No. 2008-1248

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

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

BRIEF FOR ABBOTT LABORATORIES AS AMICUS CURIAE IN SUPPORT OF DEFENDANT-APPELLANT

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November 19, 2009

CERTIFICATE OF INTEREST

Counsel for Amicus Curiae Abbott Laboratories certifies the following pursuant to Federal Circuit Rule 47.4:

1. The full name of every party or amicus represented in this appeal is:

   Abbott Laboratories

2. The names of the real parties in interest represented in this appeal are:

   As indicated in item 1.

3. The names of all parent corporations and any publicly held companies that own 10 percent or more of the party represented are:

   None.

4. The names of all law firms and attorneys that are expected to appear in this case for the amicus listed above are:

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Abbott did not participate in the proceedings below.

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Dated: November 19, 2009

TABLE OF CONTENTS

Page

CERTIFICATE OF INTEREST i

TABLE OF AUTHORITIES iv

INTEREST OF AMICUS CURIAE 1

SUMMARY OF THE ARGUMENT 1

ARGUMENT 5

I. THE COURT SHOULD REAFFIRM THAT SECTION 112, ¶ 1 CONTAINS A WRITTEN DESCRIPTION REQUIREMENT 5

A. Section 112, ¶ 1 Contains A Written Description Requirement Distinct From Enablement 5

B. Sound Policy Considerations Support A Separate Written Description Requirement 7

II. THE WRITTEN DESCRIPTION REQUIREMENT APPLIES TO ALL CLAIMS, BUT AT THE VERY LEAST SHOULD BE PRESERVED AS A CHECK AGAINST CLAIMING NEW MATTER 11

A. The Written Description Requirement Applies To All Claims, And Failure To Comply With It Invalidates A Claim 11

B. At a Minimum, The Written Description Requirement Prevents Patentholders From Claiming A Priority Date For Subject Matter Not Disclosed In The Specification 12

C. The Enablement Requirement And Section 132's Prohibition On Introducing New Matter By Amendment Are Not Adequate Substitutes For the Written Description Requirement 14

1. Enablement is not an adequate substitute for the written description requirement 14

2. Section 132 is not an adequate substitute for the written description requirement 18

III. THE COURT HAS ALREADY DEVELOPED A FLEXIBLE AND APPROPRIATE STANDARD FOR APPLYING THE WRITTEN DESCRIPTION REQUIREMENT 22

A. The Description Needed To Establish Possession Of An Invention Varies With The Nature And Scope Of The Invention And The Predictability Of The Art 22

B. The Court Should Clarify Its Prior Statements Regarding What Constitutes An Adequate Description Of Antibody Technology 25

IV. RECENT LITIGATION AGAINST ABBOTT DEMONSTRATES THE IMPORTANCE OF MAINTAINING A ROBUST WRITTEN DESCRIPTION REQUIREMENT 27

CONCLUSION 30

CERTIFICATE OF SERVICE

CERTIFICATE OF COMPLIANCE

TABLE OF AUTHORITIES

CASES

Page(s)

Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003) 5, 9, 24

Capon v. Eshhar, 418 F.3d 1349 (Fed. Cir. 2005) 5, 8, 23, 24, 25

Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004).....16, 17, 18

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) ..... *passim*

Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822) 6

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002).....5, 7

Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993) 16, 22

Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361 (Fed. Cir. 1997).....17

ICU Medical, Inc. v. Alaris Medical Systems, Inc., 558 F.3d 1368 (Fed. Cir. 2009) 29

In re Alonso, 545 F.3d 1015 (Fed. Cir. 2008).....8, 15

In re Curtis, 354 F.3d 1347 (Fed. Cir. 2004).....15

In re DiLeone, 436 F.2d 1404 (C.C.P.A. 1971).....15

In re Rasmussen, 650 F.2d 1212 (C.C.P.A. 1981).....18, 19, 20

In re Smith, 481 F.2d 910 (C.C.P.A. 1973) 5

In re Wands, 858 F.2d 731 (Fed. Cir. 1988).....16

In re Wilder, 736 F.2d 1516 (Fed. Cir. 1984).....5, 22

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).....7

Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985 (Fed. Cir. 1999) 21

KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007) 25

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974) 7

LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336 (Fed. Cir. 2005) 14

Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003) 12, 13

Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004).....3, 26, 27

Pennwalt Corp. v. Akzona Inc., 740 F.2d 1573 (Fed. Cir. 1984) 20

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).....23, 24

Rengo Co. v. Molins Machine Co., 657 F.2d 535 (3d Cir. 1981).....9

TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001).....18

University of Rochester v. G.D. Searle & Co., 375 F.3d 1303 (Fed. Cir. 2004) 13, 23

