. at 120-21.

Morse's eighth claim was held invalid for failing to satisfy the separate written description requirement set forth in the 1836 statute—Morse had not invented or described what he claimed as his invention. *See, e.g., Ariad*, 560 F.3d

at 1371 (citing *Morse* as supporting a separate written description requirement to ensure the inventors have actually invented or conceived of claimed subject matter); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)(same holding); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)(same holding); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 n.9 (Fed. Cir. 2004)(same holding).[1]

The Supreme Court specifically cited *Morse* for this proposition in *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928): "That the patentee may not by claiming a patent on the result or function of a machine extend his patent to devices or mechanisms not described in the patent is well understood." The Court further explained that such a broad claim, "if allowed, would operate to enable the inventor, who has discovered that a defined type of starch answers the required purpose, to exclude others from all other types of starch, and so foreclose efforts to discover other and better types. The patent monopoly would thus be

[1] The facts in *Morse* are analogous to the facts here in that both patentees attempted to claim every possible way of carrying out a particular function. (*See* Lilly Blue Br. 30-33.) Such claims are invalid under § 112, first paragraph "[w]hether the flaw in the specification is regarded as a failure to demonstrate that the patentee possessed the full scope of the invention . . . or a failure to enable the full breadth of that claim." *LizardTech*, 424 F.3d at 1345; *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983)(citing *Morse* and rejecting a claim that "covers every conceivable means for achieving the stated result").

extended beyond the discovery, and would discourage rather than promote invention." *Id.*

In addition, the Supreme Court in *Morse* explicitly addressed the argument that the language of the claim provided its own support. The Supreme Court explained that the unsupported claim "can derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it. And if it stands, it must stand simply on the ground that the broad terms abovementioned [the language of the claim] were a sufficient description, and entitled him to a patent in terms equally broad. In our judgment the act of Congress cannot be so construed." *Morse*, 56 U.S. at 119-20. Thus, even after the amendments to the patent statute of 1793, there was still a robust written description requirement as of 1836 that examined whether an inventor sought to claim subject matter he had not invented and could thus not describe.

Further, although the statute was amended again in 1870, the written description requirement was not eliminated. In *Railroad Company v. Mellon*, 104 U.S. 112, 117-18 (1881), the Court observed that "[t]he act of July 4, 1836 . . . requires that an applicant for a patent shall not only 'deliver a written description of his invention or discovery,' but 'shall also particularly specify and point out the part, improvement, or combination which he claims as his own invention or

discovery.' This provision is substantially re-enacted in the act of July 8, 1870 . . . and remains in force."

The Supreme Court confirmed the existence of a separate written description requirement in *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), a case cited by Ariad. (Ariad Br. 12.) Ariad quotes the following language from *Schriber-Schroth*:

> 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.

(Ariad Br. 12 (citing *Schriber-Schroth*, 305 U.S. at 57).) Ariad argues that this quote is referring to (1) the description requirement, whose sole purpose—according to Ariad—is enablement, and (2) the "claim requirement of § 26 of the 1870 Act." (*Id.*) The problem with Ariad's argument is that the quote is not addressing the claiming requirement at all, but only the description requirement. This is made abundantly clear by the text omitted by Ariad immediately before and after its block quote.

In *Schriber-Schroth*, the Gulick patent at issue concerned a piston that contained a structural element called a "web." 305 U.S. at 51. The patent specification made no mention of the web being flexible but instead expressly described the web element as "extremely rigid." *Id.* at 54-55. The parties

challenging the patent's validity argued that a "flexible web element," which was later claimed by the patentee but not disclosed in the original patent specification, was "excluded from the Gulick patent by reason of his failure to ***describe*** that element in his application as filed." *Id.* at 56. In addressing this argument, the Supreme Court cited the description requirement of the statute—and not the section dealing with claims:

> The statute, R.S. s 4888, 35 U.S.C.A. s 33 [§ 26 of the 1870 patent act], provides that the application which the inventor must file as a prerequisite to a patent shall contain "a written description of (his invention) . . . and of the manner and process of making, constructing . . . and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to . . . construct . . . 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 . . . ."

Id. After citing the statute, the Supreme Court then explained how the language of the statute applied to the description issue in the case. For the Court's convenience, the part of the quote included in Ariad's brief is underlined:

> 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." ***It follows that the patent monopoly does not extend beyond the invention described and explained as the statute requires, that it cannot be enlarged by claims in the patent not supported by the description, and that the application for a patent cannot be broadened by amendment so as to embrace an invention not described in the application as filed*** . . . .

Id. at 57 (citations omitted). This bold and italicized language, which was omitted from Ariad's brief, makes the very point set forth by Judge Newman in her concurring opinion in *Enzo Biochem, Inc. v. Gen-Probe Inc.* in 2002, some seventy years later: "[t]he description of the invention has always been the foundation of the patent specification. It sets forth what has been invented, and sets boundaries of what can be claimed." 323 F.3d 956, 975 (Fed. Cir. 2002)(Newman, J., concurring).

After citing the controlling legal standard, the Supreme Court held that the flexible web elements were "beyond the scope of the device described in the application as filed," and that "[i]f 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." *Schriber-Schroth*, 305 U.S. at 58.

The petitioners had argued that they satisfied the description requirement because those skilled in the art could make and use the flexible web elements—i.e., the disclosure was enabling. "Flexibility, it is said, as is well known to those skilled in the art, is an inherent property of the metal out of which the webs are made." *Id.* at 57. The Supreme Court, however, ***disagreed***, explaining that "[e]ven if those skilled in the art would have known that a piston with webs which would yield enough laterally to accommodate the constriction of the split skirt . . . would

work most effectively if the webs were laterally flexible rather than rigid, ***that was not the invention which Gulick described*** by his references to an extremely rigid web." *Id.* at 58-59.

Diamond v. Chakrabarty, 447 U.S. 303 (1980), provides yet additional evidence concerning the existence of a separate written description requirement. In addressing the scope of patentable subject matter under 35 U.S.C. § 101, the Supreme Court addressed petitioner's argument that the Plant Patent Act of 1930 was enacted because the terms "manufacture" or "composition of matter" in § 101 did not include living things and that there was thus a need to pass separate legislation to protect plants. *See id.* at 311. The Supreme Court rejected this argument, explaining that one of the obstacles to "patent protection for plants was the fact that plants were thought not amenable to the 'written description' requirement of the patent law. Because new plants may differ from old only in color or perfume, differentiation by written description was often impossible.'" *Id.* at 312 (citation omitted). For this reason, the Supreme Court explained that Congress "relaxed the written description requirement in favor of 'a description . . . as complete as is reasonably possible.'" *Id.* (citation omitted).

