No. 01-1230

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ENZO BIOCHEM, INC.,
Plaintiff-Appellant,

v.

GEN-PROBE INCORPORATED, CHUGAI PHARMA U.S.A., INC., CHUGAI PHARMACEUTICAL CO., LTD., BIOMERIEUX, INC., and BECTON DICKINSON AND COMPANY,
Defendants-Appellees.

Appeal from the United States District Court for the Southern District of New York in 99-CV-4548, Judge Alvin K. Hellerstein

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BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF REHEARING *EN BANC*

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INTRODUCTION

Pursuant to the June 25, 2002 letter from the Court, the United States respectfully submits this *amicus curiae* brief in support of the petition for rehearing *en banc*. See also Fed. R. App. P. 29 & 35.

INTEREST OF THE UNITED STATES

The United States has a substantial interest in this case. The panel has invalidated a patent that refers to three deposits of biological material on the ground that the patent failed to provide an adequate "written description of the invention." See 35 U.S.C. § 112 ¶ 1. The decision will require the United States Patent & Trademark Office to make significant changes in its examination of biological patent applications. Moreover, the reasoning of the panel majority calls into question the validity of many existing patents which, like the patent in this case, refer to deposits of biological material as part of their written description.

STATEMENT

1. The United States Patent and Trademark Office (USPTO) "shall be responsible for the granting and issuing of patents* * * ." 35 U.S.C. § 2(a). "Whoever invents or discovers any new and useful * * * composition of matter * * * may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. To obtain a patent, the inventor must submit to the USPTO an application that includes a "specification as prescribed by section 112" of Title 35. 35 U.S.C. § 111. Section 112 requires that the specification "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same * * * *." 35 U.S.C. § 112 ¶ 1.

The Director of the USPTO causes "an examination to be made of the [patent] application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 35 U.S.C. § 131.

2. The USPTO has adopted regulations governing the placement of biological matter in public depositories. See Deposit of Biological Materials for Patent Purposes, 54 F.R. 34864, 34879 (Aug. 22, 1989); 37 C.F.R. § 1.801-1.809. The regulations refer to "biological matter," which includes "bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds" and "other non-living material existing in and reproducible from a living cell * * * ." 37 C.F.R. § 1.801. "Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material." Id. at § 1.802(a). "Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112." Id. at § 1.802(b). "For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository." Id. at § 1.809(d).

3. This case involves the adequacy of the written description contained in a patent issued to Enzo Biochem, Inc. (Enzo) concerning biological probes useful for detecting the bacteria that causes gonorrhea. Of most interest here, Enzo's fourth claim involves three probes deposited with the American Type Culture Collection

(ATCC).[1] Enzo sued Gen-Probe Inc. and others for infringement. The defendants moved for summary judgment, arguing that the patent was invalid because it did not satisfy the written description requirement contained in 35 U.S.C. § 112. See 35 U.S.C. § 282(3) (defenses to infringement action include that a patent is invalid for failure to comply with requirements of section 112). The district court, in oral remarks from the bench, granted that motion.

A divided panel of this Court affirmed. 285 F.3d 1013. The majority held "that Enzo's description of its reduction to practice," – i.e., the reference to the three probes – "unaccompanied by any written disclosure of meaningful, distinguishing characteristics of the claimed invention, does not satisfy the written description requirement of 112, ¶ 1." Id. at 1023. Judge Dyk dissented. In his view, a "specification that describes the invention by reference to a deposit of a sample of the invention in a recognized depository is an ideal way of satisfying the written description requirement." Id. at 1027.

[1] For the purposes of this brief, we do not address the portion of the fourth claim that refers to "mutated" nucleotide sequences and "mixtures." We also note that this case involves amended rather than original claims. See C.A. App. 642-643.

