REPORT OF THE TASK FORCE SUBCOMMITTEE ON THE FEDERAL CIRCUIT'S REHEARING EN BANC OF *ARIAD PHARMACEUTICALS, INC. V. ELI LILLY & CO.*

To: ABA IP Council & ABA IP Section Committee 112 (Patent Litigation) Members

From: Jonathan Muenkel, Chris McGeehan, and Athar Khan

CC: Don Martens, Rob Lindefjeld, Jeannine Sano, Mark Whitaker, and Greg Hayden

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On August 21, 2009, the Federal Circuit granted Ariad Pharmaceuticals Inc.'s petition for rehearing en banc in the patent appeal *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 2009 WL 2573004, at *1 (Fed. Cir. Aug. 21, 2009) (Docket No. 2008-1248). In granting Ariad's petition, the court vacated its earlier April 3, 2009 decision in this matter, and asked the parties to file new briefs addressing the following two questions relating to the written description requirement for patentability under 35 U.S.C. § 112, paragraph 1:

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

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

Ariad's opening brief is due on Monday, October 5, 2009. Lilly's opposition brief is due Wednesday, November 4, 2009. The court further advised that they will accept briefs of amici curiae, and that such briefs may be filed without first seeking leave.

While the written description requirement is typically seen in pharmaceutical and biotechnology patent cases, it is becoming increasingly popular in software patent litigation. Many hope that the en banc *Ariad* decision will resolve years of confusion and uncertainty concerning the written description requirement, and also believe that it will have a significant impact both on how patents are prosecuted and litigated.

The purpose of this report is to provide background information helpful to the Council and 112 Committee when voting on the two proposed resolutions concerning the questions on written description above, and which may become the ABA's position should it file an amicus brief in the *Ariad* case. To this end, the report is divided into the following sections: (1) the two proposed resolutions for consideration by the 112 Committee and Council; (2) a list of past Section actions relating to the written description requirement; (3) a brief primer on the written description requirement; (4) a history of the Federal Circuit's written description jurisprudence in the lead up to *Ariad*; (5) a discussion of the Federal Circuit's April 3, 2009 *Ariad* decision (now vacated); (6) a discussion of the arguments made within Ariad's brief in support of its petition for rehearing en banc, and Eli Lilly's brief in opposition; and (7) an explanation of the arguments in favor of, and against, the two proposed resolutions.

I. Current Proposed Resolutions

The following are the proposed resolutions for consideration by the Council and 112 Committee Members:

Proposed Resolution No. WD-1

RESOLVED, that the Section of Intellectual Property Law opposes, in principle, that Section 112 ¶ 1 of the Patent Act be construed to include a written description requirement separate from the enablement requirement.

NOW, THEREFORE, the Section supports clarification that the Section 112 ¶ 1 written description requirement merely requires that the patentee describe his or her invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the claimed invention, and recommends that the American Bar Association file an amicus brief advocating this position in the case of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, Fed. Cir. No 2008-1248 *rehearing en banc* granted August 21, 2009.

Proposed Resolution No. WD-2

RESOLVED, that the Section of Intellectual Property Law supports, in principle, that Section 112 ¶ 1 of the Patent Act be construed to include a written description requirement separate from the enablement requirement.

NOW THEREFORE, the Section supports clarification that the Section 112 ¶ 1 written description requirement requires more than describing the claimed invention so that one skilled in the art is enabled to make and use the claimed invention, but instead mandates adequate disclosure of that which is claimed by the invention, and recommends that the American Bar Association file an amicus brief advocating this position in the case of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, Fed. Cir. No 2008-1248 *rehearing en banc* granted August 21, 2009.

II. Past Action Relating To Written Description

It does not appear that any previous actions by this Section on the topic of written description are sufficiently on point to support either side in the *Ariad* case. Research by Gregory Hayden, at the ABA, uncovered the following resolutions:

216 (Passed 1992, AR121-R108-4; Retained 2003)

Section opposes, in principle, amendment of Title 35 to change the requirement of Section 112 that an application contain a written description sufficient to constitute an enabling disclosure.

234 (Passed 2000, AR63-R108-1)

Section opposes, in principle, application of an omitted element test, for Section 112 written description compliance, and favors that determination of compliance with the written description requirement be based on the disclosure of the specification as a whole.

218a (Passed 1988, SP 73-R605-1; Retained 1999)

Section favors in principle the concept that 35 U.S.C. Section 112 does not and should not require patent application disclosures to include mechanical tolerances of any particular specimen or model embodying the invention beyond that sufficient to enable a person of ordinary skill in the art to which the invention pertains to make and use the invention utilizing the engineering of those of such ordinary skill; and, Specifically, the Section believes that the Federal Circuit opinion in *Christiansen v. Colt Industries*, 3 U.S.P.Q. 2d 1241 (Fed. Cir. 1987) is essentially correct insofar as it concerns the disclosure requirements of 35 U.S.C. Section 112

III. 35 U.S.C. §112 – An Introduction To The Written Description Requirement

Title 35, § 112 of the United States Code ("§ 112") is one of several sections codified from the 1952 Patent Act that provides specific requirements for a United States patent to be valid. Section 112 contains two paragraphs. Only the first paragraph is relevant to this discussion. The first paragraph of § 112 states that:

> The specification [of the patent] shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (emphasis added).

It has generally been understood that § 112, ¶ 1 mandates that the patent applicant meet the following three requirements within its patent specification[1]: (1) the written description requirement (*i.e.*, that the invention is adequately described); (2) the enablement requirement (*i.e.*, that the invention is described in a manner a such that one of ordinary skill in the art can make and/or use the invention); and (3) the best mode requirement (*i.e.*, that the inventor described the best mode contemplated by the inventor for carrying out his or her invention). Failure to meet

[1] The patent specification, also called the disclosure, consists of everything within a patent other than the numbered patent claims (which define the metes and bounds of the invention). Parts of the specification include, *inter alia,* the title, the background of the invention, the summary of the invention, the detailed description of the invention, a description of any drawings or figures contained in the patent, and in the case of certain biotechnology patents, genetic sequence (*i.e.*, DNA) information. The specification helps to, *inter alia*, properly define the scope of the claims.

any one of these requirements when looking at a particular patent claim can result in that claim being rendered invalid.

The idea behind the written description requirement is to guarantee that the public will receive the full benefit and knowledge of the patent's underlying invention, in exchange for the limited monopoly granted to the named inventor(s). The Federal Circuit has stated that the purpose is also to ensure that the patent applicant was in "possession" of the claimed invention as of the patent application's filing date. In other words, the specification of the patent must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventor was in "possession" of whatever is now being claimed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

IV. A Brief History Of The Federal Circuit's Written Description Jurisprudence Prior To *Ariad*

Historically, the issue of written description has arisen in patent actions in the context of *priority*. Such cases involve situations where a new patent claim was added to a patent application at some stage *after* the original application was filed with the U.S. Patent and Trademark Office ("PTO"). The defendant would argue that the specification in the *original application* (often relied on by the patentee for purposes of priority, and to antedate certain prior art) did not adequately describe the *new claim* (*i.e.*, show that the applicant was in "possession" of the claimed invention). Assuming the defendant was successful with this argument, the patent owner could not rely on the earlier filing date when asserting the new claim.