Similarly, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, a case not addressed by Ariad, the Court made abundantly clear that § 112, first paragraph, has ***three*** requirements: "[T]he patent application must ***describe***,

enable, and set forth the ***best mode*** of carrying out the invention. . . . What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue." 535 U.S. 722, 736 (2002); *Enzo*, 323 F.3d at 971 (Lourie, J., concurring)(citing *Festo*). The Court explained that "if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better ***description***—estoppel may apply." *Festo*, 535 U.S. at 736.

Further, as discussed in *Stone Container Corp. v. United States*, 229 F.3d 1345, 1349-50 (Fed. Cir. 2000), this language in *Festo* cannot be ignored: "According to Stone, those statements are mere dicta, and we are free to disregard them. We are required to decline Stone's invitation. As a subordinate federal court, we do not share the Supreme Court's latitude in disregarding the language in its own prior opinions. . . . The Supreme Court can accept for review only a limited number of cases, and it must give guidance to the lower federal and state courts in broad language. Here, the Court's statements are both explicit and carefully considered, and we must follow them."

The above cases consistently indicate the existence of a separate and robust written description requirement, and Ariad has not cited a single Supreme Court case that says otherwise. The cases to which Ariad points (Ariad Br. 18-20) are garden-variety patent cases where the Court either examined the specification to

assist in determining the scope of the claims at issue (*e.g.*, *Smith v. Snow*, 294 U.S. 1, 9 (1935); *Universal Oil Products Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944); *Tilghman v. Proctor*, 102 U.S. 707, 729 (1880);[2] *Deering v. Winona Harvester Works*, 155 U.S. 286, 302 (1894)) or addressed the issue of enablement (*e.g.*, *The Telephone Cases*, 126 U.S. 1, 535-36 (1888); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923)). Ariad's stringing together of isolated quotations from these cases does not assist Ariad here because not one of these cases held that a separate written description requirement does not exist.

Ariad's reliance on *The Telephone Cases* is unavailing. (Ariad Br. 19, 47-50.) There, the issue was whether Alexander Graham Bell's claim could cover both of the methods described in the specification or only the method for which an apparatus was constructed. *The Telephone Cases*, 126 U.S. at 537. The Supreme Court distinguished *Morse* on its facts, explaining that Bell's claim language explicitly stated that the claim covered at most only the methods "substantially as set forth" in the specification. *Id.* at 534-35, 537. Since Bell taught two ways of transmitting speech telegraphically, the patent was held to cover "both . . . the magneto and variable resistance methods." *Id.* at 538. *The Telephone Cases* never even addressed whether methods beyond the two provided in the specification

[2] *See* Lilly Gray Brief at 11 for a discussion of the *Tilghman* case.

would have been enabled, and certainly has nothing to do with the written description issue.

Moreover, to the extent *The Telephone Cases* talks about ***two*** requirements, separated by the conjunction "and," it actually supports Lilly's position—not Ariad's. "[I]t is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to [1] understand what the process is, ***and*** [2] if he points out some practicable way of putting it into operation." *Id.* at 536 (enumeration added). The Court then unambiguously noted that Bell had done both separate acts: "He described clearly and distinctly his process . . . . He then pointed out two ways . . . this might be done." *Id.* Similarly, the Court stated that "in his specification [1] he did describe accurately, and with admirable clearness, his [invention] . . . and [2] he also described, with sufficient precision to enable one of ordinary skill to make it . . . ." *Id.* at 535 (enumeration added).

2. The Precedent of the C.C.P.A.

Consistent with the above Supreme Court precedent, the C.C.P.A. repeatedly held that § 112 contains a separate written description requirement, and Ariad has failed to cite a single case from the C.C.P.A. that states otherwise. The following cases are illustrative.

In *In re Moore*, 155 F.2d 379, 382 (C.C.P.A. 1946), the C.C.P.A. held originally filed claims invalid because they were broader than the written

description of the invention set forth in the application. The claims at issue recited methods of killing insects with a toxic amount of a mono-substituted halogen acetonitrile and were broad enough to cover using the substituted acetonitriles in either solid or liquid form. *Id.* at 380, 381-82. The specification of the patent, however, only discussed using the acetonitriles as "fumigants," dispersed in a gas, and not as solids or liquids. *Id.* at 381. The PTO had rejected the claims because "the present claims are not confined to the subject matter disclosed, and fail to set forth the alleged invention with the particularity required by statute." *Id.* at 382.

On appeal, there was no evidence in the record that the claimed acetonitriles would not have been effective in either solid or liquid form. In this regard, the applicant had specifically argued that use of the claimed compounds as fumigants did not "exclude the ability of those materials to kill by other methods, that is, as a contact poison." *Id.* Nevertheless, the C.C.P.A. explained that the invention set forth in his specification was the use of the compounds as fumigants, and "[i]t is well settled that claims in an application which are broader than the applicant's disclosure are not allowable." *Id.* Accordingly, the C.C.P.A. affirmed the rejection.

Similarly, in *In re Sus*, 306 F.2d 494, 497-98 (C.C.P.A. 1962), the court found that the generic term "aryl and substituted aryl radicals" appearing in the original claims was not supported by the specification. The court stated that

despite the claim's broad language, "only ***certain aryl radicals*** and certain specifically substituted aryl radicals" as described in the specification "would be suitable" for the purposes of the invention. *Id.* at 504. The court thus explained that "[t]he public purpose on which the patent law rests requires the granting of claims commensurate in scope with the invention disclosed," and that "the invention claimed shall be no broader than the invention set forth in the written description forming a part of the specification." *Id.* at 497. As such, the court held that the claims at issue failed "to meet the requirements of 35 U.S.C. § 112 in that they are broader than the invention described in the written description thereof" and thus invalid. *Id.*[3]

Contrary to Ariad's assertions (Ariad Br. 23), the C.C.P.A. likewise applied its understanding of distinct written description and enablement requirements in *Jepson v. Coleman*, 314 F.2d 533, 536-37 (C.C.P.A. 1963), a case concerning thermal blanket technology. The court explained that under the "proper rule" for resolving interferences, a party instituting an interference can only prevail if "their teachings . . . clearly cover each limitation of the counts." *Id.* at 537. The court,

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[3] Ariad relies on *In re Wilke*, 314 F.2d 558 (C.C.P.A. 1963), as support for its argument that the C.C.P.A. did not interpret § 112 as having a separate written description requirement. (Ariad Br. 22.) But, the issue in *Wilke* was solely enablement and thus does not bear on this question. Further, *Wilke* stated that "35 U.S.C. § 112 requires that the specification shall contain ***not only*** a written description of 'the invention' ***but also*** 'of the manner and process of making and using it.'" 314 F.2d at 562.

however, explained that in conducting this analysis, an inquiry solely into enablement would ***not*** be sufficient. "It is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device." *Id.* at 536.