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991).....5, 9, 22, 23, 25

Yasuko Kawai v. Metlesics, 480 F.2d 880 (C.C.P.A. 1973) 21

STATUTES

U.S. Const. art. I, § 8, cl. 8.....7, 9

35 U.S.C.
§ 102 17
§ 112 ..... *passim*
§ 119 21
§ 120 21
§ 132 ..... *passim*
§ 251 .....19, 20
§ 282 12

OTHER AUTHORITIES

Drakulich, Corrin N., University of Rochester v. G.D. Searle & Co.*: In Search of a Written Description Standard*, 21 Berkeley Tech. L.J. 11 (2006).....10, 23

Kelley, James J., & Gregory A. Cox, *The "Anti"-Written Description Requirement? Antibodies, Example 16, The Guidelines, and* Noelle v. Lederman, 87 J. Pat. & Trademark Off. Soc'y 705 (2005).....27

Sampson, Margaret, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233 (2000).....10

University of California Office of Technology Transfer, *UC Technology Transfer Annual Report 2008*, *available at* http://www.ucop.edu/ott/genresources/documents/OTTRptFY08.pdf.....11

INTEREST OF AMICUS CURIAE

Abbott Laboratories is a global, broad-based health care company devoted to the discovery, development, manufacture, and marketing of pharmaceuticals and medical products. Its products span the continuum of care, from nutritional products and laboratory diagnostics to medical devices and pharmaceutical therapies. Abbott has experience both as a patent owner required to comply with the written description requirement and as a defendant who depends on the requirement to shield it from the enforcement of invalid patents.

Abbott has authority to file this brief under the Court's August 21, 2009 Order authorizing the filing of amicus briefs without prior leave of court.

SUMMARY OF THE ARGUMENT

This Court and its predecessor have repeatedly reaffirmed that Section 112, ¶ 1 contains a written description requirement distinct from enablement. The en banc Court should not disturb that longstanding interpretation. The language of Section 112, ¶ 1 requires a written description "of the invention" and, separately, "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 make and use the same." Attempts to collapse the two requirements gloss over critical language and do not find support in Section 112, ¶ 1's drafting history.

Recognition of a separate written description requirement is not only the proper reading of the statute, but also sound policy. The patent system grants inventors a limited monopoly in exchange for the disclosure of their inventions. The amount of disclosure necessary to enable a person of ordinary skill to make and use the invention may vary with the knowledge and level of skill in the art. In contrast, a separate written description requirement imposes on inventors the independent duty to describe the invention such that persons skilled in the art will know that the applicant actually invented the subject matter claimed. This separate requirement is just as fundamental a part of the quid pro quo between an inventor and the public as a description of how to make and use the invention. It serves as a critical check against overreaching by inventors who attempt to claim subject matter they did not possess at the time of filing. Without the requirement, applicants could prematurely claim subject matter they did not invent or lie in wait for others to discover it and then amend their claims. The result would be to stifle rather than encourage innovation.

The written description requirement's placement in Section 112 indicates that it is not limited to policing priority and that failure to comply with the requirement invalidates a claim. Even if there were questions about the requirement's application to original claims, however, the Court should not allow that debate to obscure the requirement's vital role in preventing subsequent

claiming of subject matter never disclosed in a priority application. Ariad's argument that Section 112, ¶ 1 contains no written description requirement whatsoever is not only wrong as a textual matter, but would have the effect of throwing the baby out with the bathwater—preventing use of the requirement even as a check against late claiming. At a minimum, therefore, the Court should reject Ariad's reading of the statute in order to preserve the written description requirement's role in policing priority.

The Court has already developed an appropriate standard for determining whether the written description requirement is met: The specification must demonstrate that, at the time of filing, the inventor had possession of the subject matter now claimed. Critics of this Court's written description jurisprudence tend to caricature its decisions as creating a rigid "heightened" standard for biotechnology inventions, but in reality the Court's biotech cases have taken a nuanced and flexible approach to determining whether an inventor had possession of the claimed subject matter. Rather than abandoning this body of precedent, the Court should focus on continuing to develop and refine the possession standard as it is applied in the context of particular cases. The Court should take this opportunity, however, to clarify the confusion caused by *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), which implied in dicta that a detailed description of an antigen entitles a patentee to claim all antibodies that bind to it. That statement

rests on an erroneous assumption about the ability to predict an antibody's structure from its function and should be clarified before it causes additional confusion.

