United States Court of Appeals for the Federal Circuit

01-1230

ENZO BIOCHEM, INC.,

Plaintiff-Appellant,

v.

GEN-PROBE INCORPORATED,

and

CHUGAI PHARMA U.S.A., INC. and CHUGAI PHARMACEUTICAL CO., LTD.,

and

BIOMERIEUX, INC.,

and

BECTON DICKINSON AND COMPANY,

Defendants-Appellees,

and

BIOMERIEUX SA,

Defendant.

Richard L. Delucia, Kenyon & Kenyon, of New York, New York, filed a petition for rehearing en banc for plaintiff-appellant. With him on the petition were Charles A. Weiss and Bradley S. Corsello.

The appellees filed a consolidated response to the petition for rehearing en banc. William F. Lee, Hale and Dorr LLP, of Boston, Massachusetts, for defendant-appellee Gen-Probe Incorporated. With him on the response was William G. McElwain.

Robert J. Gunther, Jr., Latham & Watkins, of New York, New York, for defendants-appellees Chugai Pharma U.S.A., Inc. and Chugai Pharmaceutical Co., Ltd. With him on the response was Jeffrey A. Tochner. Of counsel was Kurt M. Rogers.

Daniel A. Boehnen, McDonnell Boehnen Hulbert & Berghoff, of Chicago, Illinois, for defendant-appellee Biomerieux, Inc. With him on the response was Joshua R. Rich.

Donald R. Ware, Foley Hoag & Eliot LLP, of Boston, Massachusetts, for defendant-appellee Becton Dickinson and Company. With him on the response was Barbara A. Fiacco.

Frank P. Porcelli, Fish & Richardson P.C., of Boston, Massachusetts, filed a brief for amicus curiae Fish & Richardson P.C. Of counsel on the brief were Robert E. Hillman and Charles H. Sanders.

Mark S. Davies, Attorney, Appellate Staff, Civil Division, Department of Justice, of Washington, DC, filed an amicus curiae brief for the United States in support of rehearing en banc. With him on the brief were Robert D. McCallum, Jr., Assistant Attorney General, and Scott R. McIntosh, Attorney. Of counsel on the brief was John M. Whealan, Solicitor, U.S. Patent and Trademark Office, of Arlington, Virginia.

Appealed from: United States District Court for the Southern District of New York

Judge Alvin K. Hellerstein

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DECIDED: July 15, 2002

Before LOURIE, DYK, and PROST, Circuit Judges.

ON PETITION FOR REHEARING

LOURIE, Circuit Judge.

Enzo Biochem, Inc. petitions for rehearing of this appeal following our prior decision, reported at 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002), in which we affirmed the decision of the United States District Court for the Southern District of New York. The district court had granted Gen-Probe Incorporated, Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., Biomerieux, Inc., Biomerieux SA, and Becton Dickinson and Company's (collectively, "the defendants'") motion for summary judgment that claims 1-6 of U.S. Patent 4,900,659 are invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. Enzo Biochem, Inc. v. Gen-Probe Inc., No. 99 Civ. 4548 (S.D.N.Y. Apr. 4, 2001) (final order). Having considered Enzo's petition for rehearing and the defendants' response,[1] we have determined that our prior decision that a deposit may not satisfy the written description requirement was incorrect. We therefore grant Enzo's petition for rehearing, vacate the prior decision, and reverse the district court's grant of summary judgment that Enzo's claims are invalid for failure to meet the written description requirement. Because genuine issues of material fact exist regarding satisfaction of the written description requirement, we remand.

BACKGROUND

Enzo is the assignee of the '659 patent, which is directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that cause gonorrhea, Neisseria gonorrhoeae. N. gonorrhoeae reportedly has between eighty and ninety-three percent homology with Neisseria meningitidis. '659 patent, col. 2, ll. 61-64. Such a high degree of homology has made detection of N. gonorrhoeae difficult, as any probe capable of detecting N. gonorrhoeae may also show a positive result when only N. meningitidis is present. Enzo recognized the need for a chromosomal DNA probe specific for N. gonorrhoeae, and it derived three such sequences that preferentially hybridized to six common strains of N. gonorrhoeae over six common strains of N. meningitidis. Id. at col. 3, l. 49 to col. 4, l. 14; col. 4, ll. 45-50. The inventors believed that if the preferential hybridization ratio of N. gonorrhoeae to N. meningitidis were greater than about five to one, then the "discrete nucleotide sequence [would] hybridize to virtually all strains of Neisseria gonorrhoeae and to no strain of Neisseria meningitidis." Id. at col. 12, ll. 60-65. The three sequences that the inventors actually derived had a selective hybridization ratio of greater than fifty. Id. at col. 13, ll. 9-15. Enzo deposited those sequences in the form of a recombinant DNA molecule within an E. coli bacterial host at the American Type Culture Collection. Id. at col. 13, ll. 27-31.