Further, it cannot reasonably be denied that the C.C.P.A. applied a separate written description requirement in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1327 (Fed. Cir. 2003)(Bryson, J., concurring)("*In re Ruschig* . . . held that 35 U.S.C. § 112, paragraph 1, contains a written description requirement that is separate from the enablement requirement found in the same paragraph.").

In *Ruschig*, the court held that the specification at issue did not "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound" encompassed by the disclosed genus. 379 F.2d at 996. Further, although the patentee argued that the making of the compound was enabled, the court explained that the portions of § 112 implicated by the rejection were those requiring that the specification contain a "written description" of the invention. *Id.* at 995-96. Indeed, the C.C.P.A. explicitly stated: "While we have ***no doubt*** a person so motivated would be ***enabled*** by the specification to make it, this is beside the point for the question

is ***not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented.***" *Id.* at 995. Ariad's strained reading of this case to argue that this inquiry was part of "enablement" (*see* Ariad Br. 24-27) should not be accepted, and, to this date, has been rejected by many judges on this Court. *Enzo*, 323 F.3d at 971 (Lourie & Newman, JJ., concurring); *id.* at 977-78 (Rader, J., dissenting and writing that *Ruschig* applied a separate written description requirement); *Moba*, 325 F.3d at 1327 (Bryson, J., concurring).

In *In re DiLeone*, 436 F.2d 1404, 1405-06 (C.C.P.A. 1971), the C.C.P.A. expressly held that original claims must satisfy the written description requirement. There, the majority concluded that "it is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention. The first paragraph of 112 requires both description and enablement." *Id.* at 1405.

The court further confirmed that § 112 contains three separate inquiries in *In re Moore*, 439 F.2d 1232, 1235 (C.C.P.A. 1971): (1) "whether the subject matter defined in the claims is described in the specification, [(2)] whether the specification disclosure as a whole is such as to enable one skilled in the art to make and use the claimed invention, and [(3)] whether the best mode contemplated by the inventor of carrying out that invention is set forth."

In *Fields v. Conover*, 443 F.2d 1386, 1391 (C.C.P.A. 1971), the court explained that "a specification may provide adequate teachings of how to make and use subject matter which is subsequently claimed and yet fail to contain a written description thereof which complies with the first requirement of the first paragraph of 35 U.S.C. § 112." From a policy standpoint, if the statute is satisfied "merely because the application is sufficient to teach how to make and use the subject matter thereof and points indistinctly and ambiguously in the general direction of that subject matter, the socially valuable incentive to further research and development provided by the opportunity to obtain subservient patents will be considerably diminished." *Id.* at 1392.

In *Barker*, 559 F.2d at 591, discussed in more detail below, two of the judges on the panel wrote an opinion that addressed the statutory language of § 112, and explained that it contained separate requirements for written description of the invention and enablement. "This court has clearly recognized that there is a description of the invention requirement in 35 U.S.C. s. 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.* (citations omitted). A third judge, Judge Rich, concurred in the judgment, writing that there existed a "distinct" written description requirement,

though it was "comingled with enablement." *Id.* at 594. Accordingly, there is simply no basis in the precedent of the C.C.P.A. for the proposition that a separate written description requirement does not exist.

3. The Precedent of this Court

The precedent of this Court also makes clear that there is a separate written description requirement. "The description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision." *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984); *see also Ariad*, 560 F.3d at 1371; *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1377-78 (Fed. Cir. 2009); *In re Alonso*, 545 F.3d 1015, 1019, 1021-22 (Fed. Cir. 2008); *Carnegie Mellon*, 541 F.3d at 1125-26; *LizardTech*, 424 F.3d at 1344-45; *Rochester*, 358 F.3d at 921; *Enzo*, 323 F.3d at 968-69; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-69 (Fed. Cir. 1997); *Fiers*, 984 F.2d at 1171 & n.12; *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561-63 (Fed. Cir. 1991).

Like that of the Supreme Court and the C.C.P.A., this Court's precedent holds that to satisfy the written description requirement, the specification must provide sufficient detail such that those skilled in the art would understand that the inventor was in possession of and, in fact, had invented the full scope of the claimed subject matter. The requirement ensures "that the scope of the right to

exclude . . . does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000).

The existence of a separate written description requirement has been so clearly established by this Court's precedent that Ariad did not argue at the merits stage of this appeal that a separate written description requirement does not exist. Indeed, Ariad's *en banc* brief relies on dissenting opinions and fails to cite even a single panel decision from this Court supporting its position. *Kennecott Corp. v. Kyocera International, Inc.*, 835 F.2d 1419 (Fed. Cir. 1987), cited by Ariad, is not such a case. (*See* Ariad Br. 30.) Ariad cites the statement from *Kennecott* that "[t]he purpose of the description requirement is to state what is needed to fulfill the enablement criteria." (Ariad Br. 30.) This case, however, did ***not*** hold that a separate written description requirement does not exist but instead stated that the "incorporation of the requirements of section 112 into section 120 ensures that the inventor had possession of [i.e., described] the later-claimed invention on the filing date of the earlier application." *Kennecott*, 835 F.2d at 1421.

Further, the *Kennecott* decision was specifically addressed in *Vas-Cath*, which made the point that to the extent *Kennecott* was inconsistent with prior precedent, it should not be followed. 935 F.2d at 1563. In *Vas-Cath*, the panel stated that this "court in *Wilder* (and the C.C.P.A. before it) clearly recognized, and

we 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." *Id.* In explaining the purpose of the description requirement, the panel stated that 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.***" *Id.* at 1563-64 (emphasis in original). Ariad has not cited a contrary panel decision.

B. Ariad's Analysis of the Statute Is Not Correct and Conflicts with This Precedent

Supported by the nearly two hundred years of precedent discussed above, Lilly submits that there are the following three requirements under the first paragraph of § 112:

> (1) "The specification shall contain a written description of the invention, ***and***"
>
> (2) "The specification shall contain a written description . . . 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***"
>
> (3) "The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."

35 U.S.C. § 112; *see also Rochester*, 358 F.3d at 921 (construing § 112). As stated by the Supreme Court as recently as 2002, § 112 requires an applicant to "describe, enable, and set forth the best mode of carrying out the invention." *Festo*, 535 U.S. at 736.

The principal argument advanced by Ariad (and its supporting amici) for why this Court should abandon its long-standing precedent is based upon a fine grammatical parsing of the statute. Yet, in considering such arguments, this Court should note the comments of Judge Rich in *Barker* concerning the text of § 112.

