

2008-1248

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees,

v.

ELI LILLY & CO.,

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*
THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
IN SUPPORT OF APPELLANT ON REHEARING *EN BANC*

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November 19, 2009

CERTIFICATE OF INTEREST

Counsel for the American Intellectual Property Law Association, *amicus curiae*, certifies the following:

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

American Intellectual Property Law 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:

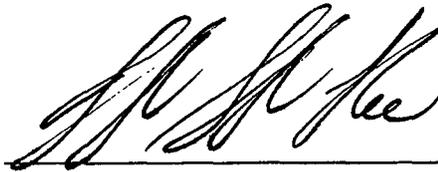
Not applicable.
3. All parent corporations and any publicly held companies that own 10 percent or more of stock of the party or amicus curiae represented by me are: N/A

None.
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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Dated: November 19, 2009



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STATEMENT OF INTEREST

This brief is submitted by the American Intellectual Property Law Association (“AIPLA”).

AIPLA is a national bar association of more than 16,000 members drawn from private and corporate practice, government service, and the academic community. AIPLA represents a diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law. AIPLA members represent both owners and users of intellectual property.

AIPLA submits this brief pursuant to the authorization provided in the Court’s August 21, 2009 Order.

RESPONSE TO *EN BANC* QUESTIONS

AIPLA, *amicus curiae*, responds to the Court's *en banc* questions as follows and as further explained in this brief:

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

Answer: Yes, Section 112, ¶ 1 contains a written description requirement that is distinct from, but related to, an enablement requirement.

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

Answer: The purpose and scope of the written description requirement is to act in concert with the other requirements of Section 112 to advance the disclosure objectives of the patent system. In the patent validity context, the requirement should be applied not as an independent measure of compliance with the disclosure requirement of Section 112, but together with the other specification requirements of enablement under Section 112, ¶ 1, and identification of the invention in the claims under Section 112, ¶ 2. Compliance with Section 112 should therefore be judged by the sufficiency of the disclosures as a whole, not by the sufficiency of the disclosure under any one requirement.

While AIPLA answers Question 1 above in line with the position of appellant Eli Lilly & Co. ("Lilly"), it does not take a position on the validity of appellee Ariad Pharmaceuticals, Inc.'s ("Ariad's") patent claims at issue in this appeal.

SUMMARY OF ARGUMENT

Section 112 of the Patent Act sets forth the ways a patent applicant must disclose his invention: in a written description of the invention, in an enabling description of how to make and use the invention, and in patent claims that particularly point out and distinctly claim the invention. In considering whether those requirements are satisfied, the Court should ask whether the specification “as a whole” advances the well-recognized patent policies of disclosure, *i.e.*, (1) particularly and distinctly identifying the invention, (2) putting the invention in the hands of the public at the end of the patent term as part of the *quid pro quo* bargain for exclusive rights, (3) ensuring that the applicant was in possession of his/her invention at the time of filing to limit any exclusive rights to the subject matter he/she actually invented, and (4) informing the public of the patent scope so that potential competitors know how to avoid infringement and can reasonably design around the claimed invention.

The “written description” requirement under Section 112 and this court’s precedent serves the important public policy objective that calls on an inventor to disclose and describe the full scope of his or her invention. The “enablement requirement” under Section 112, and this Court’s authority, serves a different and distinct purpose – allowing one of ordinary skill to put the invention into practice. In some instances, the specific disclosure enabling the practice of an invention may

be narrower than the full scope of the invention, as the inventor may rely on ordinary skill in the art and reasonable experimentation to supplement the patent's disclosure. In other instances, an enabling disclosure may supply methods, materials or technology that allow one of ordinary skill to produce subject matter very different from any invention identified by the inventor as his/her own. Accordingly, collapsing the written description requirement and the enablement requirement to require a single "enabling disclosure" serves neither interests of the public nor the interests of inventors.

Thus, in determining whether there is a sufficient "written description" of an invention as claimed in a patent, the application as originally filed should be considered as a whole, as it would be understood by one of ordinary skill in the relevant art.

ARGUMENT

The dispute in this case tempts the parties and *amici* to re-plow the oft-covered ground on how to interpret the disclosure requirements of 35 U.S.C. § 112 ¶ 1, a provision which is not easily susceptible to a definitive grammatical construction despite the efforts of the best minds on the Court and in the bar. AIPLA submits that the Court should resist the temptation to dwell on parsing the statutory language to the point of drawing legal conclusions based on the placement of commas.

Instead, AIPLA submits that an approach to Section 112 that considers the specification “as a whole” is faithful to the statute’s literal language and policy objectives, does not call for a radical departure from this Court’s precedent, and conforms to Supreme Court precedent. This approach is also sufficiently flexible in its application to avoid an unfair standard of compliance that fails to take account of inherent differences in technologies and claim format which can affect the sufficiency of a particular disclosure.