Claim 1 is as follows:

1. A composition of matter that is specific for Neisseria gonorrhoeae comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater

than about five, said ratio being obtained by a method comprising the following steps;

(a) providing a radioactively labeled form of said nucleotide sequence;

(b) providing a serial dilution series of purified chromosomal DNA from each of the N. gonorrhoeae strains; (1) ATCC 53420, (2) ATCC 53421, (3) ATCC 53422, (4) ATCC 53423, (5) ATCC 53424, (6) ATCC 53425, and forming test dots from each of said dilution series on a matrix;

(c) providing a serial dilution series of purified nucleotide sequences from each of the N. meningitidis strains: (1) ATCC 53414, (2) ATCC 53415, (3) ATCC 53416, (4) ATCC 53417, (5) ATCC 53418, (6) ATCC 53419, and forming test dots from each of said dilution series on a matrix;

(d) hybridizing equal portions of the labeled nucleotide sequences to the matrix provided in step (b) and (c), respectively; wherein the hybridization is conducted in a solution having a salt concentration of 2X SSC at (i) 65°C. in cases in which the sequence has greater than 50 base pairs or (ii) at Tm (°C.) minus 30°C. in cases in which the sequence has less than 50 base pairs, wherein Tm is the denaturation temperature of the sequence;

(e) quantifying the labeled nucleotide sequence hybridized in step (d) to each test dot;

(f) subtracting from the data of step (e) an averaged amount of radioactivity attributable to background to obtain a corrected amount of hybridized radioactivity at each test dot;

(g) normalizing the data of step (f) by multiplying the amount of corrected radioactivity at each test dot by a factor which adjusts the amount of radioactivity to equal amounts of chromosomal DNA at each test dot;

(h) selecting two normalized values that are most nearly the same and that correspond to adjacent members of the dilution series for each of the above strains of N. gonorrhoeae and obtaining the average of the selected values;

(i) selecting two normalized values that are most nearly the same and that correspond to adjacent members of the dilution series for each of the above strains of N. meningitidis and obtaining the average of the selected values;

(j) dividing the lowest average obtained in step (h) by the highest average obtained in step (i) to obtain said ratio.

Id. at col. 27, l. 29 to col. 28, l. 27 (emphasis added). Claims 2 and 3 depend from claim 1 and further limit the hybridization ratio to greater than about twenty-five and fifty, respectively. Id. at col. 2, ll. 27-30. Claim 4 is directed to the three deposited sequences (referenced by their accession numbers) and variants thereof as follows:

4. The composition of claim 1 wherein said nucleotide sequences are selected from the group consisting of:

a. the Neisseria gonorroheae [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof,

b. mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof; and

c. mixtures thereof.

Id. at col. 28, ll. 31-39. Claim 5 is directed to an assay for detection of N. gonorrhoeae using the composition of claim 1. Id. at ll. 40-46. Claim 6 further limits the method of claim 5 to the nucleotide sequences that Enzo deposited (i.e., those in claim 4) and variants thereof. Id. at ll. 47-56.

Enzo sued the defendants for infringement of the '659 patent, and the defendants moved for summary judgment that the claims were invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. The district court, in oral remarks from the bench, granted that motion. Tr. of Hr'g at 42, Enzo Biochem, Inc. v. Gen-Probe, Inc., No. 99-CV-4548 (S.D.N.Y. Jan. 24, 2001). It concluded that the claimed composition of matter was defined only by its biological activity or function, viz., the ability to hybridize to N. gonorrhoeae in a ratio of better than about five with respect to N. meningitidis, which it was held was insufficient to satisfy the § 112, ¶ 1 requirement set forth in this court's holdings in Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). Tr. of Hr'g at 28. The court rejected Enzo's argument that the reference in the specification to the deposits of biological materials in a public depository inherently disclosed that the inventors were in possession of the claimed sequences. Id. at 35. It distinguished this court's precedents concerning deposits as relating to the enablement requirement of § 112, ¶ 1. Id. at 38-40. Enzo appealed to this court; we have jurisdiction pursuant to 28 U.S.C. § 1295 (a)(1).