There, two judges on the panel wrote that the very reading of § 112 that Ariad urges here is incorrect. *Barker*, 559 F.2d at 591-92. The court explained that if such an interpretation were correct, the words "the manner and process of making and using" would be superfluous, which would violate the fundamental principle of statutory construction that Congress does not use superfluous words. *Id.* As discussed above, Judge Rich, concurred in the judgment, writing that there existed a "distinct" written description requirement, though it was "comingled with enablement." *Id.* at 594. Judge Rich, one of the principal drafters of the 1952 Patent Act, wrote separately because he did not agree that § 112 should be construed by parsing the language of the statute and examining whether words were superfluous. *Id.* Instead, he stated that construction of 112 should be based on the precedent interpreting the statute over the last hundred or so years. *Id.*

"The words are of ancient lineage and, in spite of the fact they are inappropriate to some situations, they were preserved, in writing the Patent Act of 1952, ***because they were familiar and had many times been construed.***" *Id.* In other words, the text of the statute was retained for the very reason that it had been previously construed by the Supreme Court and the C.C.P.A.

In this regard, it is a well-established principle of law that "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978). "[W]hen Congress amends an existing statute, a court must presume that any part of the statute left intact reflects Congress' intent to preserve the prevailing judicial interpretation of that portion." *In re Air Crash Disaster*, 210 F. Supp. 2d 570, 575 (E.D. Pa. 2002). Ariad's attempt to construe the words divorced from such precedent, and then read the precedent in a way that supports its construction, is exactly backwards.

However, even if one is to examine the text of the statute in isolation, the literal words of the statute still define two separate requirements, as demonstrated by the word "and" between the description and enablement requirements of the statute. *Enzo*, 323 F.3d at 971 (Lourie, J., concurring). Indeed, Ariad itself admits that the words of the statute indicate that there are two requirements: "[A] written description [i] of the invention, and [ii] of the manner and process of making and

using it." (Ariad Br. 3.) Ariad, nevertheless, contends that the standard for satisfying both of these criteria is solely the enablement standard. Ariad asserts that this must be the case because otherwise the words of the statute do not provide a standard for written description. (*Id.* at 6.) However, as is often the case with statutes, the legal standards for applying them are developed by courts over time, particularly with respect to a statute such as § 112 where the words were specifically retained to preserve the previously existing precedent.

Ariad does not seem troubled by the fact that the statute also does ***not*** state that enablement must be measured at the time of the filing of the application, that the specification must enable the "full scope" of the claim, and that a specification is not enabling if it takes more than "undue experimentation" to practice the invention's full scope—to say nothing of the omission of the factors under *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Similarly, there is nothing in the first paragraph of § 112 that specifies when the best mode analysis is conducted or whether an inventor has an obligation to supplement the best mode in continuing applications. That these standards were developed by previous and subsequent case law does not mean that the applicable statutory requirement does not exist. In fact, the written description requirement is very straightforward and based on common sense—inventors must describe what they have invented, which is exactly what the statute states. The required degree of description necessarily varies with

the scope of the claim, the complexity of the invention, and the predictability of the technology.

Ariad additionally argues that under the current precedent of the Court, the placement of the comma between the clauses "of the manner and process of making and using it" and "in such full, clear, concise, and exact terms" is "inexplicable." (Ariad Br. 6.) The placement of the comma is not a sufficient basis to abrogate hundreds of years of precedent, particularly where the precedent was adopted by Congress when, in 1952, it codified the existing language in the face of the long and consistent prior judicial construction.

As mentioned above, Ariad itself recognizes the necessity of a written description requirement in its formulation of the statute. Ariad, however, repeatedly asserts that this is merely the first part of the test for enablement and that it exists solely to state "what the invention is" or "identify" the invention. (*See id.* at 1, 23, 30, 43.) Ariad argues that this standard may be satisfied by merely performing a mechanical comparison to determine if the words in the claims are literally recited in the specification. However, words that have no meaning in a claim, such as "method comprising reducing NF-κB activity" (A489) or "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product" (*Rochester*, 358 F.3d at 918), have no greater meaning by virtue of placement in

the specification. They are still not sufficient for those skilled in the art to recognize that the inventors actually invented what was claimed.

This very problem was discussed in *Enzo*. There, the panel addressed "Enzo's additional argument that the written description requirement for the generic claims is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." *Enzo*, 323 F.3d at 968. The panel, however, did not agree, stating: "Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement." *Id.* The panel then provided examples of where the words themselves would not be sufficient:

> One may consider examples from the chemical arts. A description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. Similarly, the expression an antibiotic penicillin fails to distinguish a particular penicillin molecule from others possessing the same activity. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.

Id. (citations omitted). Ariad's standard for identifying the invention is too low and would improperly allow inventors to patent ideas or plans for research that

have not yet matured into inventions by merely ensuring that the words of the claim are literally regurgitated in the specification.

C. The Written Description Applies to Amended and Original Claims

1. Amended Claims

It has been argued that it is 35 U.S.C. § 132, and not § 112, that should be applied to questions of whether later added claims are supported by an earlier filed application. (*See* Ariad Br. 24 n.6, 25-27, 31-32.) This is not correct.

The issue presented by amended claims is whether the later claim is supported by the original disclosure. The same issue is presented when benefit to an earlier application filing date is sought for a claim. The relevant statutory provisions governing such entitlement to an earlier application filing date require that the later-claimed invention must be disclosed in the earlier-filed application "in the manner provided ***by the first paragraph of section 112***." 35 U.S.C. §§ 119(e)(1) & 120. There is no reference to § 132 in these statutes, nor is there any statutory authority for deciding the issue of claim support based on § 132.

The C.C.P.A. made clear that when claims are amended during prosecution the correct statutory provision for evaluating whether claim language is supported in the specification is § 112, first paragraph, ***not*** § 132. *In re Rasmussen*, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981). The C.C.P.A. in *Rasmussen* explained in no uncertain terms that a rejection under § 112 is ***not*** equivalent to a rejection under

§ 132. Rejection under § 132 is proper when new matter is added to the disclosure. *Id.* In contrast, § 112 is properly used to reject a claim amended to recite elements thought to be without support in the original disclosure. *Id.* at 1214. To the extent that prior cases approved the rejection of claims under § 132, the C.C.P.A. explicitly held that such cases are "***overruled***." *Id.* at 1215.[4]

The C.C.P.A.'s holding is in accord with Supreme Court authority and the statute. In *Schriber-Schroth*, the Supreme Court specifically relied on the 1870 version of § 112 and held that an added claim was not supported by the specification. 305 U.S. at 56-58. Further, invalidity due to the failure to comply with § 112 is expressly recognized as a defense to infringement under 35 U.S.C. § 282. In contrast, § 132, which appears in a section of the statute governing patent prosecution in the PTO, is not. Section 112 is the correct statutory basis for determining whether claims are supported by the specification.