Over the years, district courts have had difficulty applying the written description requirement due to the Federal Circuit's and C.C.P.A.'s failure to present a cohesive and consistent body of case law on this subject. *See, e.g., Vas-Cath Inc. v. Mahurkar*, 745 F. Supp. 517, 522 (N.D. Ill. 1990) ("[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is" with respect to written description). The Federal Circuit's decision in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (discussed below), resulted in even greater confusion and uncertainty, when the court arguably articulated a heightened standard for written description as applied to biotechnology inventions involving genes. Indeed, the *Lilly* decision was the first time the Federal Circuit applied the written description requirement for the sole purpose of deciding patent *validity* rather than patent *priority*. *Cf. Vas-Cath*, 935 F.2d at 1560 (wherein Judge Rich wrote that the written description requirement only "comes into play" in three circumstances: (1) examination of new claims not contained in the original application; (2) when a patentee seeks the benefit of a filing date under 35 U.S.C. §§ 119 and 120; and (3) in the interference context where priority is disputed between the parties).

Many have disagreed with the holding in *Lilly,* believing that it created a more exacting and rigorous written description requirement, that stands as an impediment to effective patent protection, especially for biotechnology inventions. Such disagreement is even seen within the ranks of the Federal Circuit itself, with Judges Rader, Linn and Gajarsa leading the charge, and voicing their discord in several dissenting opinions following *Lilly.* This division within the court has been working to a slow boil, and seemingly has come to a head with the Federal Circuit's decision to rehear en banc *Ariad.*

What immediately follows is a brief discussion of the Federal Circuit's, and its predecessor court, the C.C.P.A's, relevant written description decisions leading up to *Ariad*.

In re Ruschig (C.C.P.A. 1967)

In re Ruschig, 379 F.2d 990 (C.C.P.A. 1967), was the first case to distinguish the written description requirement from the enablement requirement of §112. The claim at issue in *Ruschig* was for a specific chemical compound. The patent applicants admitted that the claimed compound was not specifically named, or identified by formula, in the specification. Instead, the specification provided a generic class of chemical compounds, amounting to almost half a million specific compounds, and of which the claimed compound was one. *Ruschig,* 379 F.2d at 991.

Affirming the Board of Patent Appeals and Interferences' finding that the written description requirement was not met, the court stated that

> [n]ot having been specifically named or mentioned in any manner [in the specification], one is left to select from the myriad of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

Id. at 995.

Moreover, in differentiating written description from enablement, the court noted that written description is required to show inventorship, not whether someone would want to make the compound. *Id.* at 995-96.

Vas-Cath Inc. v. Mahurkar (Fed. Cir. 1991)

In *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), the Federal Circuit reinforced the distinctiveness of the written description requirement from the enablement requirements under § 112, ¶ 1.

Here, the Federal Circuit reversed the district court's decision not to give any of the claims at issue the benefit of a design patent's earlier filing date, based on failure to meet the written description requirement. Specifically, the district court found that the original design patent drawings failed to provide a "written description" adequate to support the claims at issue. While the district court admitted that the drawings in the design application showed the combination of elements claimed, the district court also improperly required the "written description" to exclude size ranges outside of those claimed. *See id.* at 1566. The Federal Circuit remanded the case for the district court to separately analyze whether the design application drawings provided adequate "written description" for each claim.

In reviewing its own development of the written description requirement, the Federal Circuit found a "fairly uniform standard" requiring the description to "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed . . . ." *Id.* at 1563 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). The court went on to state that

"the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)). The court also attempted to clarify any "app[arent] confusion," by reaffirming that the written description requirement is separate and distinct from the enablement requirement. *Id.* at 1563-64 ("The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.").

Amgen, Inc. v. Chugai Pharm. Co., Ltd. (Fed. Cir. 1991)

Although *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991), addressed the issue of *conception* as opposed to the written description requirement, the decision introduced a key concept that later formed the foundation for later written description cases involving certain biotechnology inventions.

Here, Amgen held a patent that claimed a purified and isolated DNA sequence encoding Erythropoietin ("EPO"), a key protein necessary for the production of red blood cells.[2] The defendants challenged the patent by asserting that another researcher had already invented the technique that was eventually successful in creating purified EPO, and that he was diligently working on problem of creating EPO, and eventually did so. *Id.* at 1205-06.

The Federal Circuit held that "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method of obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." The court went on to explain that *conception* of an isolated nucleotide sequence is not achieved without the precondition of reduction to practice (*i.e.* isolated the nucleotide sequence), since another inventor might otherwise have difficulty envisioning the composition of the gene to sufficiently distinguish it from other materials. *Id.* at 1206.

[2] A brief explanation of gene terminology may be useful here for those unfamiliar with the subject. Chromosomes contain a person's genetic material and are passed on from generation to generation. Each chromosome contains long stretches of DNA (a "nucleic acid") comprising individual DNA segments called "genes." Each gene contains information required to build and maintain cells in the body, and to make proteins which turn on and off certain biological functions and chemical reactions. Genes are made of certain material, including four different subunits called nucleotides. Each nucleotide consists of a sugar molecule and a base (adenine, guanine, cytosine, and thymine). Accordingly, a single strand of DNA consists of thousands, or even millions, of pairs of nucleotides linked together. Each particular combination of nucleotides forms the "gene sequence" (also referred to as the "nucleotide sequence").

Fiers v. Revel (Fed. Cir. 1993)

Two years later, the Federal Circuit utilized its decision in *Amgen* to require the same high degree of specificity for compliance with the written description requirement, in the context of a priority dispute.

In *Fiers v. Revel,* 984 F.2d 1164 (Fed. Cir. 1993), the Federal Circuit held that an application claiming a DNA sequence, but which did not disclose the specific nucleotide sequence of that DNA, did not satisfy the written description requirement by merely reciting a general strategy for isolating the claimed DNA sequence. Specifically, *Fiers* involved a patent interference to determine which of the two parties in the interference was the first to invent a specific protein in the body (human fibroblast beta interferon). To make this determination, the court looked at whether Revel provided sufficient written description for his patent related to the DNA sequence of a gene that makes the protein in question. Revel provided a method for isolating a fragment of the DNA coding for the gene, and a method for isolating the messenger RNA coding for the gene, but did not disclose the actual sequence of the gene. *Id.* at 1167.

The court held that Revel's patent was invalid for lack of written description, stating, "[i]f 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 (emphasis added). The court also stated that "[c]laiming all DNA [sequences] that achieve the result without defining what means will do so is not in compliance with the written description requirement; it is an attempt to preempt the future before it has arrived." *Id.* at 1170.

Regents of the Univ. of California v. Eli Lilly & Co. (Fed. Cir. 1997)

The world of written description jurisprudence markedly changed in 1997, with the Federal Circuit's decision in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) ("*Lilly*").

In *Lilly*, the Federal Circuit arguably expanded the requirements for demonstrating adequate written description in the biological sciences. Several claims were at issue. The first set of claims at issue were drawn to a microorganism containing human insulin cDNA.[3] The second set of claims were more broad, and were directed to vertebrate or mammalian cDNAs encoding insulin. The patent specification only described the *rat* cDNA sequence, and a process for obtaining human insulin cDNA, but did not provide the actual nucleotide sequence of human insulin cDNA.

As to the first set of claims (human insulin cDNA), the Federal Circuit determined they were invalid for lack of written description since the specification described a general method for obtaining human insulin cDNA, but did not disclose the actual sequence for the synthetic insulin, only the sequence for the two amino acid chains that constitute human insulin. *Id.* This

[3] "cDNA" or "complementary DNA" is DNA purified and isolated from a gene, and often added to host cells to express a specific protein (*e.g.,* the gene that instructs the host cell to that produce the protein insulin).

disclosure, the court reasoned, was inadequate because the DNA sequence itself was never disclosed. *Id.*

As for the second set of claims (vertebrate or mammalian insulin cDNA), the Federal Circuit also found them invalid for lack of written description. While Regents argued that the disclosure of the rat insulin cDNA sequence, and directions for using it to obtain insulin cDNA sequences of other species, was sufficient, the Federal Circuit disagreed. *Id.* at 1568. Specifically, the court deemed this disclosure insufficient because "it does not distinguish the claimed genus from others, except by function." *Id.* The court further explained that "[t]he description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention." *Id.* The court went on to provide general guidelines on how to provide adequate written description for a class of DNA sequences, stating, "[a] description of a genus of cDNAs may be achieved by means of a recitation of a *representative number* of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* at 1569 (emphasis added).

