

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 & 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 OF AMICUS CURIAE INTELLECTUAL PROPERTY
OWNERS ASSOCIATION ON *EN BANC* REHEARING IN
SUPPORT OF ELI LILLY AND COMPANY**

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Arid Pharmaceuticals, Inc. v. Ely Lilly & Co., 08-1248

CERTIFICATE OF INTEREST

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1. The full names of every party or amicus represented by me is:
Intellectual Property Owners Association
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: **NONE**
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are: **NONE**
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The Intellectual Property Owners Association (“IPO”) submits this brief as an *amicus curiae* pursuant to Fed. R. App. P. 29(a) and Rule 29(a) of this Court to address, on behalf of its members, the questions set forth by this Court in its August 21, 2009 Order setting the case for *en banc* rehearing. The Order provides that amicus briefs may be filed without leave of this Court. Both the plaintiffs and the defendant have consented to the filing of this brief.

INTEREST OF *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and more than 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the Patent and Trademark Office to U.S. nationals. IPO regularly represents the interests of its members before Congress and the PTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the

SUMMARY OF THE ARGUMENT

Over the past decade, debate has increased over whether the written description requirement under 35 U.S.C. § 112, paragraph 1, is separate from the enablement requirement or whether enablement alone satisfies the written description. IPO believes that 35 U.S.C. § 112, paragraph 1 *does* contain a written description requirement separate from the enablement requirement.

The courts have long interpreted the patent laws as requiring a separate written description requirement. This interpretation has been affirmed repeatedly over many years in opinions by the courts. The patent community, including patent applicants, USPTO examiners and members of the public evaluating the scope and validity of patent claims, has relied on this prior body of case law.

Compelling reasons justify the existence of a separate written description requirement. The written description requirement operates as the *quid pro quo* in the carefully crafted bargain of the federal patent system. The written description

¹ IPO procedures require approval of positions in briefs by a three-fourth majority of directors present and voting. Eli Lilly is a member of the IPO Board of Directors; however, it did not participate in the discussions regarding or vote on the decision to file this brief and did not participate in its preparation.

requirement mandates that an inventor provide a meaningful description of the invention demonstrating that the inventor actually was in possession of the invention and providing the public notice of the subject matter that the inventor claims as his own. The written description thus functions to prevent the inventor from attempting to obtain protection for that which he has *not* invented.

Although the enablement requirement assists in the policing of the *quid pro quo*, situations can arise in which the enablement requirement is satisfied but the written description requirement is not. Without a separate written description requirement, an inventor would be able to obtain protection of subject matter that is unfairly broad.

There exists no “bright-line rule” by which the adequacy of a written description is measured. IPO submits that it would be inappropriate to attempt to create a bright-line rule in this case. Instead, the written description should continue to be evaluated on a case-by-case basis, with an understanding that the sufficiency of a written description varies with both the technology being described and the state of development of that technology. Although this inherently allows the possibility of uncertainty for some situations, IPO submits that an inflexible, bright-line rule for satisfying the written description requirement would either be too stringent for incremental improvements in well-developed

technologies or too lenient for ground-breaking discoveries in undeveloped technologies.

IPO respectfully urges this Court to reaffirm that there is a separate written description requirement that operates as the *quid pro quo* of the carefully crafted bargain of the patent system. IPO further urges this Court to be wary of adopting a bright-line standard or test for evaluating the adequacy of the written description, and to express instead the need for continued reliance on a flexible case-by-case analysis.

IPO expressly declines to take any position on the validity of the claims of the Ariad patent.

ARGUMENT

I. Yes, 35 U.S.C. § 112, paragraph 1, does contain a written description requirement separate from the enablement requirement.