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[4] One such case appears to be *In re Gay*, 309 F.2d 769 (C.C.P.A. 1962), which Ariad contends supports its argument that there is not a separate written description requirement under § 112, first paragraph. (Ariad Br. 21-22.) But the Court in *Gay* conducted two separate analyses, one for a § 132 rejection in a manner consistent with how written description is determined today, *id.* at 770-71 (whether substantially "non-porous" was supported by the original specification), and a second for enablement/best mode. *Id.* at 772-74. Further, Judge Rich in *Gay* did not say that there was not a separate written description requirement. Instead, he noted that the PTO's position was contrary to "two of the ***several*** requirements of the first paragraph of 35 U.S.C. § 112"—the two being enablement and best mode. *Id.* at 772. The other requirement in § 112 is written description.

2. Original Claims

Some of the commentary on the written description requirement suggests that it is acceptable to apply § 112 to amended claims but not acceptable to apply it to original claims. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307 & n.2 (Fed. Cir. 2004)(Rader, J., dissenting from denial of petition for rehearing *en banc*); (NYIPLA Br. 16-20); (Novozymes Br. 5-10). Entities that advance this position also incorrectly argue that *UC v. Lilly* constituted a wholesale change in the law. As discussed above, courts in *Moore* (1946), *Sus*, *DiLeone*, and *Jepson*, all stated, or otherwise applied, the written description requirement to original claims. *Morse* itself stated that under certain circumstances, a claim's language would not provide its own support. 56 U.S. at 119-20.

The same was true of this Court's panel decision in *Fiers*, 984 F.2d at 1171. There, in an attempt to obtain priority of invention, Revel argued that its original "Israeli application satisfies the written description requirement." *Id.* at 1170. Revel pointed "***to a claim in the original Israeli application*** that corresponds substantially to the language of the count." *Id.* "Revel thus urges that only similar language in the specification ***or original claims*** is necessary to satisfy the written description requirement." *Id.* The panel, however, specifically stated, "***We disagree***." *Id.* The court explained that such original language was not sufficient as it "just represents a wish, or arguably a plan, for obtaining the DNA. If a

conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived." *Id.* at 1171. This decision was reached in 1993—four years before the panel decision in *UC v. Lilly*. Indeed, the district court in *UC v. Lilly* had relied on *Fiers* to hold the asserted claims of UC's patent invalid under the written description requirement. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q. 2d 1225, 1239-41 (S.D. Ind. 1995). The panel's decision merely affirmed the district court's well-reasoned opinion. *UC v. Lilly*, 119 F.3d at 1569.

That the written description issue in *Fiers* was decided in the context of an interference is of no moment. There is simply no basis in the statute or this Court's precedent for different standards under § 112 depending on whether the issue arises in the context of a district court litigation or an interference. The same standard must apply to both circumstances. *See Enzo*, 323 F.3d at 975 (Newman, J., concurring)("The dissent's citation of cases in which the description of the invention has been relied on to antedate references and in interference contests reinforces, not reduces, the role of the description of the invention in establishing what has been invented.").

Indeed, this was the very point made by Judge Bryson in his concurring opinion in *Moba*, where he wrote that it is illogical to have different legal standards

for amended claims and original claims. 325 F.3d at 1327. The usual response to this argument is to cite *In re Gardner*, 480 F.2d 879 (C.C.P.A. 1973), and argue that an original claim is necessarily part of the written description of the invention. (*See* Ariad Br. 44.) Yet, while an original claim is part of the specification, this fact does not mean that original claims must always be an adequate written description of the invention.

For both original and amended claims, a written description of the invention may either be satisfactory or deficient depending on whether the patent specification, including the original claims, provides a demonstration that the patent applicant actually invented and was in possession of the claimed subject matter. In cases where an original claim provides an adequate written description of the claimed invention, the inquiry need not go any further. Where an original claim read in light of the specification fails to provide an adequate written description of the invention because, for example, it claims the invention by what it does rather than what it is, then the original claim is invalid.[5] An amended claim warrants the same inquiry, and there is no logical reason to treat such claims differently.

[5] If functional language in an original claim was sufficient, then there would be no need for 35 U.S.C. § 112, paragraph 6, which limits means plus function claims to the disclosed means and their equivalents.

D. Claims Can Be Enabled But Not Satisfy the Description Requirement

Ariad, citing Judge Markey's dissent in *Barker*, argues that there cannot be a case where the enablement standard is satisfied, but written description is not. (Ariad Br. 29 & n.7.) This is simply not accurate. For example, there are cases where a prior application disclosed a genus and presumptively enabled the making of species within the genus, but claims to a species of the genus lacked written description support. *See, e.g.*, *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570-71 (Fed. Cir. 1996)(application disclosing a genus lacked written description to add a count to an undisclosed sub-genus); *Ruschig*, 379 F.2d at 994-96 (disclosure of a large genus of compounds did not provide a written description of a claimed species encompassed thereby but not described in the application). Conversely, there are cases where the description of a species was found insufficient to describe a claimed genus encompassing that species. In *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004), for example, generic claims to dental floss with a friction-enhancing coating were expressly held to be enabled, *id.* at 1350, but the disclosure of a single species in the parent application failed to provide written description support for the generic claims. *Id.* at 1352-58.

In cases involving numerical ranges, claims have been found not to be adequately supported where the claims recited undescribed numerical limitations, even though there was no question of enablement. *E.g.*, *Eiselstein v. Frank*, 52

F.3d 1035, 1040 (Fed. Cir. 1995)(grandparent application only disclosing an alloy with a nickel range of 45-55% did not describe about 50-60%); *Barker*, 559 F.2d at 593 (disclosure of a repetitive pattern of eight shingles did not describe "at least six"); *In re Wertheim*, 541 F.2d 257, 263-64 (C.C.P.A. 1976)(disclosure in parent application of 25%-50% did not describe "at least 35%"). Mechanical cases with sufficient drawings, such as *Gentry Gallery*, are usually enabled, yet the claims at issue in *Gentry* lacked a sufficient written description. The specification there was "limited to sofas in which the recliner control is located on the console," but the claims allowed the control to be in other locations. 134 F.3d at 1479. Similarly, and contrary to Ariad's assertions (Ariad Br. 34), UC's claims in *UC v. Lilly* may have been enabled, in that UC had actually obtained the rat proinsulin sequence, and the specification contained a detailed prophetic example concerning how to obtain the human cDNA. 119 F.3d at 1567-68. In fact, *Schriber-Schroth*, *Alonso*, *Fiers*, and *Sus* are all cases where the claims were enabled but lacked an adequate written description.

E. If the Written Description Precedent Should Be Changed, It Should Be Done by Congress

This Court should not abrogate by judicial decision its decades of precedent applying a separate written description requirement. In both *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997), and *Festo*, 535 U.S. at 739, the Supreme Court explicitly stated that this Court should ***not*** upset the settled

expectations of the patent community. If the law should be changed, it should be done by Congress.