I. Statutory Language, Legislative History, And Judicial Precedent Fail To Solve The Puzzle

The parties, Ariad and Lilly, have presented an exhaustive history and analysis of Section 112, ¶ 1. AIPLA does not necessarily agree with all that they argue, but the parties’ work product illustrates that the dispute about the nature of a

patent's disclosure under Section 112 has been controversial at least since Judge Rich's 1967 opinion in *In re Ruschig*, 379 F.2d 990 (CCPA 1967). In this decade, *en banc* review of the issue was denied by a 9-3 vote in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002); it was again denied by a 7-5 vote in *University of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303 (Fed. Cir. 2004), despite extensive dissenting opinions. Although the issue has "percolated" through many panel rulings, as Judge Pauline Newman said in her concurrence to the *en banc* denial in *Searle*, there still appears to be no convergence of views under the traditional analysis.

II. Application Of Section 112 Disclosure Requirements Must Be Policy Driven

Section 112 imposes a strict and solemn obligation on every patent applicant to adequately disclose that which she considers to be his/her invention, in order to meet the policy objectives that justify a grant of exclusive rights to the inventor and his/her assigns. Consequently, the patent specification at the time it is filed must:

- 1) Sufficiently identify the invention;
- 2) Put the invention in the hands of the public at the end of the patent term as part of the *quid pro quo* bargain for exclusive rights;
- 3) Ensure that the applicant was in possession of his/her invention at the time of filing to limit any exclusive rights to subject matter he/she actually invented; and

- 4) Inform the public of the patent scope so that potential competitors know how to avoid infringement and can reasonably design around the claimed invention.¹

These policy objectives must be fully met by the patent specification, and the courts must continue to require a high standard of disclosure.

However, the heart of the matter in this case is not related to the strictness or high standard of disclosure required to meet the policy objectives. Rather, it is that a flawed “written description” was considered “by itself” sufficient to invalidate a patent, without any consideration of the other aspects of the disclosure acting in concert with the written description. As Judge Richard Linn observed in his separate opinion to the panel decision, the Court ended its inquiry into the applicant’s disclosure as soon as it found the written description deficient. *See*

¹ *See, e.g., Fes to Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (these disclosure “requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (“a carefully crafted bargain”); *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891) (“The object ... is not only to secure to [the patentee] all to which he is entitled, but to apprise the public of what is still open to them.”); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008) (“ensuring that the patent specification adequately notifies the public of the scope of the patentee’s right to exclude”); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims”); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (“To fulfill the written description requirement, the patent specification ‘must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.’”) (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)).

Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1381 (Fed. Cir. 2009) (Linn, J., concurring opinion). According to Ariad, the error was the Court’s failure to recognize that an enabling disclosure inherently satisfies the written description requirement, whereas Lilly insists on the exact opposite.

AIPLA submits that this impasse can be overcome by recognizing that Section 112 contains a number of distinct disclosure requirements that must be met, but which operate together and, in a sense, interactively for purposes of assuring that the disclosure of the specification is sufficiently complete to meet the policy objectives, and thus support the scope of protection afforded by the issued claims. The literal language of Section 112, ¶ 1 certainly does not state that a complying disclosure must be separated into sections designated as a “written description” and an “enabling description.”

To the contrary, as fairly read, the statute calls on one of ordinary skill to read the specification as filed *in its totality* to ascertain both what the inventor recognized and contemplated as his invention, and how to practice it. Such an interpretation of Section 112 advances the fundamental policies served by the patent disclosures, particularly the interest of ensuring that inventors obtain the appropriate scope of protection available for his or her invention.²

² The “as a whole” approach in the patent disclosure context is in some ways similar to the “as a whole” approach applied in making obviousness determinations under 35 U.S.C. § 103. For Section 103, the question is what is understood from

Accordingly, with respect to the first question asked by the Court in this proceeding, AIPLA believes that Section 112 contains a written description requirement separate from an enablement requirement. However, with respect to the second question, AIPLA believes that the purpose and scope of the written description requirement is to act in concert with the other requirements of Section 112 to advance the disclosure objectives of the patent system. Thus, for purposes of determining whether a patent is invalid for failing to comply with the disclosure requirements, a specification should be judged by the sufficiency of the disclosures in the application as filed, taken as a whole, not by the sufficiency of the portion of a specification deemed the “written description” or the separate portion deemed the “enabling disclosure.”

the prior art, and for Section 112, the question is what is understood from the patent specification. In both instances, it is the understanding of a person of skill, and the Supreme Court has made clear in the obviousness context that this understanding will be grounded in a variety of sources which must be evaluated “as a whole.” See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). It is no less true in the patent disclosure context that the understanding of a person of skill about a claimed invention will also be grounded in multiple sources, which likewise must be evaluated “as a whole.” It is also the case that determinations of a disclosure’s sufficiency, based on the understanding of a person of skill, would require review under a standard similar to that applied to obviousness as a legal conclusion based on underlying findings of fact.