ARGUMENT

THIS PROCEEDING INVOLVES QUESTIONS OF EXCEPTIONAL IMPORTANCE THAT WARRANT THE COURT'S *EN BANC* REVIEW

Title 35, section 112 provides that the "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112 ¶ 1. This Court has explained that section 112 ¶ 1 has three requirements: (1) a "written description" requirement, which is at issue here; (2) an "enablement" requirement, which serves to permit those skilled in the art to "make and use the claimed invention without undue experimentation," In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); and (3) a "best mode" requirement, which serves to convey "the preferred mode contemplated by the applicant" for carrying out the invention, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

Although this Court has addressed the "written description" requirement of section 112 on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement. In this case, that uncertainty has contributed to a decision that appears to exclude from the written description analysis any references to a deposit of biological material. Such a holding puts at risk numerous biological patents that rely on a reference to a deposit to help meet section 112. Rehearing *en banc* would provide a useful opportunity for the

Court to give plenary consideration to the meaning of the written description provision, including the role of biological deposits in meeting that requirement, so as to provide needed guidance to inventors, the public, and the USPTO.

1. To place the present controversy in context, we begin by reviewing the state of the law prior to this case regarding the "written description" requirement of section 112. A review of the plain text of section 112, and the case law of this Court, reveals at least three different possible tests for an adequate "written description."

A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention. The statute provides that the "specification shall contain a written description of the invention * * * in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." 35 U.S.C. § 112 ¶ 1. Thus, an adequate written description assures that others can "make and use" the invention. Even if a written description provides the "manner and process of making and using" the invention, a description of the invention itself is still necessary to enable others to make and use it. Indeed, consistent with the plain text of the statute, this Court has suggested that "[t]he purpose of the [written] description requirement [of section 112, first paragraph] is to state what is needed to fulfill the enablement criteria." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991) (citing Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421, 5 U.S.P.Q.2d 1194, 1197 (Fed. Cir. 1987), cert. denied, 486 U.S. 1008 (1988)). In Vas-Cath, however, the Court declined to adopt this straightforward reading of the statute. The Court did not rely on the text of the statute. Instead, the

Vas-Cath panel felt bound by an earlier decision, In re Wilder, 736 F.2d 1516, 1520, 222 U.S.P.Q. 369, 372 (Fed. Cir. 1984), cert. denied, 469 U.S. 1209 (1985), which had stated that the written description requirement is "separate and distinct" from the enablement requirement. 935 F.2d at 1563 ("decisions of a three-judge panel of this court cannot overturn prior precedential decisions").

A second test for an adequate written description – one that is "separate and distinct" from the enablement requirement – is whether or not the description establishes that the inventor had "possession" of the invention. In the context of disputes about whether an amendment to an existing patent impermissibly includes new matter, the "description of the [patented] invention guards against the inventor's overreaching 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 (quotation and citation omitted). In this and similar contexts, there is a "fairly uniform standard for determining compliance with the 'written description' requirement has been maintained throughout: * * * whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had **possession** at that time of the later claimed subject matter." Id. at 1563 (quotation and citations omitted) (emphasis added).[2] Accord Lockwood v. American Airlines, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961 (Fed. Cir. 1997) ("all that is

[2] The panel majority states that the possession test is "useful when a patentee is claiming entitlement to an earlier filing date under 35 U.S.C. §§ 119 or 120, in interferences in which the issue is whether a count is supported by the specification of one more of the parties, and in ex parte applications in which a claim at issue was filed subsequent to the application." 285 F.3d at 1021.

necessary to satisfy the description requirement is to show that one is 'in possession' of the invention"). We note, however, that the word "possession" does not appear in section 112.[3]

In addition to the enablement and possession tests, this Court arguably recognized a third purpose of the written description requirement in Regents of the University of Cal. v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1601 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). There, the Court stated that the written description must be "sufficient to distinguish" the claimed subject matter "from other materials." Id. at 1568. Prior to Eli Lilly, however, this Court had not emphasized the "sufficient to distinguish" test for an adequate written description. See, e.g., Vas-Cath, 935 F.2d at 1560 (noting that the written description requirement "was a part of the patent statutes at a time *before* claims were required").[4] Moreover, Eli Lilly relied heavily on cases stating that the test for written description is

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[3] An alternative analysis of new matter and similar disputes would ask directly whether the contested matter is "new." See, e.g., In re Barker, 559 F.2d 588, 594 (C.C.P.A. 1977) (Rich, J., concurring) ("basic problem here is simple: new matter, in violation of 35 U.S.C. § 132, was inserted * * *), cert. denied, 434 U.S. 1064 (1978). This Court, however, has held that the "proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure [] is § 112, first paragraph, not § 132." In re Rasmussen, 650 F.2d 1212, 1213, 211 U.S.P.Q. 323 (C.C.P.A. 1981).