In discussing the long-standing precedent concerning the doctrine of equivalents, the Supreme Court stated that "the lengthy history of the doctrine of equivalents strongly supports adherence to our refusal in *Graver Tank* to find that the Patent Act conflicts with that doctrine. Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court." *Warner-Jenkinson*, 520 U.S. at 28. Similarly, in *Festo*, the Supreme Court explained that the Federal Circuit "ignored the guidance of *Warner-Jenkinson*, which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community. . . . The responsibility for changing them rests with Congress. . . . Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." 535 U.S. at 739.

This is true even if the interpretation of the statute was initially incorrect. In *Square D Co. v. Niagara Frontier Tariff Bureau, Inc.*, 476 U.S. 409 (1986), the Supreme Court noted that "[*s*]*tare decisis* is usually the wise policy because in most matters [of statutory construction], it is more important that the applicable rule of law be settled than that it be settled right . . . . This is commonly true, even

where the error is a matter of serious concern, provided correction can be had by legislation." *Id.* at 424 (citation omitted). "We are especially reluctant to reject this presumption in an area that has seen careful, intense, and sustained congressional attention. If there is to be an overruling of the *Keogh* rule, it must come from Congress, rather than from this Court." *Id.*

Similarly, in *Watson v. United States*, 552 U.S. 74 (2007), the Supreme Court explained:

> [a] difference of opinion within the Court . . . does not keep the door open for another try at statutory construction, where *stare decisis* has 'special force [since] the legislative power is implicated, and Congress remains free to alter what we have done.' What is more, in 14 years Congress has taken no step to modify *Smith's* holding, and this long congressional acquiescence 'has enhanced even the usual precedential force' we accord to our interpretations of statutes[.]

Id. at 82-83 (citations omitted).

Here, even Ariad admits that since *Ruschig*, which was decided in 1967, there has existed a separate written description requirement. (Ariad Br. 24, 27.) Thus, for at least the last forty years, inventors and the public have operated under that assumption. Similarly, there can be no reasonable debate that the written description requirement was applied to original claims in *Fiers*—some sixteen years ago, and in *UC v. Lilly*—some twelve years ago. Congress has amended the patent statute many times and is currently in the process of changing the statute yet

again. If Ariad is truly correct that all of the above precedent is wrong or unwise, it should be changed by Congress, not this *en banc* Court.

F. The Written Description Requirement Promotes the Policies Underlying the Patent System

In addition to having the virtue of being supported by precedent and the text of the statute, the written description requirement as currently applied represents sound patent policy—policy that should not be disturbed by this Court.

1. The Written Description Requirement Keeps the Overreaching Inventor in Check

Lilly submits that an important purpose of the written description requirement is to protect the public from overreaching inventors who attempt to claim as their own subject matter they have not invented. Lilly submits that the public would not be served by allowing entities, such as Ariad, to dominate and preempt a natural biological process based on little more than a plan for further research. "That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans." *Fiers*, 984 F.2d at 1169. To prevent patentees from "preempt[ing] the future before it has arrived," the written description must demonstrate that the inventor had possession of the claimed invention at the time of filing. *Id.* at 1171. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its

successful conclusion." *Rochester*, 358 F.3d at 930 n.10 (citing *Brenner v. Manson*, 383 U.S. 519, 536 (1966)).

While the patent system encourages innovation by rewarding individuals with the right to exclude others from practicing their invention for a period of years, it does so only in those circumstances where the individuals' invention has actually been completed, represents a novel and non-obvious advance, and has been fully disclosed to the public. *Bonito Boats*, 489 U.S. at 150-51. Ariad focuses on the incentive to invent without addressing the other and equally important half of the balance—protection of the public from the issuance of patents for subject matter which the patentee has not invented. If promoting innovation were the only goal of the patent system, there would be no limit on patent terms, no requirement for an enabling disclosure commensurate in scope with the patent claims, and no requirement that the patent contain a written description demonstrating possession by the inventor of the claimed subject matter. But this is not so. The concept of written description is implicated throughout the patent law, including when addressing questions of priority, novelty, new matter, and conception.

The facts at issue here demonstrate the necessity for the written description requirement. Contrary to Ariad's assertions (Ariad Br. 53), the claims asserted

against Lilly broadly cover any and all methods of reducing NF-κB in a cell. Claim 95, rewritten in independent form, is representative:

> A method for reducing, in human 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.***

(A489, A491.)

The claims specify no disease, no particular chemical compound, no step of drug administration, and no patient population. The district court stated that the "only step required to practice the broadest patented method is to 'reduc[e] NF-κB activity in the cell such that the expression of said gene is inhibited';] [n]o particular agent or substance need be used, nor any particular step(s) performed, to reduce NF-κB activity . . . ." (A71-72.) "Each of these claims talks about a method, and each of the claims describes a method for doing something, but it doesn't say what the method is. It simply gives the end result." (A2080:3-6.) The court's construction was also reached by the PTO in rejecting the asserted claims in the ongoing reexamination: "[T]he sole method step is functional, i.e. reducing NF-κB activity in cells[;] . . . the claims would encompass any *in vitro* or *in vivo*, direct or indirect or natural or man-made means of reducing NF-κB activity in cells." (A24911.) And as correctly stated by the panel, "***Ariad claims methods***

comprising the single step of reducing NF-KB activity." *Ariad*, 560 F.3d at 1372.[6]

Despite such broad claims, the specification describes very little. As also correctly found by the panel, "[t]he '516 patent discloses ***no working or even prophetic examples of methods that reduce NF-κB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity***." *Id.* at 1376. The panel specifically stated the following:

> Ariad sought and obtained the broad claims we now hold to be invalid. . . . [A]s it stands, ***Ariad chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification of the '516 patent***. *Cf. Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (***"The motto, 'beware of what one asks for,' might be applicable here."***).

Id. at 1376-77. This Court's written description precedent correctly defeated Ariad's attempt to obtain broad claims, which would have preempted the entire field of NF-κB inhibition—on the basis of little more than a research plan.

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[6] The claims are so broad as to encompass a wide range of previously existing compounds with widely varying structures and activities that have been reported in scientific publications to affect the NF-κB pathway, including calcitriol, cyclosporin A, glucocorticoids, and salicylates (aspirin). (A24898-25009; *see also* http://people.bu.edu/gilmore/nf-kb/inhibitors.) Indeed, Ariad sought to obtain damages from Lilly for sales of Xigris® and Evista®, which contain active ingredients that had been described in Lilly patents filed well ***before*** Ariad's claimed 1989 priority date for the '516 patent here in suit. (A72; A74-75; A17966-87; A24811-64.)

Precisely the same evil was prevented by application of the written description requirement in *UC v. Lilly* and *Rochester*. In each of these cases, it was argued that subsequent researchers, allegedly pursuing the research plan, had succeeded in developing the prophesized inventions and that the patent disclosures were therefore enabled. Only the written description requirement, and its mandate that the patent specification demonstrate possession of the claimed subject matter at the time of filing, prevented the preemption of the future before it had arrived.