III. An “As a Whole” Approach To Section 112 Accommodates The Interaction And Co-dependence Of The Disclosure Requirements, And Allows Flexibility For Diverse Technologies

In this case, the panel reached its conclusion of patent invalidity based on a flawed written description without examining any other aspect of the disclosures required to be made in the specification.³ The key consequence of that approach is that this particular disclosure requirement can have such an effect “by itself.” Thus, the real question at issue is whether the written description requirement can be viewed in isolation from the other disclosure requirements of Section 112, in order to invalidate a patent.

AIPLA’s “as a whole” approach would allow a practical evaluation of the sufficiency of the disclosure from the standpoint of one of ordinary skill, taking into account the interaction and codependence of the Section 112 requirements. It also comports by analogy with the common sense approach for judging the patentability of an invention in view of the prior art as articulated by the Supreme Court in *KSR*. *KSR* , 550 U.S. at 420.

This approach does not relieve the patent owner of complying with the strict disclosure requirements of Section 112, nor does it relieve them of identifying in the patent a “written description” of the invention commensurate with the scope of

³ See *Ariad Pharm*, 560 F.3d at 1381 (Linn, J., concurring opinion) (“Because the court relies upon [the written description] requirement to reverse the district court, it does not reach the important enablement issue raised by Lilly.”).

the claims at issue. *See, e.g., Tronzo v. Biomet, Inc.*, 950 F. Supp. 1149, 1154 (S.D. Fla. 1996) (“The very point of the Federal Circuit in making this distinction is to alert trial courts to the importance of reading the written description requirement strictly.”), *rev’d on other grounds*, 156 F.3d 1154 (1998). It would, however, require a consideration of the specification as a whole to establish whether those of ordinary skill in the art were fairly put on notice of what the inventors contemplated as the invention encompassed by the claims at issue. This is in line with established precedent that the specification need not describe the invention in *haec verba* in order to satisfy the written description requirement. *Univ. of Rochester v. G.D. Searle*, 358 F.3d 916, 922-23 (Fed. Cir. 2004).

Such an analysis would be flexible enough to adapt to the diversity of technology, whether applied in the predictable or unpredictable arts. Some continue to believe that an enablement inherently satisfies any requirement to describe the invention. In some technologies that may well be the case, but in other fields, particularly where method claims are involved, it may not. Another example often cited to illustrate the problem is where a patent for a genus fully enables the use of the genus and species, but the specification provides no written description in respect of a claim covering only a particular species.

In the end, it is the dynamic interaction of the Section 112 requirements that produce the kind of disclosures necessary to advance the policies recited above.

Whatever the answer on the sufficiency of the written description or enabling disclosure in the case, the proposal here would not allow the court to simply stop the analysis after examining only one of the requirements in isolation, and to ignore the others. It would rather permit a party to point the court to the disclosure as a whole, which would be evaluated in light of the patent policies.

IV. The Proposed Approach Allows Analysis Of The Interacting And Co-dependent Disclosure Requirements In Section 112, Without Changing The Analysis Of The Individual Requirements

AIPLA's "as a whole" approach is supported both by a common-sense reading of the requirements of Section 112, and by the continued application of those requirements as they have been applied for decades.

Section 112 addresses three aspects of the patent application: (1) a written description of the invention, (2) an enablement of the invention, and (3) a claim which particularly points out and distinctly claims the subject matter which the applicant regards as his invention. All three of these factors must be taken into account, together, in deciding whether an invention is adequately disclosed.

The need to consider the disclosure requirements together can be illustrated in several ways. First, as stated above, there is no requirement that the written description of the invention be in a separately designated section of the specification, nor that the enablement be in a separately designated section. Both may be included and intertwined in the same section of the specification, which

consequently must be considered as a whole to determine the sufficiency of disclosure.