As indicated in later dissents from various members of the Federal Circuit (discussed below), many believe that *Lilly's* treatment of a separate written description requirement – the so-called "free-standing disclosure requirement" – goes too far and effectively supplants the enablement requirement.

Enzo Biochem, Inc. v. Gen-Probe, Inc. ("Enzo I") (Fed. Cir. Apr. 2, 2002)

The Federal Circuit momentarily extended the reach of *Lilly* in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002) ("*Enzo I*"), *vacated*, 323 F.3d 956 (Fed. Cir. 2002) ("*Enzo II*").

In *Enzo I,* the claims at issue were to nucleic acid probes that were specific for bacteria that cause gonorrhea. *Id.* at 1016. While the genetic structure of the probes (*i.e.*, the exact nucleotide sequences) were not described in the specification, reference in the specification was made to biological deposits of three nucleic acid probes that fell within the scope of the claims in question. The Federal Circuit determined this to be inadequate for the purposes of written description, and affirmed the lower court's invalidation of the claims in question.

Specifically, the Federal Circuit found that the specification only described the claimed compositions by their function (*i.e.*, their binding affinity), but not by their actual genetic structure (*i.e.,* the exact nucleotide sequence). *Id.* While Enzo might have shown a possession of the claimed invention by reducing it to practice and depositing the nucleotide sequence in a public depository, the court emphasized that *possession alone could not satisfy the statutory requirement if the claimed invention was not adequately described in the specification*. *Id.* at 1020-21.

The court went on to state that a deposit of biological materials originated as a means of enabling practice of the invention; it was not, however, part of the specification. *Id.* at 1023. Moreover, the court determined the deposits here to be "purely functional" because the hybridization conditions did not identify the nucleotide sequences themselves but merely

described what they do. *Id.* at 1018. Put simply, *the absence of specific sequence information could not be cured by the public deposit*. *Id.* at 1021. The court also held that this was not a case in which the structure of the claimed composition could not be described, and rejected Enzo's argument that it relied on the reduction to practice "safe haven" provided in the PTO's Written Description Guidelines. *Id.* at 1022-23.

(Dyk, J., dissenting)

Judge Dyk dissented from the majority opinion, arguing that whether a specification complied with the written description requirement was a fact question. *Id.* at 1025. Judge Dyk contended that *Lilly* – which imposed a unique written description requirement in biotechnology field in addition to a showing of possession and which the majority relied upon – was "open to serious question." *Id.* Judge Dyk also argued that a reference to a deposit in the specification met the written description requirement. *Id.* at 1027. The PTO suggested that deposited material might be used for written description purpose, and the examiner did not raise any written description rejections during the prosecution of the patent in the absence of any description of the nucleotide sequence of the probe. *Id.* at 1028. Therefore, Judge Dyk argued, the court should not second-guess the PTO's judgment when its insistence on a better written description was to enable the PTO's examination. *Id.* at 1029.

A huge outcry within the biotech community immediately followed the decision in *Enzo I*, especially since the PTO itself had established regulations stating that biological deposits satisfied the written description requirement. *See generally, Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, ¶ 1 "Written Description" Requirement,* 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). Some believe this public consternation caused the Federal Circuit to reexamine its decision in *Enzo I*, leading to *Enzo II.*

Enzo Biochem, Inc. v. Gen-Probe, Inc. ("Enzo II") (Fed. Cir. July 15, 2002)

The same three-judge panel in *Enzo I* reversed its opinion following rehearing, finding that not all functional descriptions of genetic material were insufficient to meet the written description requirement. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) ("*Enzo II*").

Taking judicial notice of the PTO's Written Description Guidelines, the court ruled that, in some cases, functional description of genetic material can satisfy the written description requirement. Specifically, the court stated:

> [T]he PTO has determined that the written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.

Enzo II, at 964.[4]

Moreover, the court held that reference in the specification to a deposit of biological materials in a public depository, when the contents of the biological materials were not otherwise available in written form, could satisfy the written description requirement. *Id.* at 966. To the extent that the claimed subject matter in the claims is beyond the deposited sequence, whether the written description requirement was met was a question of fact. *Id.* Additionally, the compliance of the broader genus claims with the written description requirement depended on a determination of whether Enzo's deposits were representative of the scope of the genus claims, also a fact issue. *Id.* at 966-67.

As in *Enzo I*, the court also reiterated its position that possession alone was not always sufficient to satisfy the written description requirement. *Id*. at 969-70. Specifically, the court stated that possession is merely "ancillary to the statutory mandate [of § 112]," and without more than possession, renders the disclosure insufficient. *Id.* at 969.

(Rader, Gajarsa, Linn, JJ., dissenting from denial of rehearing en banc)

Of particular importance, Judges Rader, Gajarsa and Linn submitted a dissenting opinion from the court's decision *not* to rehear the case en banc.

Specifically, the dissenters stated that the written description requirement was created for the sole purpose of preventing introduction of new matter through claim amendments. *Id.* at 978. Where no *priority* issue existed, the statutory disclosure requirement was met as long as the claimed invention is *enabled*, regardless whether it was sufficiently described in the specification. *Id.* at 979. They went on to state that *Lilly* imposed a far more demanding disclosure requirement than § 112, 1st ¶ required. *Id*. at 982. Judges Lourie and Newman rejected such argument, stating that the statute clearly imposed a written description requirement independent of an enablement requirement. *Id.* at 972, 975.

Amgen v. Hoechst Marion Roussel (Fed. Cir. 2003)

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), the panel majority for the Federal Circuit (headed by Chief Judge Michel) affirmed the district court's finding that Amgen's patents met the written description requirement. *Id.* at 1334. Amgen's patents were drawn to methods of expressing EPO (discussed above in *Amgen v. Chugai*). *Id.* at 1319. The patents claimed EPO expressed in vertebrate and mammalian cells, but the specification disclosed only expression in monkey and hamster cells. *Id.* at 1338. At issue was

[4] It is important to note that the PTO's Written Description Guidelines did not fully embrace the Federal Circuit's heightened written description requirement with respect to nucleotide sequences. Instead, the Guidelines assert that multiple identifying properties short of an actual sequence, including functional characteristics, may be sufficient to show possession of an invention. *See* 66 Fed. Reg. 1110, n.42 (listing relevant identifying characteristics for biomolecules, including sequence, structure, binding affinity, binding specificity, molecular weight, length, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, and antibody cross-reactivity).

whether the description of selected species sufficiently described all of the claimed genus. The court held that the genus was sufficiently described because the words "vertebrate" and "mammalian" readily conveyed distinguishing information such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus." *Id.* at 1332 (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)). The court distinguished both *Eli Lilly* and *Enzo II* because the claim terms at issue, "vertebrate" and "mammalian," merely identified types of cells that could be used to produce recombinant human EPO. *Amgen Inc.*, 314 F.3d at 1332. These terms were not new or unknown materials that one of ordinary skill in the art could easily miscomprehend. *Id.*

The court again interpreted the written description requirement to be a "separate and independent" requirement from the enablement requirement. *Id.* at 1330. The court stated that the purpose of the written description requirement is to prevent the inventor from later asserting that he invented something he did not. *Id.* The written description requirement therefore mandates that that applicant "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Id.* (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). The court also noted that the enablement requirement is "often more indulgent" than the written description requirement. *Id.* at 1334 ("The specification need not explicitly teach those in the art to make and use the invention; the [enablement] requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation.'").