2. The Written Description Requirement Defines the Invention

Another important purpose of the written description is to define the invention. "[W]hile the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement)." *Rochester*, 358 F.3d at 922 n.5. "The description of the invention has always been the foundation of the patent specification. It sets forth what has been invented, and sets boundaries of what can be claimed." *Enzo*, 323 F.3d at 975 (Newman, J., concurring). In *Rochester*, the panel explained that the written description requirement was not satisfied because it failed to "steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent." 358 F.3d at 929.

When the claims broadly encompass the use of a class of chemical compounds, as do the claims of the '516 patent in covering any method of reducing NF-κB activity, the written description should identify or describe the members of the class, and it should not be sufficient to define the class members by what it is hoped they will do—i.e., their hoped-for function—or how they might be discovered. *See Rochester*, 358 F.3d at 927-28; *UC v. Lilly*, 119 F.3d at 1568; *Fiers*, 984 F.2d at 1171. For example, the '516 patent defines hypothetical NF-κB inhibitors in terms of their function, i.e., "a specific inhibitor molecule," "decoy molecules," and "dominantly interfering molecules." (A467, 37:43-38:22.) These words are merely descriptions of the tasks that unknown molecules are supposed to perform—they neither describe actual molecules nor provide a correlation between structure and function for the potentially thousands of compounds use of which is covered by the claim.

3. The Written Description Requirement Encourages Innovation in New Technological Areas

The written description requirement actually encourages innovation by preserving patent protection in new technological areas. For example, in the emerging field of cDNA cloning, this Court was confronted with a dilemma. The Court could have decided that it was sufficient to conceive, i.e., be in possession of, an invention in the cDNA cloning field if one described prophetically the application of known cDNA cloning techniques to the hoped for end of isolating

the gene appearing in humans for a desired protein. But if the Court had so held, then most of the activity in this emerging field would have been obvious from and unpatentable in view of those same known techniques. This approach would have meant that the efforts of those individuals who actually isolated and characterized a cDNA molecule of interest, representing the actual DNA sequence in humans, would not be rewarded by the patent system.

For this reason, this Court wisely held that the particular nucleotide sequence representing the reverse transcript of naturally occurring mRNA—the so-called cDNA sequence—was neither conceived nor rendered obvious by the general availability of cDNA cloning technology and the knowledge of the desired protein encoded by the cDNA. *In re Deuel*, 51 F.3d 1552, 1558-59 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharms. Co.*, 927 F.2d 1200, 1206-09 (Fed. Cir. 1991).

It is a necessary corollary of these decisions that since the simple identification of a desired research objective (i.e., the cDNA encoding a protein of interest) and a statement of the method by which it is hoped to attain the objective (i.e., cDNA cloning) does not render obvious the claimed cDNA sequence, such limited information also cannot possibly establish possession of a claimed cDNA sequence in the manner required by the written description requirement of § 112, first paragraph. This was the Federal Circuit's holding in *Fiers*, 984 F.2d at 1170-

71, and *UC v. Lilly*, 119 F.3d at 1567. Far from representing an obstacle to obtaining valuable patents, the Federal Circuit's obviousness and written description jurisprudence was actually necessary to ***preserve*** meaningful patent protection for the encouragement of true innovators.

The same rationale applies to other biotechnological inventions, such as antibodies and biologics, and would also apply to other technologies. *See ICU*, 558 F.3d at 1377-79 (applying the written description requirement to medical device technology); *LizardTech*, 424 F.3d at 1344-46 (applying the written description requirement to digital imaging technology). The lower the threshold to obtain a patent under the written description requirement of § 112, the easier it will become to subsequently invalidate later patents under 35 U.S.C. §§ 102 and 103. This will be a disincentive to researchers who make real contributions to society by actually making inventions, as opposed to those merely having a plan for further research.

Some of the amici suggest, however, that this Court's current written description precedent constitutes a disincentive to innovate because it does not allow claims to a genus, which can be harmful to biotechnology companies. (*See* Novozymes Br. 17-18.) This is not accurate. The PTO's written description guidelines, endorsed by this Court, plainly allow the patenting of a genus in an appropriate case.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species . . . by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Carnegie Mellon, 541 F.3d at 1124 (citing guidelines).[7] What is not allowed are the broad unsupported claims of the sort asserted against Lilly by Ariad. In this regard, it is important to note that the level of detail required in the description varies in proportion to the complexity and unpredictability of the technology and the scope of the claims: "what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Id.* at 1126 (citation omitted).

[7] Ariad ignores this standard at pages 37 and 45 of its brief. In further defining the standard for adequately describing a representative number of species, the guidelines require that one skilled in the art "would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." *Carnegie Mellon*, 541 F.3d at 1124. In other words, enough species need to be disclosed such that plausible scientific conclusions informing the scope of the genus claim can be drawn.

4. The Written Description Requirement Is Necessary For Properly Assessing the Prior Art

As noted above, the question of what constitutes an adequate "description" of an invention also has implications for the application of prior art. If an invention is "described" in a prior art disclosure, the prior art description negates novelty, and § 102 prevents others from patenting the thing so described. The consequence of finding an anticipatory "description" in the prior art is severe. All objective evidence of nonobviousness, such as unexpected results, failure of others, or commercial success, which would otherwise establish patentability, instantly becomes irrelevant to patentability. *See In re Wiggins*, 488 F.2d 538, 543 (C.C.P.A. 1973). But, if a "description" of the invention appears nowhere in the prior art—even if the prior art otherwise provides full, enabling technology for carrying out the invention—then the invention remains novel and potentially patentable.

In parallel with the disclosure requirements, the law relating to prior art has also developed safeguards to insure that broad disclosures are not viewed as an anticipatory "description" of every species encompassed by them, even though each such species may have been enabled. *See, e.g., In re Ruschig*, 343 F.2d 965, 973-75 (C.C.P.A. 1965). If this Court holds, as Ariad urges, that an invention can be described by nothing more than a broad generic albeit enabling disclosure, it would have serious, detrimental, and unintended consequences on the scope of

anticipatory descriptions in the prior art. It could dramatically limit available patent protection for subsequent actual inventors of improvement inventions within the scope of the generic disclosure and discourage such innovation. *See Fields*, 443 F.2d at 1392 (explaining that if an application merely had to satisfy the "how to make and use" requirement of § 112, but did not comply with the separate written description requirement, it would "considerably diminish[]" the "socially valuable incentive to further research and development provided by the opportunity to obtain subservient patents").