The patent community – including the United States Patent and Trademark Office (USPTO), courts, attorneys, inventors and the business community – have long understood that both the currently existing 35 U.S.C. § 112, paragraph 1 (“Section 112”) and the predecessor patent acts include a written description requirement that is separate and distinct from the enablement requirement. This

understanding has been affirmed repeatedly in opinions by the Supreme Court as well as this Court and its predecessor.²

In its earliest incarnation, the Patent Act of 1790, United States patent laws required an inventor to:

deliver ... a specification in writing, containing a description ... of the thing or things ... invented or discovered ... which specification shall be so particular ... as not only to distinguish the invention or discovery from other things before known and used, but also to enable a ... person skilled in the art ... to make, construct or use the same

Patent Act of 1790, 1st Cong. ch. 7, 1 Stat. 109, 110 (2d Sess. 1790). Only minor changes were made to this language in subsequent patent legislation. Congress did not significantly modify this language, even after adding a requirement for claims in the description that “particularly point out and distinctly claim the invention.”³

² For a more detailed discussion of the historical development of the patent laws and its statutory construction, see the discussion of this Court in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), and of this Court’s predecessor in *In re Barker*, 559 F.2d 588 (C.C.P.A. 1977).

³ See 3 Donald S. Chisum, Chisum on Patents § 7.02, n.12 (2009) (noting that the new act restated the old disclosure requirement “with some language changes”). The Patent Act of 1836 provided that the inventor:

shall deliver a written description of his invention ..., and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, ... as to enable any person skilled in the art ..., to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the application of

Congress later described the requirements for a specification and claims in separate paragraphs in the Patent Act of 1952, now codified as 35 U.S.C. § 112, ¶¶ 1-2.

Extensive case law recognized that patent acts preceding 1952 set forth a written description requirement that is separate from the enablement requirement. *See, e.g., In re Barker*, 559 F.2d at 592 (“Commencing with our first patent statute, there have been separate requirements for a description of the invention and a description of how to make and use it.”); *Evans v. Eaton*, 20 U.S. 356 (1822) (finding that a patent was invalid because the specification failed to describe the invention); *O’Reilly v. Morse*, 56 U.S. 62, 120 (1853) (holding as invalid a claim directed to the use of power for printing because the claim was “not described in the manner required by law”); *In re Moore*, 155 F.2d 379 (C.C.P.A. 1946) (finding that original method claims directed to a method of using any form of insecticide was not supported by the specification’s disclosure only of fumigants).

Under the Patent Act of 1952, 35 U.S.C. § 1-376 (2007), the courts have continued to recognize a written description requirement that is separate from the enablement requirement. This Court’s predecessor first directly addressed the

that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.

Patent Act of 1836, 24th Cong. ch. 357, 5 Stat. 117, 119 (1st Sess. 1836).

nature of the written description and enablement requirements in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).⁴ The *Ruschig* opinion analogized the written disclosure to “blazing a trail” through the woods:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one’s way through the woods where the trails have disappeared- or have not yet been made ...-to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

Id. at 994-95.

In *Ruschig*, the court held that the written disclosure did not support a claim to chlorpropamide. The court reasoned that the disclosure provided support only for the broad genus, and, although the disclosure sufficiently enabled the making of the compound, such enablement was “beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented.” *Id.* at 995.

⁴ That is not to say, however, that the court had not previously recognized, at least implicitly, that there was a separate written description requirement. *See e.g., In re Lund*, 376 F.2d 982, 985 (C.C.P.A. 1967) (“There is no question but that the disputed terms – though they are the same as the terms used in the specification – are so broad that they embrace subject matter not described to be appellants’ actual invention by means of adequate representative examples.”); *In re Cavallito*, 306 F.2d 505, 510 (C.C.P.A. 1962) (finding that the language of the original claim was “broader than the written description of the invention in the specification”).

Both this Court and the Supreme Court have repeatedly recognized the distinction between the written description requirement and the enablement requirement. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (noting that “the patent application must describe, enable, and set forth the best mode of carrying out the invention”); *see also Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, *en banc reh’g denied*, 375 F.3d 1303 (Fed. Cir. 2004); *Carnegie Mellon Univ. v. Hoffman-La Roche Inc.*, 541 F.3d 1115 (Fed. Cir. 2008).