Recent litigation against Abbott—like Ariad's suit against Eli Lilly—illustrates the importance of maintaining a robust written description requirement, particularly in cases involving emerging technology. In 1995, after years of research, Abbott engineered the first fully human antibody that binds with high affinity to and neutralizes a protein that contributes to rheumatoid arthritis and other autoimmune diseases. In a 2002 patent application, however, a competitor purported to claim an invention covering Abbott's human antibody and asserted that its claims were entitled to the filing date of a 1994 application disclosing "chimeric" antibodies, an earlier generation of antibody technology. The 1994 application did not describe fully human antibodies with the characteristics of Abbott's discovery, let alone describe their structure or any correlation between structure and function. Nonetheless, a jury found that Abbott infringed, rejected its invalidity defenses, and awarded the plaintiff $1.67 *billion* in damages—the largest patent verdict in U.S. history. That verdict, which is still subject to appeal, drives home the importance of maintaining a written description requirement that protects genuine innovators from patents that belatedly claim subject matter not adequately described in the specification.

ARGUMENT

I. THE COURT SHOULD REAFFIRM THAT SECTION 112, ¶ 1 CONTAINS A WRITTEN DESCRIPTION REQUIREMENT

A. Section 112, ¶ 1 Contains A Written Description Requirement Distinct From Enablement

Section 112, ¶ 1 states:

> 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 ….

(Emphasis added.)

The Court of Customs and Patent Appeals and panels of this Court have repeatedly held that this portion of Section 112, ¶ 1 contains two separate requirements: (1) a written description requirement, and (2) an enablement requirement. *See, e.g.*, *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984); *In re Smith*, 481 F.2d 910, 914 (C.C.P.A. 1973). The en banc Court should not disturb that longstanding interpretation. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.").

The statute uses a comma and the word "and" to distinguish between the requirement to provide a description "of the invention" and the requirement to provide a 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 make and use the same." Although Ariad and others make various textual arguments for collapsing the two requirements into a single enablement standard, their interpretations gloss over this clear dividing line between the written description and enablement requirements.

Far from supporting Ariad's argument, the fact that the phrase "written description of [the] invention" originally dates from a time before separate claims were required shows, if anything, the importance Congress ascribed to the written description requirement as a means of ensuring that the public would "know what it is that is intended to be secured." *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 381 (1822). Even with the advent of claiming, Congress chose to retain the relevant statutory language requiring a "written description of the invention." *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 971 (Fed. Cir. 2002) (Lourie, J., concurring in denial of reh'g en banc). There is no basis for this Court to, in effect, amend that provision to eliminate a requirement that Congress decided to keep.

For these reasons, and those given by Eli Lilly, *see* Eli Lilly Br. 5-31, the Court should reaffirm that the statute contains separate written description and enablement requirements.

B. Sound Policy Considerations Support A Separate Written Description Requirement

Sound policy considerations support the Court's existing interpretation of Section 112, ¶ 1 as containing a separate written description requirement.

The Constitution empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to *their* respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8 (emphasis added). The Patent Act achieves this important purpose by offering inventors a limited monopoly in exchange for the disclosure of their inventions. "The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)); *see also Festo*, 535 U.S. at 736 ("exclusive patent rights are given in exchange for disclosing the invention to the public"). It is only because "such additions to the general store of knowledge are of such importance to the public" that the government is "willing to pay the high price" of granting "exclusive use for [an invention's] disclosure." *Kewanee Oil*, 416 U.S. at 481.

The written description requirement is a critical part of the exchange between an inventor and the public. The idea behind the requirement is simple: An inventor who wants to exclude the public from making, using, or selling an invention must, among other things, provide the public with "a written description of the invention." *See Capon*, 418 F.3d at 1356-1357. Although the specification must also provide an enabling disclosure that teaches one of ordinary skill in the art how to make and use the invention, fulfillment of that additional requirement in no way diminishes the public's fundamental entitlement to a description of what has been invented. Providing that description is part of the price that an applicant must pay to obtain the substantial benefits conferred by a patent. *See In re Alonso*, 545 F.3d 1015, 1019 (Fed. Cir. 2008) (written description requirement "serves a teaching function" and is part of the "*quid pro quo* in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time" (internal quotation marks omitted)); *Capon*, 418 F.3d at 1357 ("The written description requirement … satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity.").

Separate and apart from the enablement requirement, the written description requirement protects against overreaching by inventors who attempt to claim subject matter they have not actually invented and disclosed. To meet the

requirement, an inventor must provide a sufficiently detailed description to "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." *Vas-Cath*, 935 F.2d at 1563-1564 (emphasis removed). The written description requirement thus reflects the Constitutional mandate that Congress grant inventors only an "exclusive Right to *their* … Discoveries." U.S. Const. art. I, § 8, cl. 8 (emphasis added).

The written description requirement's role in preventing overreaching is particularly important where an inventor adds or amends claims that claim priority to an earlier application. There is a temptation in that situation for the inventor to expand the scope of his invention beyond what his original application disclosed in order to sweep in subsequent developments in the art or particular competitors' products. "'Adequate description of the invention guards against the inventor's overreaching,'" however, "'by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Vas-Cath*, 935 F.2d at 1561 (quoting *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551 (3d Cir. 1981)). It thereby "prevent[s] an applicant from later asserting that he invented that which he did not." *Amgen*, 314 F.3d at 1330.