[4] See also Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434 (1822) (explaining that the purpose of the written specification was to enable others to make the invention and to inform the public "what the party claims as his own invention"); Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 57, 39 U.S.P.Q. 242 (1938).

"possession," see, e.g., 119 F.3d at 1566 (quoting Lockwood), and Eli Lilly did not expressly disavow the "possession" test.

After Eli Lilly, the USPTO sought to clarify for inventors and the public how it would examine patents for an adequate written description. In 1998, the USPTO published for public comment proposed Guidelines for examination of patents for compliance with the written description requirement. Request for Comments on Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 63 F.R. 32639 (June 15, 1998). In 1999, the USPTO again sought comment on proposed written description guidelines. 64 F.R. 71427 (1999). In 2001, after extensive public discussion, the USPTO issued its final guidelines on the topic. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 F.R. 1099 (Jan. 5, 2001) (Guidelines).

The overriding theme of the Guidelines is that the touchstone of the "written description" requirement is whether the inventor has shown "possession" of the invention. Explaining the law of this Court, the Guidelines repeatedly state that "[t]he purpose of the written description analysis is to confirm that applicant had possession of what is claimed." 66 F.R. at 1100. See, e.g., ibid. ("an *adequate* written description * * * establishes that the inventor was in possession of the invention"); ibid. ("written description requirement * * * ensures that the inventor conveys to others that he or she had possession of the claimed invention"); id. at 1102 ("the Court has clearly indicated that possession is a cornerstone of the written description inquiry"); id. at 1103 ("To satisfy the written description requirement of

35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of the filing.").

While emphasizing "possession," the Guidelines observe that they are consistent with Eli Lilly. The Guidelines explain that Eli Lilly is best understood as an application of the "possession" test, noting that "Eli Lilly identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." 66 F.R. at 1100.

Despite the many efforts of panels of this Court and the extensive efforts of the USPTO, the opinions in this case reflect continuing uncertainty over the proper test for an adequate written description. The majority held that the written description must include "meaningful, distinguishing characteristics for the claimed invention." 285 F.3d at 1023. Unlike in Eli Lilly, it is not possible to explain the panel majority's decision in terms of this Court's "possession" test for an adequate written description. See, e.g., 285 F.3d at 1021 (a showing of "possession" is "secondary to the *statutory mandate* that '[t]he specification shall contain a written description'"). *En banc* consideration of the written description provision is appropriate so that the Court can provide inventors, the public, and the USPTO with an authoritative interpretation of the provision.

2. In applying its "notice" interpretation of the written description requirement to this case, the majority appears to have held that a reference to a biological deposit can never, even when words alone cannot describe the biological invention, help meet the written description requirement. That holding calls into question the validity of

numerous biological patents that refer to deposits as part of the written description requirement.

The panel majority states, correctly, that a deposit cannot "substitute" for a written description of the deposit. See, e.g., 285 F.3d at 1021, citing 66 F.R. at 1108 n.6 ("a deposit is not a substitute for a written description"). A deposit does not eliminate the need for a written description that permits examination of the invention. In re Lundak, 773 F.2d 1216, 1223, 227 U.S.P.Q. 90 (Fed. Cir. 1985) ("The examination for patentability proceeds solely on the basis of the written description."). For that reason, a patent application that provides only the accession number, date, and location of a deposited invention is never sufficient: the inventor must also "specifically identify" the invention. 37 C.F.R. § 1.804(a). A specifically identified deposit permits examination of the claimed invention for compliance with the legal requirements for issuing a patent.[5] See 54 F.R. at 34874 (rejecting suggestion that inventor must "[f]ully identify and describe the deposited material").

Nevertheless, the panel majority's holding is not confined to the rule that a deposit, without more, fails to provide an adequate written description. Instead, under the panel's opinion, a reference to a deposit appears to have no role in the notice inquiry mandated by the panel's interpretation of the written description requirement. The majority held "that Enzo's description of its reduction to practice," – i.e., the reference to its deposits of the three probes – "unaccompanied by any written disclosure of meaningful, distinguishing characteristics of the claimed

[5] For example, an inventor can limit a broad claim to deposited material, thereby distinguishing the invention from existing inventions.

invention, does not satisfy the written description requirement of 112, ¶ 1." 285 F.3d at 1023. In other words, regardless of any description of a deposit, the panel majority requires an additional description that independently provides the "meaningful, distinguishing characteristics of the claimed invention."[6] By eliminating the reference to a deposit from its written description analysis, the panel majority appears to adopt a categorical rule that prohibits inventors from relying on references to deposits to help meet the written description provision.