5. The Written Description Requirement Is *Not* More Difficult to Apply than Enablement

Ariad argues that the written description requirement is confusing, and difficult to apply, particularly because, according to Ariad, it is a subjective test. Ariad argues that enablement is much easier to apply. Ariad is incorrect. Unlike enablement, which relies on a complex assessment of the *Wands* factors to determine whether those skilled in the art could practice the invention without "undue experimentation," written description is based on the description in the patent itself. The analysis turns on whether the four corners of the specification indicate that the inventor had actually invented the subject matter claimed. *Rochester*, 358 F.3d at 926-27. Contrary to Ariad's assertions, this is not a subjective test. One does ***not*** examine whether the inventor actually believed he had invented the subject matter. Instead, the focus is on whether those skilled in

the art in reviewing the specification would understand that the inventor had put in sufficient description to establish that he or she actually invented the claimed subject matter. There could not be a more objective test.

Ariad further argues, joined by some commentators, that the written description is some kind of "super enablement" standard. (Ariad Br. 37-38.) Not so. Written description and enablement are distinct requirements with distinct purposes. The written description requirement ensures that the ***inventor*** actually invented the claimed subject matter, while the enablement standard looks to whether the invention actually works and whether ***others*** can make and use its full scope. In a case where someone actually makes an invention, the written description requirement is easy to satisfy. It is only in cases where the inventors try to claim ***more*** than they have invented that the description requirement becomes an obstacle.

Ariad also asserts that there is a problem because enablement is a question of law, but written description is a question of fact. (Ariad Br. 46.) Precisely why this is a problem is never satisfactorily explained.

Ariad also contends that there is a problem because enablement may look at post-filing evidence to demonstrate if an application is enabling as of its filing date, while the written description looks only to evidence at the time of filing. (Ariad Br. 46.) Again, this goes to the different purposes of written description

and enablement. Enablement examines whether ***others*** could have made and used the full scope of the claims as of the filing date. Thus, post-filing publications by others may, in some cases, show what was possible at the filing date and sometimes may be used as part of the enablement inquiry. Nevertheless, "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007)(quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). In contrast, written description examines whether the ***inventor*** had possession of the claimed invention as of the filing date judged by the description in the specification. As such, it is essentially irrelevant what others have published about the invention years after the applicable filing date.

G. This Court Should Strike Ariad's Improper Re-Argument of the Enablement Issues

The Court's *en banc* order was clear that the appeal was to be decided on the previously filed briefs and new briefs directed to the two *en banc* questions posed by this Court. (Order dated Aug. 21, 2009, at 2.) The last nine pages of Ariad's brief, however, reargue the enablement issue that was fully briefed during the merits stage. (Ariad Br. 50-59.) Ariad's violation of the rules should not be countenanced by this Court, and these sections of Ariad's brief should be stricken, particularly as Lilly, the appellant, has the right to file the opening and reply brief

on these issues. Nevertheless, Lilly feels constrained to briefly reply to the erroneous assertions in Ariad's brief so that they are not left unanswered in the record.

As it did at the merits stage, Ariad argues that its broad claims, which cover any conceivable method for reducing NF-κB activity (*see* Lilly Blue Br. 37-42), are enabled by the alleged disclosure of decoy molecules in the patent specification (Ariad Br. 54-55). This, however, is not correct. The panel correctly found that the specification did not describe any "completed" molecules, that the disclosure in the patent concerning decoy molecules "is not so much an 'example' as it is a mere mention of a desired outcome," and specifically labeled the use of decoy molecules to inhibit NF-κB as a "hypothetical." *Ariad*, 560 F.3d at 1375-76. But perhaps more importantly, even if the specification were to enable decoy molecules—which it does not—it certainly does not enable the "full scope" of the asserted claims, which are ***not*** limited to decoy molecules. (*See* Lilly Blue Br. 40-41; Lilly Gray Br. 5-12.) As also correctly stated by the panel, "[w]hatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims." *Ariad*, 560 F.3d at 1376.

Further, Ariad's attempt to re-argue its legally flawed "one mode" argument should be rejected by this Court. (*See* Lilly Gray Br. 5-12.) The specification must enable the "full scope" of the claims and not merely one embodiment. *See*

Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1361-62 (Fed. Cir. 2007) "We . . . ***reject*** [the] argument that because the specification enables ***one mode*** of practicing the invention, . . . the enablement requirement is satisfied." *Auto. Techs.*, 501 F.3d at 1285; (*see* cases cited in Lilly Gray Br. 7-8).

Ariad again cites *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998), and *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005), as support for its "one mode" argument. (Ariad Br. 58-59.) But Ariad misapplies these decisions. (*See* Lilly Gray Br. 8-9.) Neither of these cases purported to overrule this Court's precedent that the specification must enable the claims' full scope. In both *John Hopkins* and *Invitrogen*, the claims at issue were narrow, covering specific products, and ***not broad methods***, and the specifications only needed to disclose "one mode" sufficient to make the full scope of the subject matter covered by the claim—a particular product. In contrast, here, the asserted claims of the '516 patent broadly cover ***all*** methods of reducing NF-κB activity, without reciting any particular steps, agents, or substances. (A71-72.) As such, the specification does not enable the full scope of the asserted claims, rendering them invalid under § 112.

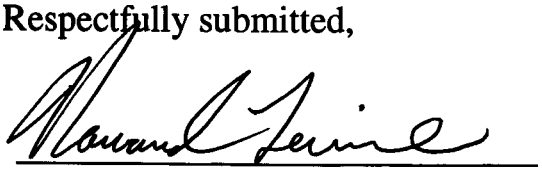
Finally, Ariad's '516 patent contains a claim to using decoy molecules to inhibit NF-κB activity, claim 203. (A493.) Ariad's problem is that Lilly does not use such a decoy molecule, and it thus could not have asserted that claim against

Lilly. It is only because Ariad claims subject matter that it did ***not*** invent—all methods of inhibiting NF-κB activity—that it could even possibly assert that Lilly's Evista® and Xigris® drug products infringe the '516 patent. (*See* note 6, *supra.*)

IV. CONCLUSION

For all the reasons noted above and in Lilly's Blue and Gray Briefs, this Court should adopt the panel's well-reasoned decision and find the asserted claims of Ariad's patent invalid under the separate written description requirement of 35 U.S.C § 112.

Respectfully submitted,



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November 9, 2009

CERTIFICATE OF SERVICE

I hereby certify that on November 9, 2009, two true copies of the **PRINCIPAL BRIEF OF DEFENDANT-APPELLANT ELI LILLY AND COMPANY ON REHEARING EN BANC** were served by the indicated means to each of the persons at the addresses listed:

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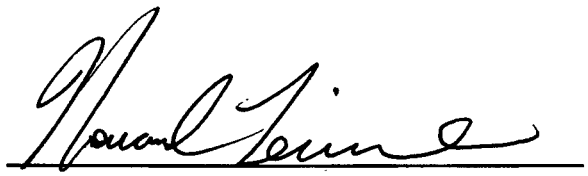

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