(Clevenger, J., dissenting-in-part)

In a dissenting opinion, Judge Clevenger found that the claims lacked meaningful limitations on the cells expressing the EPO. *Id.* at 1358-59. According to Judge Clevenger, the district court had previously overlooked whether the disclosure of *one* means of expressing EPO from vertebrate or mammalian cells entitles the inventor to patents covering *all* EPO produced in culture from vertebrate or mammalian cells, or *all* cultured vertebrate cells that produce EPO. *Id.* at 1359. Judge Clevenger further explained that he would vacate the district court's decision regarding written description, and enablement and remand for further consideration on this issue.

University of Rochester v. G.D. Searle & Co., Inc. (Fed. Cir. 2004)

The Federal Circuit continued its attack on biotech patents for lack of written description in *University of Rochester v. G.D. Searle & Co*, 358 F.3d 916 (Fed. Cir. 2004).

Here, the University of Rochester ("Rochester") asserted patent claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound that selectively inhibits activity of the COX-2 gene product. *Univ. of Rochester*, 358 F.3d at 918. Nowhere, however, within Rochester's patent specification did the inventors identify a specific compound capable of performing the claimed method, or guidance on how to make or obtain any such compound. *Id.* at 919.

On appeal, the Federal Circuit affirmed the district court's summary judgment ruling that the method claims were invalid for lack of written description. Specifically, the Federal Circuit panel (headed by Judge Lourie) found that an adequate written description requirement must "describe[] the claimed invention so that one skilled in the art can recognize what is claimed." *Id.* at 922-23. Further, the court stated:

> [r]egardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.

Id. at 926.

The court went on to reject Rochester's argument that the written description rule announced in *Lilly* should only apply to inventions claiming genetic material. *Id.* at 925; *but c.f. Hoechst*, 314 F.3d at 1332 (suggesting that the more demanding written description requirement of *Lilly* may be restricted to "new or unknown *biological* materials.")

It is important to note that the facts of *Ariad*, now before the Federal Circuit, are very similar to the facts in *Rochester*, in that *Ariad* involves method claims to achieving a specific biological result. Unlike the Rochester patent, however, the Ariad patent-in-issue disclose three hypothetical classes of molecules that can accomplish this method.

Denial of Petition for Rehearing En Banc in Univ. of Rochester (Fed. Cir. 2004)

Perhaps more interesting that the initial *University of Rochester* decision from the three-judge Federal Circuit panel, was the lengthy opinion that emanated from the Federal Circuit's decision denying Rochester's petition for rehearing en banc. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004) ("*En banc Decision*").

By a 6 to 5 decision, the court denied Rochester's petition for rehearing en banc of the court's initial decision. Within the lengthy decision, each judge expressed his or her own opinion regarding the written description requirement. Judges Lourie and Dyk concurred in separate opinions, and Judges Newman, Rader, and Linn dissented in separate opinions. Judges Gajarsa and Linn joined Judge Rader's dissenting opinion, and Judges Rader and Gajarsa joined Judge Linn's dissenting opinion. *See En banc Decision*, 375 F.3d at 1304. Notably, the Judges disagreed regarding whether it was necessary to clarify the written description requirement.

(Lourie, J., concurring)

Concurring with the decision *not* to rehear *Rochester,* Judge Lourie stated that the court's precedent is clear and consistent, necessitating no revision of written description law. *Id.* at 1307. Judge Lourie explained that there is and always has been a separate written description requirement. *See id.* at 1305. Judge Lourie then argued that the written description requirement cannot be replaced by the prohibition against new matter because this prohibition is not expressly listed in the statute as a defense to infringement. *Id.*; *see* 35 U.S.C. § 132 (2006). Judge Lourie also denied that the court has created a "heightened" written description requirement for

biotechnology inventions. *See id.* ("The statute is the same for all types of inventions, although it may be applied differently, based on the technology and what is known by one of ordinary skill in the art at the time an invention was made.") (referring to *Lilly*).

(Dyk, J., concurring)

Also writing in concurrence, Judge Dyk viewed the written description issue in the case at hand as "not even close." *Id.* Judge Dyk agreed that the patent statute contains a written description requirement separate from the enablement requirement, but added that, in his view, the court has yet to articulate satisfactory standards for written description that can be applied to all technologies. *Id.*

(Newman, J., dissenting from denial of rehearing en banc)

Writing in dissent, Judge Newman voted to grant rehearing en banc because she considered this case an appropriate forum to clarify what in Judge Newman's view had become a "fundamental conflict concerning patent scope and the support needed to claim biological products." *Id.* Judge Newman noted the differences of opinion among the Federal Circuit judges regarding a separate written description requirement. *See id.* She compared these differences to a split among circuit courts, requiring resolution through an *en banc* decision. *See id.* Judge Newman nonetheless noted that the attacks on the separate and distinct written description requirement were unwarranted, and disruptive to the stability that the court was established to maintain. *See id.*

(Linn, J., (Gajarsa, Rader, JJ. joining) dissenting from denial of rehearing en banc)

Also writing in dissent, Judge Linn stated that the court should overturn its precedent establishing written description as a separate requirement of 35 U.S.C. § 112 on which a patent may be invalidated. *Id.* Judge Linn explained that enablement is the "primary role" of the written description. *Id.* Therefore Judge Linn argued that while section 112 requires a written description requirement, patentability should be based solely on whether the written description enables one skilled in the art to make or use the invention. *See id.* While the "new-found" written description requirement in *Lilly* and *Enzo II* is, at the moment, disproportionately falling on the biotechnology industry, it will eventually affect all fields of emerging technology. *See id.*

(Rader, J., (Gajarsa, Linn, JJ. joining) dissenting from denial of rehearing en banc)

Writing in a separate dissenting opinion, Judge Rader also described the court's written description jurisprudence in *Lilly* as "new." *Id.* Judge Rader explained that in *Lilly*, the court for the first time required the written description part to "adequately support" the claims by stating a "precise definition, such as by structure, formula, chemical name, or physical properties" of the structure claimed. *Id.* at 1308, 1313. The court went further in *Enzo II* to find that submission of the invention itself may be inadequate to describe the written description requirement introduced *Lilly*. *Id.* at 1308. Judge Rader also stated that when the court introduced this "*Lilly* doctrine," it failed to provide a legal basis for this validity requirement. *See id.* at 1308. In his dissent, Judge Rader also discounted the attempts in the court's panel decision to cite precedent and policy to justify the "*Lilly* doctrine." *See id.* at 1309-12. Finally, Judge Rader argued that the enablement requirement and the "traditional" written description requirement (enforcing the actual time of

invention) would have "prevented injustice" in the *Lilly* case, without resort to a new doctrine. *See id.* at 1313.

LizardTech, Inc. v. Earth Resource Mapping, Inc. (Fed. Cir. 2005)

Finally, in *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005), the Federal Circuit affirmed the district court's decision invalidating certain patent claims at issue for lack of written description. *Id.* at 1340. While *LizardTech* was not a biotechnology patent case, it is nevertheless discussed within the context of the cases above.

The Federal Circuit, once again, construed the written description clause of 35 U.S.C. § 112 as having two requirements, *i.e.*, a written description requirement which shows that the patentee had possession of the claimed invention at the time of the application, and an enablement requirement. *Id.* at 1344-45. These two requirements, the court stated, usually rise and fall together. *Id.* at 1345.