This Court should not disrupt over 200 years of precedent beginning with the Patent Act of 1790 and continuing until today. Accordingly, this Court should hold that Section 112 does set forth a written description requirement separate from the enablement requirement.

II. The purpose of the separate written description requirement is for inventors to satisfy their portion of the *quid pro quo* by providing a meaningful disclosure of their inventions.

“The federal patent system ... embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S.

141, 150-51 (1989). “The written description requirement serves as a teaching function, as a ‘quid pro quo’ in which the public is given meaningful disclosure” in this carefully crafted bargain. *University of Rochester*, 358 F.3d at 922, n.5 (citing *Enzo Biochem*, 323 F.3d 956). Two key functions of the written description requirement in this carefully crafted bargain are to establish possession of the invention by the inventor and to provide the public notice of what the inventor believes to be the invention.

A. The separate written description requirement provides a showing that the inventor(s) had *possession* of the claimed subject matter.

An inventor is entitled to a limited monopoly on *only* that subject matter which he has *actually* invented. An invention is not simply conception of an idea defined by a “hoped-for-function.” *Fiers*, 984 F.2d at 1169. Nor is an invention a mere “research plan.” *Id.* The written description requirement serves to prevent the patent grant from being “a hunting license” – rewarding not the “search” but its “successful conclusion.” *University of Rochester*, 358 at 916, 930, n.10 (quoting *Brenner v. Manson*, 383 U.S. 519, 536 (1966)).

The written description requirement is therefore critical to protecting the balance of the patent system because it “guards against the inventor’s overreaching.” *Vas-Cath Inc.*, 935 F.2d at 1561 (quoting *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551 (3d Cir. 1981)).

The written description requirement requires the inventors to provide evidence of that which they *actually* invented, thereby demonstrating that they were in possession of the claimed subject matter. *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005) (“The ‘written description requirement’ ... serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in *possession* of the invention that is claimed.”); *see also Space Systems/Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987 (Fed. Cir. 2005) (observing that the written description serves the fundamental purpose of “making known what has been invented, including any variations and alternatives contemplated by the inventor”).

The possession function of the written description requirement therefore helps to prevent an inventor from obtaining protection beyond that which was actually discovered, ensuring that the patent system promotes, rather than discourages, future innovation and discoveries.⁵

B. The separate written description requirement provides the public notice of what the inventor(s) consider to be the invention.

⁵ Traditionally, the written description requirement and its possession function come into play with issues of priority for amendments or filing dates under 35 U.S.C. §§ 119 or 120; new matter under 35 U.S.C. § 132; and support of counts in an interference. *See Vas-Cath Inc.*, 935 F.2d at 1560.

The separate written description requirement also serves to provide the public notice of what the inventor(s) consider to be the invention. In *Evans v. Eaton*, the Supreme Court interpreted the description requirement of the Patent Act of 1793 as having the purpose “to put the public in possession of what the party claims as his own invention” so as to prevent the inventor from “pretending that his invention is more than what it really is, or different from its ostensible objects.” 20 U.S. at 433-34. See also *In re Ruschig*, 379 F.2d at 994-95 (noting that by “[n]ot having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection be made rather than any of the many others which could also be made”). The notice function of the written description requirement is supplementary to the notice function of the claims – the written description teaches the invention and the claims define the scope of protection afforded to the invention. *University of Rochester*, 375 F.3d at 1306 (J. Lourie concurring) (citing *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n. 14 (Fed. Cir. 1985)).

The written description’s notice function begins when an application is first published. The written description in a published application provides a reasonable guide to the likely scope of claims that will ultimately issue, enabling members of the public to modify their activities preemptively. By comparison, the

claims in a published application often encompass a materially broader scope than the claims that ultimately issue. The notice provided by the written description helps to minimize risk that overly broad claims in a published application will unfairly stifle competition.