As discussed more fully below, limiting Section 112, ¶ 1 to an enablement requirement without a separate written description requirement would not accomplish these objectives. A sole enablement requirement would encourage a

patentee to point to the concurrent accomplishments of its competitors as support for the level of skill in the art, despite the fact the patentee only described (and invented) a single solution to the problem.

The written description requirement thus helps preserve the incentive for continued innovation. If an applicant could claim entitlement to an entire field based on the disclosure of little more than a roadmap for making future discoveries, others would have little reason to invest the time and money necessary to actually make those discoveries. *See* Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233, 1261 (2000). "Granting an inventor rights to something he does not possess can thus erect upstream obstacles that ultimately deprive society of the benefits of valuable downstream innovation." Corrin N. Drakulich, University of Rochester v. G.D. Searle & Co.: *In Search of a Written Description Standard*, 21 Berkeley Tech. L.J. 11, 31 (2006). The written description requirement combats this problem by limiting "patent rights to that which an inventor can prove he actually invented, but nothing more." *Id*. It also discourages "submarine" patents by making it more difficult for a someone to lie in wait while others make genuine discoveries, only to surface later and claim the newly invented subject matter based on an earlier application.

Complaints by Ariad and its amici that the written description requirement makes it difficult for universities to obtain patents, *see* Ariad Br. 38-39; UC Br. 16-19, are unsupported by history or logic. This Court and its predecessor have actively enforced the written description requirement for years, but Ariad and its amici have presented no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. Indeed, the statement of interest in the University of California's own brief shows that university patent portfolios are burgeoning. *See* UC Br. 1-3; *see also* University of Cal. Office of Tech. Transfer, *UC Technology Transfer Annual Report 2008*, at 6, ex. 5, *available at* http://www.ucop.edu/ott/genresources/documents/OTTRptFY08.pdf (University of California has been issued between 224 and 331 patents per year in the past five years). The real threat to innovation—whether by universities or others—would be the elimination of the written description requirement, thereby allowing early applicants to crowd out subsequent innovation by claiming more than they actually invented.

II. THE WRITTEN DESCRIPTION REQUIREMENT APPLIES TO ALL CLAIMS, BUT AT THE VERY LEAST SHOULD BE PRESERVED AS A CHECK AGAINST CLAIMING NEW MATTER

A. The Written Description Requirement Applies To All Claims, And Failure To Comply With It Invalidates A Claim

The written description requirement's placement in Section 112, ¶ 1 indicates that the requirement applies to all claims and affects a patent's validity,

not just its priority date. The patent defenses listed in 35 U.S.C. § 282 include the "[i]nvalidity of the patent or any claim in suit for failure to comply with any requirement of section[] 112." The meaning of this provision is straightforward: failure to comply with "any" requirement of Section 112, including the written description requirement, renders a claim invalid.

Nothing in the statute limits the written description requirement to questions of priority. While the requirement has been applied by this Court most often in that context, "[t]he statute does not say 'a written description of the invention for purposes of policing priority.'" *Enzo*, 323 F.3d at 972 (Lourie, J., concurring in denial of reh'g en banc); *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1327 (Fed. Cir. 2003) (Bryson, J., concurring).

B. At a Minimum, The Written Description Requirement Prevents Patentholders From Claiming A Priority Date For Subject Matter Not Disclosed In The Specification

Even were the Court to conclude that the written description requirement does not extend to original claims or directly affect a patent's validity, it should, at a minimum, preserve the requirement's role in policing priority.

It has long been recognized that "[e]very patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office." *Enzo*, 323 F.3d at 977 (Rader, J., dissenting from denial of reh'g en banc).

"Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention." *Id*. As noted above, the written description requirement performs this critical function. *See supra*, pp. 9-10; *see also Moba, B.V.*, 325 F.3d at 1319-1320.

Even the requirement's critics have acknowledged its importance in preventing inappropriate claiming of new matter. *See, e.g., University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1311 (Fed. Cir. 2004) (Rader, J., dissenting from denial of reh'g en banc) ("The Supreme Court is entirely correct to acknowledge the requirement of full 'disclosure' *at the time of invention* that prevents updating the patent document with later inventions. Beginning in 1967, this court and its predecessor applied the written description language to achieve this vital purpose of the Patent Act—tying disclosure to the time of invention."); UC Br. 24 ("proper scope of the written description requirement" is "to ensure that later-filed claims are entitled to the benefit of an earlier filing date or to ensure that later amendments do not run afoul of the prohibition against adding new matter to the original application").