One claim in issue, which was part of the original disclosure, was directed to a method for viewing images using a seamless discrete wavelet transform (DWT)–based compression process. *Id.* at 1343, 1346. Only one embodiment for creating a seamless array of DWT was described in the specification. *Id.* at 1344. This particular step, however, was not mentioned in the specific claim in issue. *Id.* The Court therefore interpreted this claim to mean creating the seamless array of DWT coefficients "generically." *Id.* at 1345. The Court then concluded that LizardTech failed to meet either of the two requirements under the written description clause because the sole described embodiment would not reasonably convey to a person skilled in the art that the patentee had possession of the generic method or enable a skilled person to make a seamless DWT generically. *Id.* at 1345.

V. The Federal Circuit's April 3, 2009 *Ariad* Decision

Plaintiffs-Appellees Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the Presidents and Fellows of Harvard College (collectively, "Ariad") sued Defendant-Appellant Eli Lilly and Company (Lilly) in the United States District Court for the District of Massachusetts for infringement of claims 80, 95, 144, and 145 (the asserted claims) of U.S. Patent No. 6,410,516 (the '516 patent). The '516 patent was based on the discovery of NF-κB, a transcription factor, and that an artificial reduction in NF-κB activity, could ameliorate the harmful symptoms of certain diseases.

After a 14 day trial, the jury found infringement of claims 80 and 95 with respect to Lilly's drug Evista, and claims 144 and 145 with respect to Lilly's drug Xigris. The jury also concluded that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description.

Both at the close of Ariad's case-in-chief and again after the jury verdict, Lilly moved for judgment as a matter of law (JMOL) that the asserted claims were not infringed and were invalid for anticipation, lack of enablement, or lack of written description. Following a separate bench trial, the district court ruled that the asserted claims were directed to patentable subject matter and that the '516 patent was not unenforceable due to inequitable conduct or prosecution laches. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106 (D. Mass. 2007). Lilly appealed all

of the above rulings except the district court's ruling that prosecution laches did not render the '516 patent unenforceable.

In April 2009, the Federal Circuit reviewed the denial of Lilly's motion for JMOL. Ariad's asserted claims were related to reducing NF-κB activity. Lilly argued that the asserted claims were not supported by written description because the specification of the '516 patent failed to adequately disclose how the claimed reduction of NF-κB activity was achieved. The specification of the '516 patent hypothesized three classes of molecules potentially capable of reducing NF-κB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. Lilly argued that this disclosure amounted to little more than a research plan, and did not satisfy the patentee's quid pro quo as described in *Rochester*. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1373 (Fed. Cir. 2009). In an attempt to distinguish the jurisprudence of *Rochester*, Ariad argued that because it did not actually claim the molecules, it was entitled to claim the methods without describing the molecules. *Id*. at 1374. However, the Federal Circuit rejected this argument and held that regardless of whether the asserted claims recite a compound, to satisfy the written description requirement, the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-κB.

The Court then reviewed the specification's disclosure of each of the three classes of molecules, to determine whether there was substantial evidence to support the jury's verdict that the written description evidenced that the inventor possessed the claimed invention. With regard to specific inhibitors, the Court noted that the specification provided only one example, and that the DNA sequence for this example was not disclosed in the original application. Accordingly, the Court held that in the context of this invention, a vague functional description and an invitation for further research did not constitute written disclosure of a specific inhibitor. *Id*. at 1375. With regard to dominantly interfering molecules, the Court noted that the specification provided no examples of molecules in this class, and accordingly held that the description of these molecules "'just represents a wish, or arguably a plan' for future research." *Id.* at 1375. Finally, with regard to decoy molecules, the Court noted that unlike the other two classes of molecules, the specification did propose example structures for this class of molecules. Furthermore, because the specification disclosed specific example sequences, the Court found the molecules to be adequately described. However, questioning whether the specification adequately described using these molecules to reduce NF-κB activity, the Court found the disclosure to be "not so much an 'example' as it is a mere mention of a desired outcome." *Id*. at 1376.

Ultimately, the Court found that Ariad had chosen to assert claims that were "broad far beyond the scope of the disclosure provided in the specification of the '516 patent." *Id.* at 1377. Accordingly, the Court held the asserted claims to be invalid for lack of a written description. *Id.* at 1380.

In a concurring opinion, Judge Linn emphasized that the decision, though supported by precedent, is based upon the misguided approach of engrafting a separate written description requirement onto section 112, paragraph 1. *Id*. Judge Linn then stated that as he had observed in *University of Rochester*, section 112, paragraph 1 requires no more of the specification than a disclosure that is sufficient to enable a person having ordinary skill in the art to make and use the invention. *Id*. Highlighting the distinction between claims and the specification, Judge Linn

stated that both this court and the Supreme Court have recognized that the claims – and not the specification – define the invention. *Id.* at 1381. Stated differently, it is the claims, and not the specification, that provide the measure of the patentee's right to exclude. *Id.* Judge Linn further stated that the court's invention of a separate written description requirement has created confusion as to where the public and courts should look to determine the scope of the patentee's right to exclude. *Id*. Finally, Judge Linn noted that the written description causes "separate mischief" in that by relying on the written description to reverse the district court's ruling, the Federal Circuit never reaches the enablement issues raised by Lilly. *Id.* Judge Linn then explained that in order to survive the enablement requirement, the specification must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation. *Id*. That is, claims written broadly enough to cover any method of achieving a particular result may, as Lilly argued, never be valid, since the specification cannot enable unknown methods. *Id.* This, Judge Linn stated, is an important issue that has been left unresolved, and one which the court would have been compelled to reach had the case been decided on enablement grounds instead of written description grounds. *Id.*

VI. Ariad's Petition For Rehearing *En Banc* and Lilly's Opposition

On June 2, 2009, Ariad filed a Petition for Rehearing En Banc. On July 2, 2009, Lilly filed a response in opposition to Ariad's petition. Below is a brief discussion of the arguments set forth by Ariad and Lilly in their papers filed with the Court.

Ariad's Petition

In its petition for rehearing en banc, Ariad identifies two questions of exceptional importance:

> (1) Whether this Court has erred by "engrafting … a separate written description requirement onto section 112, paragraph 1…" Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009) (Linn, J. concurring).
>
> (2) What is the proper test to satisfy the requirement in Section 112, paragraph 1, that a patent specification 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"?

Ariad argues that six of the twelve Federal Circuit judges have voted to grant en banc review of the Court's written description jurisprudence (Newman, Rader, Bryson, Gajarsa, and Linn, JJ.), or have expressly noted that future en banc review may be appropriate because this Court's written description standards are unsatisfactory. (Dyk, J.). The United States has also called for en banc review to construe the statutory text and to clarify multiple conflicting views present in this Court's written description cases. Ariad then argued that the controversy will not

abate until the matter is definitely addressed by this Court en banc, or by the Supreme Court. Ariad chiefly argues that:

1. This Court's written description analysis is not consistent with the plain text of the statute.

2. This Court's written description analysis conflicts with precedent, has split this Court, and creates confusion and uncertainty.