The panel majority's categorical rejection of including deposits in its written description analysis is not altered by its assertion that, in this case, the inventor could have provided more written information about the deposited material. The panel majority states that "[t]his is not a case in which the inventors could not have provided a description of the nucleotide sequences." 285 F.3d at 1022. But, at least from the facts discussed in the court's opinion, it is unclear whether a written description of the nucleotide sequence would have been of any help to the USPTO and the public in determining the scope of the claimed invention.[7] (The panel majority declined to require a factual hearing.) In any event, it is impossible to confine the consequences of the majority's statutory reading to the particular facts of this case. See 66 F.R. at 1099 (Guidelines "applicable to all technologies").

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[6] Similarly, the majority states that a reference to a deposit "is not describing the invention in the patent." 285 F.3d at 1023. The majority also states that Enzo's showing of "'possession' of the invention" – i.e., its deposits – "does not contribute to its description of the patent specification." 285 F.3d at 1021.

[7] We note that the Background of the Invention literature cited in Enzo's patent does not identify DNA by nucleotide sequence.

Needless to say, the panel majority's prohibition on relying on references to deposits is not necessary under the enablement or possession test for an adequate written description. There is no dispute that a deposit of the invention establishes possession of the invention. See 285 F.3d at 1021. So too, there is no dispute that a deposit of the invention helps to enable others to make and use the invention. See 285 F.3d at 1023.

And, contrary to the view of the panel majority, a reference to a deposit is also part of a written description that can help to distinguish the invention. The accession numbers and other deposit information are "written" in the patent application. Although the reference may not "describe" a biological invention in the same way that (for example) a diagram or a blueprint describes a mechanical invention, an accession number and other deposit information identify the invention in much the same way that the reference number and other record information on a book in a library helps to identify the book. As a practical matter, the deposit reference is a well-recognized and useful means of identifying precisely what the applicant has invented. Anyone can use the deposit reference to obtain a sample of the deposit – i.e., the invention itself – and one skilled in the art can readily fully identify the invention by examining the deposit. Thus, to the extent that the written description requirement is meant to identify the invention, there is no textual or practical reason why an applicant should not be able to rely on a deposit reference as part of the written description.

The panel majority's holding is exceptionally important because it puts at risk numerous patents that rely on a reference to a biological deposit. For many years,

inventors have often sought to satisfy section 112 by referring to deposits of biological material.[8] Indeed, the two major Supreme Court cases on patenting living inventions, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (Patent No. 4,259,444), and J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (e.g., Patent No. 5,491,295), both involved patents that refer to biological deposits.[9] The "ability to describe the invention using a deposit has contributed to the United States biotechnology industry being a world leader in that field." Letter from Director of the USPTO to Associate Director of General Accounting Office, Oct. 4, 2000 (reproduced at p. 32 of United States General Accounting Office, Intellectual Property: Deposits of Biological Materials in Support of Certain Patent Applications, Report to Congressional Committees (October 2000)). See generally Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushifi Co., Ltd., 122 S. Ct. 1831, 1837 (2002) ("Often the invention is novel and words do not exist to describe it. The dictionary does not always keep abreast of the inventor. It cannot. Things are not made for the sake of words, but words for things.").

The panel's decision, which calls a common and critical use of the deposit system into question, warrants rehearing *en banc*.

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[8] At least 8,000 existing U.S. patents refer to biological deposits in the claims section of the patent, and at least 35,000 existing U.S. patents refer to biological deposits elsewhere in the patent.

[9] For the full text of these patents, search by patent number at http://patft.uspto.gov.

CONCLUSION

For the foregoing reasons, the Court should grant rehearing *en banc*.

Respectfully submitted,

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JULY 2002

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of July 2002, I served the foregoing **BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF REHEARING *EN BANC*** upon counsel of record by causing two copies to be sent by Federal Express for overnight delivery and one copy to be sent via fax to:

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