The Court should not lose sight of Section 112, ¶ 1's critical role in preventing late claiming. Ariad's contention that Section 112, ¶ 1 contains no written description requirement whatsoever would, if accepted, also call into

question the requirement's use in situations where amended or new claims inappropriately include subject matter not supported by the original specification. To preserve that uncontroversial and important use of the written description requirement, the Court must reject Ariad's reading of the statute.

C. The Enablement Requirement And Section 132's Prohibition On Introducing New Matter By Amendment Are Not Adequate Substitutes For the Written Description Requirement

Ariad and others argue that alternative provisions, such as the enablement requirement and 35 U.S.C. § 132's prohibition on "new matter," would adequately protect against overreaching by patentholders in the absence of the written description requirement. *See, e.g.*, Ariad Br. 24 n.6, 28, 29 n.7; Janis & Holbrook Br. 11-13. Although these provisions undoubtedly serve important functions and overlap to some extent with the written description requirement, they are not adequate substitutes for it.

1. Enablement is not an adequate substitute for the written description requirement

Typically a specification that lacks a sufficient written description of an invention will also fail to enable a person of ordinary skill in the art to make and use that invention. For this reason the enablement and written description requirements "usually rise and fall together." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). However, "it is possible for a specification to enable the practice of an invention as broadly as it is claimed,

and still not describe that invention." *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A. 1971). For example, "consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." *Id*. at 1405 n.1.

It is not correct, as Ariad claims, that the Court "is still searching for, but has yet to find, a real case" in which a patent enables an invention but does not contain an adequate written description of it. *See* Ariad Br. 29 n.7. For example, in *In re Alonso*, 545 F.3d 1015, 1018, 1021 n.6 (Fed. Cir. 2008), the Board of Patent Appeals and Interferences held that the patent at issue met the enablement requirement but not the written description requirement. This Court affirmed, noting that there was no inconsistency between the two holdings because an "invention may be enabled even though it has not been described." *Id*. at 1021 n.6 (internal quotation marks omitted). Likewise, in *In re Curtis*, 354 F.3d 1347, 1350, 1358 (Fed. Cir. 2004), the Court affirmed a Board decision holding that an invention was enabled but not described adequately to receive the benefit of the earlier priority date it needed to avoid invalidation on obviousness grounds. Both of these cases illustrate situations in which the specification enabled an invention but failed to describe it.

Indeed, the enablement requirement alone is insufficient to guard against overly broad claims or claims attempting to cover that which the inventor did not invent. Under this Court's precedent, the amount of disclosure that is necessary to satisfy the enablement requirement varies according to the nature of the invention, the knowledge of persons skilled in the art, and the level of skill in the art. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Accordingly, without a separate written description requirement, an applicant merely describing a research plan might be able to argue that the plan, in combination with the knowledge of one of ordinary skill in the art, enables an invention that is yet to be made. In this situation, an inventor could "preempt the future before it has arrived" by combining broad claims with a disclosure that presents merely a "wish" or "plan" for obtaining the invention. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). In contrast, by focusing on what is described in the application, the written description requirement limits reliance on external factors and thus ensures that it is the work of the inventor, not others in the field, that receives patent protection.

The existence of a written description requirement separate from enablement is particularly important in the wake of *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004). In *Chiron*, a 1984 application disclosed a mouse antibody but did not disclose any "chimeric" antibodies combining the "variable region from a mouse [antibody] and the constant region from a human [antibody]." *Id.* at 1250-

1251. The question before the Court was whether that 1984 application provided adequate support for a 1995 continuation-in-part application claiming chimeric antibodies that bind to the same human breast cancer antigen as the mouse antibody disclosed in 1984. This Court held that the attempt to claim chimeric antibodies did not raise an enablement question "[b]ecause the first publication documenting the successful creation of chimeric antibodies occurred after the filing of the 1984 application." *Id*. at 1254. The Court noted that "nascent technology … must be enabled with a 'specific and useful teaching,'" *id*. (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1368 (Fed. Cir. 1997)), but that "[t]he law does not expect an applicant to disclose knowledge invented or developed after the filing date," *id*. The Court accordingly concluded that "the district court erred to the extent that it attempted to create an obligation for Chiron scientists to enable nonexistent technology in the 1984 filing." *Id*. at 1255. Instead, the Court turned to the written description requirement to hold that because the applicants did not "possess and disclose" chimeric antibodies as of the filing date, the 1995 patent could not claim the benefit of the 1984 application's filing date and, therefore, was invalid as anticipated under 35 U.S.C. § 102. *Id*.[1]

[1] The Court also concluded that the 1995 patent could not claim priority to 1985 and 1986 applications because they failed to enable chimeric antibodies, which at that point were a nascent rather than a future technology. *See Chiron*, 363 F.3d at 1256.