3. The government has called for en banc review to resolve the confusion and uncertainty.

4. The Lilly doctrine harms the patent system and severely affects research universities.

5. This case provides an excellent vehicle for resolving the written description debate.

Lilly's Response

In its response, Lilly argues that Ariad's petition does not raise any issue that warrants en banc review of ***this*** case and should be denied. Lilly contends that there is a written description requirement, separate for enablement, that has been recognized for more than a hundred years, and that this precedent has been recognized by a majority of judges on the Court. This precedent, Lilly states, is correct because it protects the public from overreaching inventors who attempt to claim as their own subject matter they simply have not invented. Lilly believes this to be the case because although Ariad did not describe any molecules capable of inhibiting NF-κB in a cell, Ariad's '516 patent claims all methods of doing so, thereby preempting the field and stifling real innovation. Lilly chiefly argues:

A. The panel correctly applied this Court's precedent.

B. This case is not the "vehicle" to address any alleged "debate" as to the written description requirement.

C. Ariad overstates the nature of the alleged "debate."

D. The question of whether there is a separate written description requirement does not warrant en banc review.

    1. More than a hundred years of precedent support a separate written description requirement.

    2. There is no "confusion" concerning the application of this Court's written description precedent.

    3. The written description requirement promotes the policies underlying the patent system.

4. The Government does not support Ariad's petition.

VII. Arguments Supporting Proposed Resolutions

Below is a brief explanation of the arguments for and against the two proposed resolutions.

Arguments in Support of Proposed Resolution WD-1 ("Pro-Ariad")

A Resolution supporting Ariad's position on rehearing is in the best interests of the Committee, Council and ABA IP Section (collectively "ABA") for several reasons.

First, the ABA and its members routinely represent patent owners and patent applicants, and therefore have a strong interest in seeing that the case law emanating from the Federal Circuit and lower district courts is consistent, and avoids developing and maintaining *additional* patentability hurdles *beyond those clearly present within the patent statutes*. Here, a plain reading of § 112, ¶ 1, shows that the written description requirement is met so long as the specification of the patent describes the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. §112, ¶ 1. Regrettably, *Lilly* and its progeny have created a heightened written description requirement, beyond that required by the clear language of §112, ¶ 1, and as intended by Congress. This more exacting standard has severely and unduly limited the scope of claim coverage, and rendered unpatentable any claim that goes beyond the specific embodiments described in the specification. Moreover, as Judge Linn stated in his dissent in *Rochester*, while the "new-found" written description requirement in *Lilly* and *Enzo II* is, at the moment, disproportionately falling on the biotechnology industry, it will eventually affect all fields of emerging technology.

Second, it is in the interest of the ABA and its Members that the Federal Circuit develop a strict interpretation of § 112, ¶ 1, and one that is well-grounded in the text, structure, and history of the statute. This will ensure a similar approach to other patent statutes in the future. Moreover, the alternative possibility of allowing the "expanded" written description requirement to remain not only puts currently-issued patents at risk of being invalidated on written description grounds, but leaves open-ended the question of when and how the written description requirement is met for more complex inventions such as those in the biotechnology arena.

Finally, it is important to note that proposed Resolution WD-1 does not advocate removal of the written description requirement. Indeed, where *priority* of an invention is at issue, the written description requirement is properly utilized by determining whether the inventor had possession of the claimed invention at the time of the originally-filed patent application. However, where priority is not an issue, the written description requirement should only mandate that the inventor describe the claimed invention in such a way as to enable one of skill in the art to make and use it. This, after all, was the original purpose of the written description requirement. Therefore, WD-1 supports bringing the written description requirement back to its original intended purpose and scope.

Arguments in Support of Proposed Resolution WD-2 ("Pro-Lilly")

The Section should vote to support the continued application of the written description or "possession" requirement under Section 112 ¶1 because the written description requirement is well-established in Supreme Court and CAFC precedent; is consistent with a unitary patent system; prevents prosecution abuse by preventing patentees from claiming that which they did not invent; and promotes innovation by preventing the issuance and/or enforcement of overbroad patents that might discourage future research.

A. The statutory language describing the content of the specification has existed in essentially unchanged form since 1793.

A recurrent criticism of the written description standard is that it is a nonstatutory test. However, the Supreme Court has previously recognized a nearly identical test under prior versions of that statute. Since the statutory language has not changed, these decisions must control the interpretation of Section 112 ¶1.

The current version of the statutory specification requirement, states in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. §112 ¶1

This language has been essentially unchanged since 1793. *See, e.g.*, Patent Act of 1793, ch 11, 1 Stat. 318-323, §3 ("…every inventor…shall deliver a written description of his invention, and the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.") Patent Act of 1836, Ch. 357, 5 Stat. 117, §6 (1836) ("[the inventor]…shall deliver a written description of his invention or discovery, and the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, compound, and use the same."); Patent Act of 1870, Ch. 230, 16 Stat. 198-217, §26 (1870) ("[the inventor]..shall file… a written description of [his invention or discovery], and of the manner of and process of making, constructing, compounding, and using it, , in such full, clear, and exact terms, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same…") Accordingly decisions interpreting prior versions of the statute governing patent specification are equally applicable to current version of Section 112. *See Eldred v. Ashcroft*, 537 U.S. 186, 200 (noting that a page of history is worth a volume of logic"): *See also Graham v. John Deere Co.*, 383 U.S. 1, 16 (1966)(reviewing legislative history of 1952 Patent Act and concluding that creation of Section 103 was intended to codify "judicial precedents embracing the *Hotchkiss* condition")

Similarly, there is no evidence in the legislative history to Section 112 indicating an intention to depart from prior Supreme Court precedent.

B. The Supreme Court has repeatedly interpreted the patent specification requirement to bar broad generic claims without a corresponding written description.

Since at least as early as 1853, the Supreme Court has held that the specification requirement forbids claiming a broad genus based upon a limited number of species in the written description, especially where it appears that other members of the genus may have different characteristics than the examples disclosed in the patent specification. In *O'Reilly v. Morse*, 56 U.S. 62 (1853), the Supreme Court invalidated a broad claim to all uses of electromagnetism for telegraphic communications, holding that this claim was outside of the specification and was therefore invalid for failure to fully describe the invention:

> This court has decided, that the specification required by this law is a part of the patent, and that the patent issues for the invention described in the specification.
>
> Now whether the Telegraph is regarded as an art or machine, the manner and process of making or using it must be set forth in exact terms. The act of Congress makes no difference in this respect between an art and a machine. An improvement in the art of making bar iron or spinning cotton must be so described; and so must the art of printing by the motive power of steam. And in all of these cases it has always been held, that the patent embraces nothing more than the improvement described and claimed as new, and that any one who afterwards discovered a method of accomplishing the same object, substantially and essentially differing from the one described, had a right to use it. Can there be any good reason why the art of printing at a distance, by means of the motive power of the electric or galvanic current, should stand on different principles? Is there any reason why the inventor's patent should cover broader ground? It would be difficult to discover any thing in the act of Congress which would justify this distinction. The specification of this patentee describes his invention or discovery, and the manner and process of constructing and using it; and his patent, like inventions in the other arts above mentioned, covers nothing more.
>
> The provisions of the acts of Congress in relation to patents may 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 any one 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. And if this cannot be done by the means he describes, the patent is void. And if it can be done, then the patent confers on him the exclusive right to use the means he specifies to produce the result or

> effect he describes, and nothing more. And it makes no difference, in this respect, whether the effect is produced by chemical agency or combination; or by the application of discoveries or principles in natural philosophy known or unknown before his invention; or by machinery acting altogether upon mechanical principles. In either case he must describe the manner and process as above mentioned, and the end it accomplishes. And any one may lawfully accomplish the same end without infringing the patent, if he uses means substantially different from those described.
>
> Indeed, if the eighth claim of the patentee can be maintained, there was no necessity for any specification, further than to say that he had discovered that, by using the motive power of electro-magnetism, he could print intelligible characters at any distance. We presume it will be admitted on all hands, that no patent could have issued on such a specification. Yet this 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 above-mentioned 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.

56 U.S. at 118-120.

The *Morse* Court was also acutely concerned with the effect of upholding the validity of the generic claim and how this would discourage future invention:

> If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated -- less liable to get out of order -- less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.
>
> Nor is this all, while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. For he says he does not confine his claim to the machinery or parts of machinery, which he specifies; but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance. New discoveries in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. In fine he claims 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 opinion that the claim is too broad, and not warranted by law.