DISCUSSION

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). On motion for summary judgment, the court views the evidence and any disputed factual issues in the light most favorable to the party opposing the motion. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). A patent is presumed to be valid, 35 U.S.C. § 282 (1994), and this presumption can be overcome only by facts supported by clear and convincing evidence to the contrary, see, e.g., WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1396-97 (Fed. Cir. 1999). Compliance with the written description requirement is a question of fact. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir.

1991).

Enzo argues that the testimony of its expert, Dr. Wetmer, raised a genuine factual issue whether the reference to the deposits inherently described the claimed nucleotide sequences. Enzo also argues that its description of the binding affinity of the claimed nucleotide sequences satisfies the requirement set forth in the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) ("Guidelines"). Enzo asserts that the court erred in not evaluating the patentability of the claims separately, pointing out that claims 4 and 6 are directed to the three deposited sequences and variations and mixtures thereof. Enzo further asserts that the claims per se meet the written description requirement because they appear in ipsis verbis in the written description. Enzo also argues that this court's articulation of the written description requirement for genetic material in Eli Lilly should not apply to this case because Enzo reduced the invention to practice and deposited the derived biological materials, thereby demonstrating its "possession" of the invention.

The defendants respond that the district court properly granted summary judgment because the patent described the claimed nucleotide sequences only by their function, which they state is insufficient to meet the requirements of § 112, ¶ 1 as a matter of law, even as to the narrower claims directed to the deposited materials. The defendants also assert that Dr. Wetmur's opinion that the deposited genetic materials could have been sequenced did not cure the actual failure of the inventors to identify them by some distinguishing characteristic, such as their structure. Moreover, the defendants point out that claims 4 and 6, which are directed to the deposited materials, each cover a broad genus of nucleic acids. The defendants also urge that in ipsis verbis support for the claims in the specification does not per se establish compliance with the written description requirement. Finally, the defendants assert that the district court did not err in its determination that Enzo's "possession" of three nucleotide sequences that it reduced to practice and deposited nevertheless did not satisfy the written description requirement of § 112, ¶ 1.

The written description requirement of § 112, ¶ 1 is set forth as follows:

> 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 (1994) (emphasis added). We have interpreted that section as requiring a "written description" of an invention separate from enablement. Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1117 (recognizing the severability of the "written description" and "enablement" provisions of § 112, ¶ 1). Compliance with the written description requirement is essentially a fact-based inquiry that will "necessarily vary depending on the nature of the invention claimed." Id. (citing In re DiLeone, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971)). We have also previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has been defined only by a statement of function or result, and have held that such a statement alone did not adequately describe the claimed invention. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. In Eli Lilly, we concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. Id. at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. Id. We stated that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention," and that none of those descriptions appeared in that patent. Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The specification in the Eli Lilly case thus did not show that the inventors had possession of human insulin cDNA.

It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. The PTO has issued Guidelines governing its internal practice for addressing that issue. The Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the

statute. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10, 33 USPQ2d 1823, 1828 n.10 (Fed. Cir. 1995). In its Guidelines, the PTO has determined that the written description requirement can be met by "show[ing] 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." Guidelines, 66 Fed. Reg. at 1106 (emphasis added). For example, the PTO would find compliance with § 112, ¶ 1, for a claim to an "isolated antibody capable of binding to antigen X," notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/patents/guides.htm ("Application of Guidelines"). Thus, under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to N. gonorrhoeae over N. meningitidis were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement.

Applying those principles, we first inquire whether Enzo's deposits of the claimed nucleotide sequences of claims 4 and 6 may constitute an adequate description of those sequences. Secondly, we will consider whether the description requirement is met for all of the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to strains of N. gonorrhoeae that are accessible by deposit.

As to the first question, Enzo asserts that the claimed sequences are inherently described by reference to deposits of three sequences that are within the scope of its claims. Whether reference to a deposit of a nucleotide sequence may adequately describe that sequence is an issue of first impression in this court. In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, we hold

that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.