Chiron should give pause to anyone who contends that the written description requirement is unnecessary in light of the enablement requirement. The inventors in *Chiron* were attempting to claim a priority date for technology that was not even *in existence* at the time of their 1984 application, let alone possessed and described in their specification. Even so, this Court concluded that the enablement requirement did not come into play, and that it was only under the written description requirement that the inventors could be prevented from laying claim to subject matter they never invented. It is not clear how the Court would have prevented that unfair outcome without the written description requirement.

2. Section 132 is not an adequate substitute for the written description requirement

Like enablement, Section 132's prohibition on adding "new matter" by amendment is not an adequate substitute for the written description requirement. "The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001). These "related but distinct statutory provisions," however, are not "interchangeable." *In re Rasmussen*, 650 F.2d 1212, 1214 (C.C.P.A. 1981).

Section 132 states that "[n]o amendment shall introduce new matter into the disclosure of the invention."[2] In *Rasmussen*, the Court of Customs and Patent Appeals held that Section 132 does not provide a proper basis for rejecting a *claim* that is broadened through amendment. The Court noted that Section 132 and Section 112, ¶ 1 involve "two distinct concepts: (1) the adding of new matter to the disclosure; and (2) the broadening of a claim." *Rasmussen*, 650 F.2d at 1214. It explained:

> Broadening a claim does not add new matter to the disclosure. Disclosure is that which is taught, not that which is claimed.…
>
> The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph, not § 132. The latter section prohibits addition of new matter to the original disclosure. It is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings attempting to add new disclosure to that originally presented. Past opinions of this court, in cases in which a § 132 claim rejection was reviewed on a § 112 analysis, should not in future be viewed as having approved the employment of § 132 as a basis for claim rejection. The amended claims involved in those cases should have been rejected under § 112, first paragraph.

Id. at 1214-1215. Although *Rasmussen* involved "amended claims," the Court observed that its holding applied "by implication" to the "rejection of entire new claims submitted after filing." *Id*. at 1214 n.5. "Similarly, rejections of claims for lack of support when required in reissue applications should be made under § 112,

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[2] A similar provision in 35 U.S.C. § 251 states that where a patentee requests reissue, "[n]o new matter shall be introduced into the application for reissue."

first paragraph, rather than under the new matter prohibition of 35 U.S.C. § 251." *Id*. at 1215 n.6; *see also Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1578 n.11 (Fed. Cir. 1984) ("Claims which are amended with limitations unsupported by the original disclosure are rejected under 35 U.S.C. § 112 (first paragraph) as lacking support in the specification, while such amendments to the abstract, specification, and drawings are objected to as being drawn to *new matter*.").

In light of *Rasmussen*, Section 132 cannot be used as an effective substitute for the written description requirement in policing priority. The elimination of the written description requirement would, therefore, leave a hole in this Court's jurisprudence. Given the widely acknowledged need for a mechanism to prevent patentees from expanding the scope of their claims beyond what they initially disclose, *see supra*, pp. 12-13, that is not a step the Court should take.

Even if the Court were to reconsider *Rasmussen* and hold that Section 132's prohibition on "new matter" applies to claims, it is not clear that Section 132 would be sufficient on its own to fulfill the critical function currently performed by the written description requirement. Because Section 132 states only that "[n]o *amendment* shall introduce new matter into the disclosure of the invention" (emphasis added), questions would undoubtedly arise about its proper scope.[3] For

[3] Section 251 is even narrower than Section 132 and applies, by its terms, only to an "application for reissue."

example, the Court would need to determine whether an application that attempts to claim new subject matter while receiving the benefit of an earlier application's filing date under 35 U.S.C. §§ 119 or 120 is properly considered an "amendment" within the meaning of Section 132. *See* NYIPLA Br. 18 (arguing that "because Sections 119 and 120 refer to Section 112 for determining entitlement to priority, it is not sufficient to rely on Section 132(a) for this purpose and abandon the written description requirement of Section 112").

By contrast, the link between Section 112, ¶ 1 and Sections 119 and 120 is clear. Section 120 applies by its plain terms to "an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States." Thus, "[u]nder 35 U.S.C. § 120, claims are granted the benefit of the filing date of an earlier-filed application only if the earlier application provides support according to 35 U.S.C. § 112, ¶ 1 for the later claims." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 993 (Fed. Cir. 1999). Likewise, a foreign application must meet the requirements of Section 112 in order to establish priority under Section 119. *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 889 (C.C.P.A. 1973) ("[T]he extent of the right of priority is measured by the content of the foreign specification," which must be "weighed under the first paragraph of section 112 in the same manner as would a United States application under section 120.").