Id. at 113.

In 1895, the Supreme Court returned to written description requirement in *The Incandescent Lamp Patent*, 159 U.S. 465 (1895) a case where Thomas Edison was the accused infringer. The claim related to an incandescent lamp, where the carbon incandescent conductor "was made from a vegetable fibrous material." The patentee's lamp used carbonized paper as the conductor, whereas Edison used a specific type of bamboo. The Court noted the exhaustive experiments undertaken by Edison to determine the best conductor and how he and his agents had scoured the globe for suitable materials available in sufficient quantities, ultimately deciding on a specific type of bamboo from Japan. The Court noted that the patentees had not identified any specific property common to their claimed genus, while noting that Edison had discovered the principle of operation that determined which materials performed best as a filament.

> Is the complainant entitled to a monopoly of all fibrous and textile materials for incandescent conductors? If the patentees had discovered in fibrous and textile sub-stances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad. If, for instance, minerals or porcelains had always been used for a particular purpose, and a person should take out a patent for a similar article of wood, and woods generally were adapted to that purpose, the claim might not be too broad, though defendant used wood of a different kind from that of the patentee. But if woods generally were not adapted to the purpose, and yet the patentee had discovered a wood possessing certain qualities, which gave it a peculiar fitness for such purpose, it would not constitute an infringement for another to discover and use a different kind of wood, which was found to contain similar or superior qualities. The present case is an apt illustration of this principle. Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. Instead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over six thousand vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose. Was everybody then precluded by this broad claim from making further investigation? We think not.
>
> The injustice of so holding is manifest in view of the experiments made, and continued for several months, by Mr. Edison and his assistants, among the different species of vegetable growth, for the purpose of ascertaining the one best adapted to an incandescent conductor. Of these he found suitable for his purpose only about three species of bamboo, one species of cane from the Valley of the Amazon, impossible to be pro-cured in quantities on account of the climate, and

one or two species of fibres from the agave family. Of the special bamboo, the walls of which have a thickness of about three-eighths of an inch, he used only about twenty-thousandths of an inch in thickness. In this portion of the bamboo the fibres are more nearly parallel, the cell walls are apparently smallest, and the pithy matter between the fibres is at its minimum. It seems that carbon filaments cannot be made of wood -- that is, exogenous vegetable growth -- because the fibres are not parallel and the longitudinal fibres are intercepted by radial fibres. The cells composing the fibres are all so large that the resulting carbon is very porous and friable. Lamps made of this material proved of no commercial value. After trying as many as thirty or forty different woods of exogenous growth, he gave them up as hope-less. But finally, while experimenting with a bamboo strip which formed the edge of a palmleaf fan, cut into filaments, he obtained surprising results. After microscopic examination of the material, he despatched a man to Japan to make arrangements for securing the bamboo in quantities. It seems that the characteristic of the bam-boo which makes it particularly suitable is, that the fibres run more nearly parallel than in other species of wood. Owing to this, it can be cut up into filaments having parallel fibres, running throughout their length, and producing a homogeneous carbon. There is no generic quality, however, in vegetable fibres, because they are fibrous, which adapts them to the purpose. Indeed, the fibres are rather a disadvantage. If the bamboo grew solid without fibres, but had its peculiar cellular formation, it would be a perfect material, and incandescent lamps would last at least six times as long as at present. All vegetable fibrous growths do not have a suitable cellular structure. In some the cells are so large that they are value-less for that purpose. No exogenous, and very few endogenous, growths are suitable. The messenger whom he despatched to different parts of Japan and China sent him about forty different kinds of bamboo, in such quantities as to enable him to make a number of lamps, and from a test of these different species he ascertained which was best for the purpose. From this it appears very clearly that there is no such quality common to fibrous and textile substances generally as makes them suitable for an incandescent conductor, and that the bamboo which was finally pitched upon, and is now generally used, was not selected because it was of vegetable growth, but because it contained certain peculiarities in its fibrous structure which distinguished it from every other fibrous sub-stance. The question really is whether the imperfectly successful experiments of Sawyer and Man, with carbonized paper and wood carbon, conceding all that is claimed for them, authorize them to put under tribute the results of the brilliant discoveries made by others.

It is required by Rev. Stat. § 4888 that the application shall contain a written description of the device "and of the manner and process of making, constructing, compounding, and using it in such full, clear, concise, and exact terms as to enable any person, skilled in the art or science to which it appertains or with which it is most nearly connected, to make, construct, compound, and use the same." The object of this is to apprise the public of what the patentee claims as his own, the courts of what they are called upon to construe, and competing manufacturers and dealers of exactly what they are bound to avoid. If the

> description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void.
>
> Applying this principle to the patent under consideration, how would it be possible for a person to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by the most careful and painstaking experimentation? If, as before observed, there were some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose, the man who discovered such quality might justly be entitled to a patent; but that is not the case here. An examination of materials of this class carried on for months revealed nothing that seemed to be adapted to the purpose; and even the carbonized paper and wood carbons specified in the patent, experiments with which first suggested their incorporation therein, were found to be so inferior to the bamboo, afterwards discovered by Edison, that the complainant was forced to abandon its patent in that particular, and take up with the material discovered by its rival. Under these circumstances, to hold that one, who had discovered that a certain fibrous or textile material answered the required purpose, should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention. If Sawyer and Man had discovered that a certain carbonized paper would answer the purpose, their claim to all carbonized paper would, perhaps, not be extravagant; but the fact that paper happens to belong to the fibrous kingdom did not invest them with sovereignty over this entire kingdom, and thereby practically limit other experimenters to the domain of minerals.

159 U.S. at 472-76.

The Incandescent Bulb Patent contains two key points. First, a person claiming a genus must be able to identify some common characteristic running through the genus. If the inventor cannot, or subsequent research shows some members of the genus are inoperative for the function described in the patent, the claim is invalid. Second, allowing overbroad claims "extend[s] the patent monopoly beyond the discovery and discourage[s] rather than promote invention." *See Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928);

The *Incandescent Bulb Patent's* holdings were further fleshed out by *Corono Cord Tire Co v. Devon Chemical Corp.*, 276 U.S. 358 (1928). In *Corona Cord Tire*, the patent in suit related to a process for vulcanizing rubber using accelerators from a group of substances known as disubstituted guanidines. The evidence showed that approximately 150 substances met this description. However, some of these members of this genus did not act as accelerators when used in the process. The Court held that since the inventor did not demonstrate the existence of any common characteristic in this genus, this claim was void, citing *The Incandescent Lamp Patent*.

In *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), the Supreme Court invalided a patent claim overbroad patent claim to a genus of starch-based glues. The record showed that the patentee was the first to successfully make a starch glue suitable for wood veneering and similar uses. Prior to Perkins's invention, glue made from animals was the only known glue sufficient for these purposes. The patent described a process of making the glue from a specific type of starch. The accused infringer had discovered a different type of starch that did not require the process disclosed by Perkins to function and therefore was not covered by Perkin's specific claims. The Supreme Court held Perkins's broader claim to starch-based glues having properties "similar to animal glues" was invalid both as functional claim and because it was overbroad since not all starches could be used to create glue.