Thus, the notice function of the written description requirement blazes a trail both before and after the patent issues to reduce public uncertainty about the scope of the claims.

C. The bargained-for exchange of the patent system cannot be satisfied solely by the enablement requirement.

The enablement requirement is insufficient to satisfy the possession and notice functions served by a separate written description requirement, as situations exist in which the enablement requirement may be satisfied without providing evidence that the inventor was in possession of the invention and without providing sufficient notice to the public of the scope of the invention. *See In re DiLeone*, 436 F.2d 1404, 1405, n.1 (C.C.P.A. 1971).

The court in *DiLeone* made clear that enablement alone cannot always be relied upon to demonstrate that the inventor was in possession of the invention. Although the *DiLeone* court found sufficient written description of the patent at issue, it offered a hypothetical example in which a specification may enable an invention, but not satisfy the written description requirement:

For greater clarity on this point, 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.

In re DiLeone, 436 F.2d at 1405, n.1 (emphasis added). In such a scenario, an original claim directed to a class consisting of A, B, and C would be unsupported by the written description even though it may be enabled. Although the original claim is a part of the written description, “the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement.” *University of Rochester*, 375 F.3d at 1307 (J. Lourie concurring).

In *In re Ahlbrecht*, 435 F.2d 908 (C.C.P.A. 1971), the court considered whether a parent application complied with Section 112 for purposes of obtaining the benefit of a filing date in a later-filed application. The claims at issue were directed to a class of esters having from 2 to 12 methylene groups while the parent application described a class of esters having from 3 to 12 methylene groups. *Id.* The court found that although the method in the parent application “may very well be sufficient to teach one skilled in the art how to make the claimed esters,” the parent application did not satisfy the written description requirement because there was no disclosure of an ester having just 2 methylene groups. *Id.* Thus, the written description of the parent application failed to show that the inventor had

possession of the invention and failed to provide notice to the public of what the inventor considered to be the invention.

III. The written description requirement is satisfied if it provides a description sufficient to demonstrate that the patentee was in possession of the invention that is claimed.

The separate written description requirement requires the applicant to set forth the invention with sufficient particularity to demonstrate possession of the claimed invention. “[T]he description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)). The applicant 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* – the invention being “whatever is now claimed.” *Vas-Cath Inc.*, 935 F.2d at 1563.

IPO does not propose creating a new “bright-line” rule by which the scope or sufficiency of the written description requirement should be measured. A rigid rule for evaluating the written description is not practical when the very nature of the disclosure of an invention can vary so significantly among the arts. Adoption of a rigid rule would also be inconsistent with Supreme Court precedent, which has repeatedly rejected rigid analysis when evaluating other patent law issues. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 402 (2007) (rejecting “a rigid rule” to

limit obviousness); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006) (rejecting a “categorical rule” to establishing a right to injunctive relief); *Festo Corp.*, 535 U.S. at 739 (rejecting a “bright-line rule” to establish prosecution history estoppel).

The sufficiency of written description should therefore be evaluated under a flexible standard on a case-by-case basis, with an understanding that what is sufficient to satisfy the written description requirement will vary according to the art to which the invention pertains and as the knowledge of those skilled in the art develops. See e.g., *Capon*, 418 F.3d 1349; *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313 (Fed. Cir. 2003); *In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527 (Fed. Cir. 1992).

While a patentee need not have carried out the invention, he must be able to describe that invention “in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.” *University of Cal.*, 119 F.3d at 1566 (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). An applicant may describe the invention “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572. The written description can show “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.” MANUAL OF PATENT EXAMINATION AND PROCEDURE § 2163 (II)(A)(3)(a) (8th Ed. 2008).