The contrast between the written description requirement's proven track record of resolving priority questions and Section 132's unsettled scope reinforces the need to retain the written description requirement. This Court and its predecessor have recognized and applied that requirement for decades, during which time it has served as an effective bulwark against overreaching by patentholders. The sudden elimination of the requirement could leave gaps in the framework that protects against such overreaching, and far from contributing to the certainty and consistency of patent law, would raise a host of difficult and unanswered questions.

III. THE COURT HAS ALREADY DEVELOPED A FLEXIBLE AND APPROPRIATE STANDARD FOR APPLYING THE WRITTEN DESCRIPTION REQUIREMENT

A. The Description Needed To Establish Possession Of An Invention Varies With The Nature And Scope Of The Invention And The Predictability Of The Art

The Court should retain its existing test for determining whether a patent's specification contains a "written description of the invention" within the meaning of Section 112, ¶ 1. In *Vas-Cath*, this Court held that to satisfy the written description requirement, a patent's specification must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." 935 F.2d at 1563-1564 (emphasis removed). A "wish, or arguably a plan, for obtaining" the invention does not suffice. *Fiers*, 984

F.2d at 1171; *see also In re Wilder*, 736 F.2d at 1521 (specification must do more than "outline[e] goals … and the problems the invention will hopefully ameliorate"). *Vas-Cath*'s possession test provides an appropriate standard for evaluating the sufficiency of an invention's written description.

Within the general framework of the possession standard, "[t]he descriptive text needed to" satisfy the written description requirement "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon*, 418 F.3d at 1357. For biotechnology and other fields with unpredictable art, a more detailed description is typically required. This does not mean that the "possession" standard itself changes, but merely that the application of that standard depends on the context in which it is applied. *See G.D. Searle*, 375 F.3d at 1306 (Lourie, J., concurring in denial of reh'g en banc) ("statute is the same for all types of inventions, although it may be applied differently, based on the technology"); Drakulich, 21 Berkeley Tech. L.J. at 30 n.158 ("patent law can be technologically responsive without being technologically different" (internal quotation marks omitted)).

Critics of the written description requirement tend to caricature this Court's jurisprudence since 1997 as creating a "heightened" written description requirement for biotechnology inventions, based on the statement in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), that

"written description of an invention involving a chemical genus … requires a precise definition, such as by structure, formula, or chemical name of the claimed subject matter." *Id*. at 1568 (internal quotation marks and brackets omitted). But *Eli Lilly* did not announce a rigid formula for determining whether the requirement is met in every case. The Court was instead making two main points: First, that merely naming an invention or describing a method for its preparation does not necessarily describe the invention itself. *Id*. at 1567. Second, that in "complex biochemical claims" a "definition by function" often fails to describe the invention because "[i]t is only a definition of a useful result rather than a definition of what achieves that result." *Id*. at 1568. "The 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*.

Subsequent panel decisions have expanded upon and clarified *Eli Lilly*. For example, the Court has made clear that "*Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law." *Amgen*, 314 F.3d at 1332. Rather, a functional description may suffice if "the disclosed function is sufficiently correlated to a particular, known structure." *Id*. The Court has also clarified that "[a]s each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." *Capon*, 418 F.3d at 1358. Thus, the showing necessary to establish "possession" of an

invention depends on, among other things, "the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Id*. at 1359.

Collectively, *Vas-Cath*, *Eli Lilly*, and the decisions that followed have articulated workable and appropriate standards for applying the written description requirement to a variety of technologies. Going forward, the Court should focus on continuing to develop and refine these standards as they are applied in the concrete factual context of particular cases, rather than attempting to replace them with a new standard cut from whole cloth. *See Vas-Cath*, 935 F.2d at 1562 (written description requirement "must be left to case-by-case development" (internal quotation marks omitted)); *cf. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007) (given the "diversity of inventive pursuits and of modern technology," courts should avoid "rigid and mandatory formulas").

B. The Court Should Clarify Its Prior Statements Regarding What Constitutes An Adequate Description Of Antibody Technology

Even though further development of the written description standard should generally proceed on a case-by-case basis, the Court should take this opportunity to clarify an erroneous statement regarding the standard's application to antibody technology that has caused confusion.

The problem initially arose in *Enzo* when the Court attempted to identify an example of an invention that might be defined by "functional characteristics …

coupled with a known or disclosed correlation between function and structure." 323 F.3d at 964 (internal quotation marks and emphasis omitted). *Enzo* did not involve antibody technology, but the Court noted in dicta that the PTO's training materials for patent examiners contained an example of an antibody described in functional terms based on its ability to bind to a fully characterized antigen. *Id*.

