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

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

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On March 22, 2010, the Federal Circuit issued its *en banc* decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 2010 WL 1007369, at *1 (Fed. Cir. Mar. 22, 2010), which concerned the written description requirement for patentability. In a 9-2 decision, the court held that the written description requirement under 35 U.S.C. § 112, first paragraph, is a separate and distinct requirement from that of enablement. The court also emphasized that the written description requirement does not only apply in the context of priority determinations (*i.e.*, whether a patent applicant may rely on its original filing date with the United States Patent and Trademark Office ("PTO") based on disclosures in the patent specification when the applicant later amends or broadens its claims). In other words, written description may be used to invalidate patent claims, even as originally filed. In addition to the majority decision, two separate dissenting opinions were provided by Judges Rader and Linn.

Questions arise over whether the U.S. Supreme Court will have the final word on this subject. Under Supreme Court rules, Ariad has 90 days from the date of the Federal Circuit's decision to file a petition for writ of certiorari. This due date would be June 21, 2010. Since Lilly will then have the opportunity to file opposition papers, Ariad's petition will likely not be decided until the end of the Summer, leaning towards the Supreme Court's new October 1, 2010 term.

Should the Supreme Court grant Ariad's petition, the ABA will want to be in a position to consider filing an amicus brief in this matter. Accordingly, the purpose of this report is to provide background information helpful to the Council and 112 Committee when considering, and voting on, a proposed resolution that will encapsulate the ABA's position within an amicus brief should one be filed. To this end, the report is divided into the following sections: (1) the current proposed resolution 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 Panel decision ("Ariad I"), (now vacated); and (6) a discussion of the Federal Circuit's March 22, 2010 *en banc* decision ("Ariad II"), as well as the two dissenting opinions by Judges Rader and Linn.

I. Proposed Resolution For Consideration by Council and 112 Committee Members

RESOLVED, that the Section of Intellectual Property Law supports, in principle, that Section 112, paragraph 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, paragraph 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 also mandates specific written disclosure in the specification in the parent application to support that which is later claimed as 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.*, should it be heard by the United States Supreme Court.

This resolution considers the following issues previously raised by 112 Cmte Members:

A. The limited role of the written description requirement will appeal to those in favor of the proposed resolution that there is no separate written description requirement. The proposed WD resolution does not require possession. The proposed WD does not require verbatim claim language in the specification (as amendments are sometimes reflected in drawings).

B. The proposed WD resolution can be reconciled with Supreme Court cases (*Morse*; *Incandescent bulb case*; and *Halliburton*) that interpret the patent specification requirement to bar broad generic claims without a corresponding written description. By requiring the applicant to identify the broader aspect or knowledge in the art that he/she relies on for a claim scope beyond the detailed disclosures of the specifications and specifically describing that support, the written description requirement will continue to bar broad generic claims by limiting it to the "support" in the specification.

C. The proposed WD resolution follows the argument that written description does not play a substantive role in restraining the breadth of the claims and that the enablement requirement is well-equipped to ensure that the specification is commensurate in scope with the full scope of the claims. Rigorous application of the enablement requirement and a separate written description requirement address the following concerns from members: how does the written description deal with situations in which the claims are broader than what is disclosed in the spec and how the scope of the claims would be determined (*i.e.,* whether it is limited to particular embodiments)?

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. As most will recall, previous attempts at passing a resolution for the purposes of submitting an amicus brief in the Federal Circuit *en banc* proceeding failed. Immediately below is the resolution voted on/discussed by 112 Committee Members on September 21, 2009.

Last Resolution voted on/discussed by 112 Committee Members on 9/21/09

RESOLVED, that the Section of Intellectual Property Law supports, in principle, that Section 112, paragraph 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, paragraph 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 also mandates specific written disclosure in the specification to provide notice of the broadest reasonable interpretation of the stated claim, 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.

In addition, 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 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).

[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.

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 came 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.

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

[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").

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 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

[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).

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

[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).

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 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 Panel decision ("Ariad I")

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. The Federal Circuit's *en banc* decision ("Ariad II")

In a 9-2 decision, the Court reaffirmed that § 112, first paragraph, contains a written description requirement separate from enablement, and again reverses the district court's denial of JMOL and holds the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement.

Majority opinion (Lourie, J. et al.)

In reaching this decision, the court began with the language of the statute itself, and agreed with Lilly's proposed interpretation which parsed the statute as follows:

(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 the invention."

Furthermore, similar to Lilly's argument, the court read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims.

The court then went on to state that in addition to the statutory language and Supreme Court precedent, *stare decisis* compels the Court to uphold the existence of a written description separate from enablement.

The court found Ariad's arguments regarding *In Re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), to be unpersuasive because, in practical terms, Ariad's approach also required a written description of the invention in the specification. Under either approach, if the claimed invention did not appear in the claims, the claim would fail regardless of whether one of skill in the art could make or use the claimed invention.

The court held that although the issue arises primarily in cases involving priority, nothing in the language of § 112 provides a basis for restricting the written description requirement to establishing priority.

With regard to genus claims defined by function, the court stated that a sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus. Ariad's claims recited methods encompassing a genus of materials achieving a stated useful result. However, the specification did not disclose a variety of species that accomplish the result. Therefore, the court found the generic language insufficient to satisfy the written description requirement.

The court then turned to the standard for, and application of, the written description requirement. Specifically, the court held that a more complete formulation of the term "possession" would be "possession as shown in the disclosure." The test (for "possession") would require an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to the skilled artisan and show that the inventor actually invented the invention claimed.

This inquiry is a question of fact, and the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and the complexity and predictability of the relevant technology. For generic claims, the factors for evaluating the adequacy of the disclosure include the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.

The court declined to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. However, a few broad principles hold true across all cases. The written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. Conversely, actual "possession" or reduction to practice outside of the specification is not enough. Rather, it is the specification itself that must demonstrate possession. And, while the description requirement does not demand any particular form of disclosure, or that the specification recite claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.

Recognizing that written description and enablement often rise and fall together, the court stated that requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.

Because the court reaffirmed its written description doctrine, it adopted the analysis of the panel's application of the written description requirement to the facts of this case.

Concurring opinion (Gajarsa, J.)

Judge Gajarsa, in a short concurring opinion, expressed his doubt that the decision (specifically, the endorsement of a freestanding written description requirement) would have any real impact on patent validity determinations. He noted that empirical evidence demonstrated

that "outside the priority context the written description doctrine seldom serves as a separate vehicle for invalidating claims." While Judge Gajarsa further stated that the statutory language – and resulting written description jurisprudence – were somewhat ambiguous, he considered Congress to be best suited to provide ultimate clarification on this subject

Dissenting opinions (Rader & Linn, JJ.)

In separate dissenting opinions, Judges Rader and Linn both expressed disappointment at the majority's decision, stating that a separate written description requirement has no support in the statutory language. They further explained that the current written description test enunciated by the court provided little clarification and would be confusing to apply practically. Indeed, Judge Linn noted that the factors offered by the majority opinion mirror the factors for enablement as prescribed in *In re Wands*. Finally, and perhaps inviting the Supreme Court to consider this case, Judge Linn took issue with the majority's statement that Supreme Court precedent supports its position.