The Supreme Court's last substantive analysis of the written description requirement occurred in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946) While this case is best known for inspiring the amendment of the Patent Act to support means-plus-function claiming, its holding regarding the relationship between the written description and the claims go much further. In *Halliburton*, the Supreme Court held that the patent was invalid because the patentee had failed to make the "full, clear, concise and exact" description of the claimed invention as required by Section 112's predecessor. Further, under *Halliburton*, any claim that literally reads on non-equivalents of the invention disclosed in the specification is invalid under the written description requirement:

> This patent and the infringement proceedings brought under it illustrate the hazards of carving out an exception to the sweeping demand Congress made in Rev. Stat. 4888. [the specification statute.]
>
> ***
>
> Under these circumstances the broadness, ambiguity, and overhanging threat of the functional claim of Walker become apparent. What he claimed in the court below and what he claims here is that his patent bars anyone from using in an oil well any device heretofore or hereafter invented which combined with the Lehr and Wyatt machine performs the function of clearly and distinctly catching and recording echoes from tubing joints with regularity. Just how many different devices there are of various kinds and characters which would serve to emphasize these echoes, we do not know. The Halliburton device, alleged to infringe, employs an electric filter for this purpose. In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose. Yet if Walker's blanket claims be valid, no device to clarify echo waves, now known or hereafter invented, whether the device be an actual equivalent of Walker's ingredient or not, could be used in a combination such as this, during the life of Walker's patent.

> Had Walker accurately described the machine he claims to have invented, he would have had no such broad rights to bar the use of all devices now or hereafter known which could accent waves. For had he accurately described the resonator together with the Lehr and Wyatt apparatus, and sued for infringement, charging the use of something else used in combination to accent the waves, the alleged infringer could have prevailed if the substituted device (1) performed a substantially different function; (2) was not known at the date of Walker's patent as a proper substitute for the resonator; or (3) had been actually invented after the date of the patent..Certainly, if we are to be consistent with Rev. Stat. 4888, a patentee cannot obtain greater coverage by failing to describe his invention than by describing it as the statute commands.

Id. at 11-13.

Morse, The Incandescent Lamp Patent, and *Halliburton* demonstrate the Supreme Court's concern that allowing broad claiming of inventions unsupported by the written description, would suppress inventions not even contemplated by the patentee and that such claims should be invalidated for noncompliance with the specification requirement. These decisions clearly indicate that the CAFC's written description standard is consistent with Supreme Court precedent.

C. The CAFC's written description precedent is consistent with the pre-1952 Supreme Court cases.

In written description cases, part of the claim scope—at least one species—is typically enabled. However, the generic claim's scope includes species that are not enabled. Further, these undescribed species may have different characteristics, properties or functions than the described species. As a result, some written description cases are sometimes characterized as enablement decisions where the patentee "failed to enable to full breadth of his claims."

These CAFC decisions are comparable to *Morse* and the *Incandescent Lamp Patent* in that they focus on the large number of alternatives that fall within the scope of the claim but are not remotely similar to the described embodiments:

One example of this is *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) which characterizes itself as an enablement decision, but now would be considered a written description case:

> It is well established that a patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the requirements of Section 112. Here, however, despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate

> support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.
>
> In affirming the district court's invalidation of claims 7, 8, 23-27, and 29 under Section 112, we do not intend to imply that generic claims to genetic sequences cannot be valid where they are of a scope appropriate to the invention disclosed by an applicant. That is not the case here, where Amgen has claimed every possible analog of a gene containing about 4,000 nucleotides, with a disclosure only of how to make EPO and a very few analogs.

927 F.2d at 1213-14.

A more recent example is *Carnegie Mellon University v. Three Rivers Biologicals, Inc*, 541 F.3d 1115 (Fed. Cir. 2008), where the patents claimed a *E Colo polA* gene "isolated from a bacterial source." The description described a single method of generating the gene (from *e Coli*) but claimed the use of an unknown number (thought to be in the thousands or millions) of bacterial species. The Federal Circuit held that the disclosure of a single species was insufficient to claim the entire genus. Id. at 1126.

As *The Incandescent Lamp Patent* held, generic claims are not per se impermissible. However, the patentee must demonstrate that all applications covered by the claim include a common characteristic. The Federal Circuit has made clear that if there is a common characteristic known to those of skill in the art, generic claims will be allowed. *See Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005)(The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence… Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science"); See *Bilstead v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004) ("If the differences between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members, i.e. if the art is unpredictable, then disclosure of more species may be required to adequately show possession of the entire genus.")

D. The written description test is technology-neutral and consistent with the Section's policy of a unitary patent system.

A repeated criticism of the written description test is that that discriminates against biotechnology and pharmaceutical patents and constitutes an additional test for patents in these arts. This criticism is contrary to the facts. As shown by the Supreme Court and Federal Circuit cases previously discussed, the written description requirement is most commonly is at issue in cases involving emerging technologies, where early movers seek to obtain overbroad patent protection. Such broad claims typically do not survive examination in more mature arts. However, when they do, the written description requirement is applied.

The Federal Circuit has applied the written description to non-biotech inventions on multiple occasions. For example, in *Lizardtech, Inc. v. Earth Resource Mapping, Inc*, 424 F.3d 1336 (Fed. Cir. 2005), the CAFC has applied the written description standard to invalid claims to discreet wavelet transforms for integrating the edges of large digital images stored in pieces, such as maps.

In addition, the CAFC has also applied the written description test to invalidate patent claims in more mature arts that were not supported in the original application for lack of priority. *See Deval Turbocare Division of Demag Delaval Turbomachinery Corp.* v. *General Electric Co*., 264 F.3d 1111 (Fed. Cir. 2001)(invalidating a claim under Section 112 ¶1 for failure to describe spring and location of spring used in turbine seal in original disclosure); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (using under Section 112 ¶1 to strike priority claim to joint replacement cup prosthesis where the continuation patent claimed cup having different shapes than disclosed by original specification); *Lockwood v. American Airlines, Inc*., 107 F.3d 1565 (Fed. Cir. 1997)(invalidating patent that purportedly read on SABRE reservation system for claiming structure not described by priority application)

E. The written description requirement prevents patent prosecution abuse.

One purpose of the written description requirement of 35 U.S.C. §112 ¶1 is to prevent applicants from adding new matter to a patent application after the application has been filed. In particular, this provision prevents an applicant from adding new claims to inventions that he did not invent, such as products that the applicant sees in the marketplace. *See Amgen Inc. v. Hoechst Marion Roussel Inc*., 314 F.3d 1313, 1330 (Fed. Cir. 2003)("The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is there-fore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'")

This written description requirement is applicable to any claims added after the original filing date, including claims in continuation applications. If the originally-filed specification does not reasonably convey to one of skill in art that the inventor possessed the later-claimed subject matter at the time the original application was filed, the newly added claims are not entitled to the filing date of the original application and can be invalidated by intervening prior art. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) Further, it is insufficient for the later claimed invention to be obvious in light of the original disclosure, rather the original disclosure must describe the claimed invention with all its limitations. *Lockwood v. American Airlines, Inc*., 104 F.3d 1565, 1572 (emphasis added)

F. Preservation of the written description requirement is consistent with the expectation of the patent community and will not affect research

The argument that the continued existence of the written description rule will serve as a disincentive to innovate is unsupported attorney argument. Further, the same argument was made by the University of Rochester and rejected by the CAFC. Patentees argue with great frequency that any unfavorable decision on infringement liability or patent validity somehow diminishes the incentive to innovate.

However, as first noted more than 150 years ago in *Morse* and then again more than a century ago in *The Incandescent Lamp Patent*, overbroad patent protection is an evil that actually may discourage rather than promote innovation. Further, it is important to note that the patent in suit indicates that the underlying research was funded in part by government grants. The Government is unlikely to withdraw its funding for research because of potential difficulties in patentability.

IMPORTANT NOTICE

This document does not represent the opinions of the ABA IP Council, or the ABA IP Section Committee 112 (Patent Litigation) Members. As stated, the purpose of this report was to provide background information regarding the written description requirement.