Second, the written description and enablement requirements in Section 112, ¶ 1, which are directed to the “invention,” must be considered in light of the ¶ 2 requirements for a claim, the very thing that identifies what the “invention” is. *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1320 (Fed. Cir. 2002) (the invention referred to in Section 112, ¶ 1 “is the invention defined by the claims.”). This has always been the case for enablement. *Christianson v. Colt Indus. Operating Corp.*, 870 F.2d 1292, 1299 (1989) (indicating that “the invention” referred to in the enablement requirement of Section 112 is “the *claimed* invention”) (emphasis in original). Taking ¶ 1 and ¶ 2 together, it is not the written description requirement but the claim, interpreted in light of the specification and the patent file-history, that identifies the invention. Thus the “written description of the invention” is a written description of the subject matter which is particularly pointed out and distinctly claimed as that which the applicant regards as his invention.⁴ *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991) (“[T]here is a subtle relationship between the policies underlying the description and definiteness requirements, as the two standards, while

⁴ This would perhaps be more clear if Section 112, ¶ 2 came before Section 112, ¶ 1. However, the order of those paragraphs instead follows the order in which the elements are to appear in the application specification.

complementary, approach a similar problem from different directions.”) (quoting *Rengo Co. Ltd. v. Molins Mach. Co.*, 657 F.2d 535, 551 (3d Cir. 1981)). Written description and enablement, as is the case for definiteness, must be considered in light of each claim separately, *i.e.*, for each claimed invention, and not by looking at the description portion of the specification alone.

Consequently, one seeking to evaluate the specification’s disclosure cannot look at ¶ 1 without also looking at ¶ 2 since adequate disclosure depends, in the first instance, on a well-drafted (particular and distinct) identification of the invention in the claim. If, for example, the claim is flawed as indistinct and it fails to clearly point out what the invention is, a search for a satisfactory written description of the “invention” in the description part of the application would be difficult at best. Likewise, the enablement requirement applies to the “invention” that is defined by the claim, not to some vague notion of an “invention” that is somehow contained in the description.

Third, a claim can and will very often identify the invention without “describing” it. *Ko ito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004) (“This Court has interpreted 35 U.S.C. § 112, ¶ 1, to require the patent specification to ‘describe the claimed invention so that one skilled in the art can recognize what is claimed.’”) (quoting *Enzo Biochem*, 323 F.3d at 968). A claim will often point out the subject matter of the claimed invention in patent-

legal language, consistent with Section 112, ¶ 2, with language that is not generally accessible to a person of ordinary skill in the art, who is usually a non-lawyer. To make the identification of the invention accessible to the public, Section 112, ¶ 1 requires a “written description” of the invention that is accessible to one of ordinary skill in the art, over and above the patent-legal language in the claim that identifies the invention. *See Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (“Thus, an applicant complies with the written description requirement ‘by describing the invention, with all its claimed limitations...,’ and by using ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.’”) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1989)).

Fourth and finally, there is an inherent circularity in the analysis of the disclosure requirements, which points to the necessity for an “as a whole” analysis. As stated above, the analysis of the written description and enablement requirements must be undertaken in light of the invention as identified individually in each claim of the application or patent. But the claim is required to be “read in view of the specification.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). Thus, the description must describe the invention identified in the claim, and the claimed invention must be interpreted in light of the

description. Only an “as a whole” approach could encompass the totality of this analysis.

If AIPLA’s “as a whole” analysis is adopted, the content of each individual requirement would remain unchanged; only the ultimate determination on the sufficiency of the disclosure for deciding patent validity would change. That determination would be required to take into account the effect of the specification as a whole, including all of the disclosure requirements of Section 112, based upon the understanding of the invention by a person of skill in the art.

In summary, the three aspects of patent disclosure under Section 112, ¶¶ 1 and 2 – a claim which identifies the invention particularly and distinctly, a written description of that invention, and enablement of the invention to one of skill in the art – must all be considered together to determine whether the disclosure requirements of Section 112 are met. The analysis must be done separately in light of each claim, *i.e.*, for each claimed invention, and not by looking at the descriptions alone.

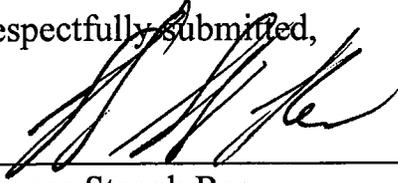
CONCLUSION

For the foregoing reasons, the Court should adopt an “as a whole” approach to determining compliance with the disclosure requirements of Section 112.

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I hereby certify that on November 19, 2009, I caused two true and correct copies of the foregoing Brief Of Amicus Curiae The American Intellectual Property Law Association In Support Of Appellant On Rehearing En Banc to be served via Federal Express, next day delivery, to the counsel of record listed below:

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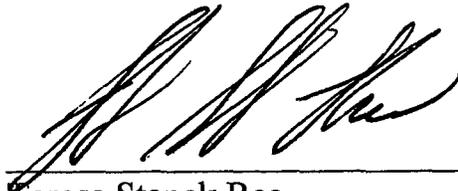


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