The problem was compounded in *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), which repeated the antibody example, again in dicta, without attributing it to the PTO. The actual holding of *Noelle* was that a description of the mouse CD40CR antibody and antigen did *not* support a genus claim to human CD40CR antibodies. *Id*. at 1349-1350. The Court remarked, however, that if the applicant "had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the 'fully characterized' antigen." *Id*. at 1349. The Court based this dicta on *Enzo* without engaging in its own analysis of the relationship between antibody structure and function. *Id*.

The dicta in *Enzo* and *Noelle*, and the underlying PTO example, are based on an erroneous assumption. Although "much is known about antibody structure generally and about the general relationship between certain portions of the antibody structure and particular antibody functions," "the antibody structures responsible for the claimed function of 'binding antigen X' are precisely the

structures that are not known … and that cannot be predicted from a structure-function correlation." James J. Kelley & Gregory A. Cox, *The "Anti"-Written Description Requirement? Antibodies, Example 16, The Guidelines, and* Noelle v. Lederman, 87 J. Pat. & Trademark Off. Soc'y 705, 721 (2005); *see also* Holman Br. 8-10 (describing flaws in PTO's application of written description requirement to antibodies). A description of a fully characterized antigen, therefore, fails to describe the most critical component of the antibodies that bind to it. Accordingly, the Court should take this opportunity to clarify that, despite its statements in *Enzo* and *Noelle*, there is no *per se* rule that an applicant can describe a genus of antibodies simply by describing the antigen to which they bind.

IV. RECENT LITIGATION AGAINST ABBOTT DEMONSTRATES THE IMPORTANCE OF MAINTAINING A ROBUST WRITTEN DESCRIPTION REQUIREMENT

A recent suit against Abbott—like Ariad's suit against Eli Lilly—illustrates the importance of maintaining a robust written description requirement, and is briefly described to provide the Court with another concrete example to consider as it determines the future existence and scope of the written description requirement.

The plaintiff in the Abbott litigation filed a patent application in 1994 that described and claimed a "chimeric" antibody (made from a human "constant region" and a mouse "variable region") that binds to and neutralizes a human protein associated with auto-immune diseases such as rheumatoid arthritis.

Although the specification contained a few references to "human antibodies" or antibodies with a "human" variable region, it did not: (1) describe fully human antibodies of the type later invented by Abbott, (2) disclose the relevant structure of a human variable region that binds to the target antigen, or (3) describe fully human antibodies having the claimed characteristics through a known correlation between function and structure. In short, nothing in the 1994 application established that the plaintiff possessed fully human antibodies with the relevant characteristics needed to treat rheumatoid arthritis and other diseases. Indeed, one of the named inventors on the 1994 application testified that "it was never our intention to make a human antibody." 6/22 p.m. Tr. 18:15-24.[4]

Meanwhile, Abbott had been working to develop a fully human antibody using entirely different technology that involved a "very, very difficult" process comparable to "looking for a needle in a field of haystacks." 6/23 p.m. Tr. 153:5-154:10. In 1995, it succeeded in isolating the high-affinity neutralizing antibody used in Abbott's biologic Humira®, which became the first fully human antibody therapy approved by the Food and Drug Administration and was awarded the biopharmaceutical industry's highest prize. The inventors filed a patent application claiming their discovery in 1996 and obtained a patent in 2000.

[4] The record citations in this section of the brief are from the trial transcript in *Centocor, Inc. v. Abbott Laboratories*, No. 2:07-cv-00139 (E.D. Tex.).

Two years *after* Abbott's patent issued, the plaintiff filed a continuation application—their thirteenth application overall—containing claims that the court construed as covering certain fully human antibodies that neutralize the same antigen as Humira®. Based on the patent that subsequently issued, which claimed priority to the plaintiff's 1994 application, a jury found that Abbott infringed, rejected Abbott's invalidity defenses, and awarded the plaintiff $1.67 *billion*—the largest patent verdict in history.

That decision, which is still subject to appeal, highlights the written description requirement's vital role as a check against an applicant's ability to lie in wait as an industry develops and then assert new claims based on an earlier application that fails to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the applicant] was in possession of the invention." *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1377 (Fed. Cir. 2009) (internal quotation marks and emphasis omitted).[5] Without that check preventing applicants from claiming more than they actually invented, the type of groundbreaking research that led to Humira's development would be chilled, to the detriment of patients who depend on such research to develop new treatments for

[5] On October 1, 2009, the district court denied without opinion Abbott's motion for JMOL or, in the alternative, a new trial based on the plaintiff's failure to comply with the written description requirement. Abbott will appeal once a final judgment has been entered.

debilitating and life-threatening diseases. Rather than eliminating or weakening the written description requirement, the Court should reaffirm its important role in protecting those who actually invest the time, money, and effort needed to develop new technology against improper attempts by others to claim an invention they did not possess.

CONCLUSION

For the foregoing reasons, the panel's decision should be affirmed.

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Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I hereby certify:

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