Several well-established tenets help delineate the boundaries of the written description requirement. For example, it is commonly understood that the written description requirement does *not* require:

1. Examples: “[E]xamples [explicitly covering the full scope of the claim language] are not necessary to support the adequacy of a written description.” *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).
2. Actual Reduction to Practice: “[A]n actual reduction to practice is not required for written description.” *Falkner*, 448 F.3d at 1366; *see also University of Rochester*, 358 F.3d at 922, n.5 (although “[c]onstructive reduction to practice” is sufficient so long as the application “describe[s] the claimed subject matter in terms that establish that [the applicant] was in possession of the ... claimed invention, including all of the elements and limitations.”) (alteration in original) (citation omitted).

3. Literal Support for the Claimed Invention: The disclosure need not match the claim word for word to satisfy the written description requirement. *See Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.”); *see also Martin v. Johnson*, 454 F.2d 746, (C.C.P.A. 1972) (noting that “the description need not be *in ipso verbis* to be sufficient”).
4. Identical Type or Depth of Disclosure for Each Invention: The written description requirement does not require “that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” *Capon*, 418 F.3d at 1357-58.
5. Express Disclosure of Each and Every Species in a Genus: “Mention of representative compounds encompassed by generic claims language clearly is not required by §112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide implicit description upon which to base generic claim language.” *In re Robins*, 429 F.2d 452, 456-57 (C.C.P.A. 1970).

IV. IPO does not advocate that claims should be limited to disclosed embodiments or that unclaimed details of such embodiments should necessarily be used to limit claim scope.

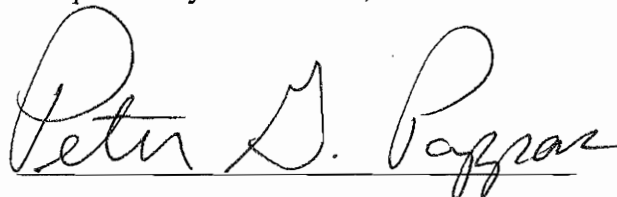
Application of the separate written description requirement should not be implemented in a way that limits the claims to the specific disclosed embodiments. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004); *see also E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364 (Fed. Cir. 2003) (noting the “inherent tension” in evaluating “whether a statement is a clear lexicographic definition or a description of a preferred embodiment”). The separate written description requirement also should not undermine the courts’ reluctance to narrow claim scope by importing limitations appearing in the specifications. “[I]t is important not to import claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). To the contrary, IPO submits merely that the separate written description requirement is a necessary and essential element of a patent that insures the *quid pro quo* of the patent system is satisfied.

CONCLUSION

For the foregoing reasons, IPO believes that this Court should uphold the long-standing interpretation of 35 U.S.C. § 112, paragraph 1, as having a written

description requirement separate from the enablement requirement. The separate written description requirement works in conjunction with enablement, but serves different purposes, thereby helping to maintain the carefully crafted bargain of the patent system – establishing that an inventor had possession of the invention and providing the public notice of what the inventor believes to be the invention. IPO further believes that this Court should not adopt a new bright-line rule in evaluating the adequacy of the written description requirement, but rather should clarify that the written description requirement is evaluated on a case-by-case basis, delineating the boundaries using the currently existing, well-established tenets.

Respectfully submitted,



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APPENDIX⁶

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**United States Court of Appeals
for the Federal Circuit**

Ariad Pharmaceutical v. Eli Lilly, 2008-1248

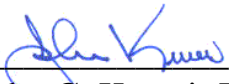
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November 11, 2009



John C. Kruesi, Jr.

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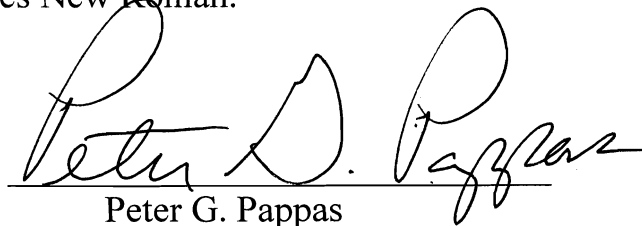
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Peter G. Pappas