The practice of depositing biological material arose primarily to satisfy the enablement requirement of § 112, ¶ 1. For example, in In re Argoudelis, the patent application claimed antibiotic compounds that were produced by a microorganism. 434 F.2d 1390, 1390, 168 USPQ 99, 100 (CCPA 1970). The applicants deposited the microorganism because they could not "sufficiently disclose by written word how to obtain the microorganism starting material from nature." Id. at 1392, 168 USPQ at 102. By making the biological material accessible to the public, they enabled the public to make and use the claimed antibiotics. Id. at 1393, 168 USPQ at 102-03. In Amgen, we noted the relevance of deposit practice to satisfaction of the enablement requirement but rejected the defendants' argument that a deposit was necessary in that case to satisfy the best mode requirement of § 112, ¶ 1. See 927 F.2d at 1210, 18 USPQ2d at 1024; see also In re Lundak, 773 F.2d 1216, 1217, 227 USPQ 90, 92 (Fed. Cir. 1985) (discussing deposit practice primarily in relation to an enablement rejection and noting that "[a]n accession number and deposit date add nothing to the written description of the invention" in the context of proven availability of a cell line prior to filing date).

Recognizing the importance of biological deposits to patent practice, the PTO has promulgated rules to address the procedural requirements relating to such deposits, but it has declined to expressly correlate substantive requirements relating to deposits with particular statutory requirements. See Deposit of Biological Materials for Patent Purposes, 53 Fed. Reg. 39,420, 39,425 (Oct. 6, 1988) (notice of proposed rules) (codified at 37 C.F.R. Part 1) ("The rules are not intended to address which requirements of 35 U.S.C. 112 may be met by the making of deposits."). The Office does offer guidance, however, in determining when a deposit may be necessary, such as "[w]here the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner." MPEP § 2402 (8th ed. Aug. 2001). The PTO has also issued a regulation stating when a deposit is not necessary, i.e., "if it is known and readily available to the public

or can be made or isolated without undue experimentation." 37 C.F.R. § 1.802(b) (2001). Inventions that cannot reasonably be enabled by a description in written form in the specification, but that otherwise meet the requirements for patent protection, may be described in surrogate form by a deposit that is incorporated by reference into the specification. While deposit in a public depository most often has pertained to satisfaction of the enablement requirement, we have concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material.

In this case, Enzo's deposits were incorporated by reference in the specification. A person of skill in the art, reading the accession numbers in the patent specification, can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences. '659 patent, col. 13, ll. 27-36. The sequences are thus accessible from the disclosure in the specification. Although the structures of those sequences, i.e., the exact nucleotide base pairs, are not expressly set forth in the specification, those structures may not have been reasonably obtainable and in any event were not known to Enzo when it filed its application in 1986. See '659 patent, col. 3, ll. 40-46 (noting severe time constraints in sequencing DNA). We therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.

As the defendants point out, however, Enzo's claims 4 and 6 are not limited to the deposited sequences. Claim 4 is directed to nucleotide sequences that are selected from the group consisting of the three deposited sequences, "discrete nucleotide subsequences thereof . . . mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof[,] and . . . mixtures thereof." '659 patent, col. 28, ll. 31-39. Claim 6 is also similarly directed to the three deposited sequences and subsequences and mutated variations thereof. Id. at ll. 47-56. The specification defines a subsequence non-specifically as a nucleotide sequence "greater than about 12 nucleotides." '659 patent, col. 3, ll. 29-30. As the deposited sequences are about 850, 850, and 1300 nucleotides long, id. at col. 13, ll. 47-49, there are at least hundreds of subsequences of the deposited

sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that "astronomical" numbers of mutated variations of the deposited sequences also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make a minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact that is best resolved on remand.[2] Because the district court's grant of summary judgment was based on its conclusion that Enzo's deposits could not satisfy the written description requirement as a matter of law, we reverse the district court's grant of summary judgment that claims 4 and 6 are invalid for failure to meet the written description requirement. On remand, the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims.

We next address the question whether the compositions of the broader genus claims 1-3 and 5 are sufficiently described to meet the requirements of § 112, ¶ 1, on the basis of Enzo's deposits of three sequences. If those sequences are representative of the scope of the genus claims, i.e., if they indicate that the patentee has invented species sufficient to constitute the genera, they may be representative of the scope of those claims. See In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) (discussing circumstances in which a species may be representative of and therefore descriptive of genus claims). Because the district court concluded that the deposited sequences were not themselves described, it did not determine whether that description was representative of the genera in those claims. Such determination should be made on remand.

When we addressed a similar issue in Eli Lilly, we determined that a disclosure of the sequence of rat cDNA was not descriptive of the broader invention consisting of mammalian and vertebrate

cDNA, although it was a species falling within the scope of those claims. Eli Lilly, 119 F.3d at 1567-68, 43 USPQ2d at 1405. In Eli Lilly, the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others. Id. at 1568, 43 USPQ2d at 1405. Nor did the specification describe a sufficient number of species within the very broad genus to indicate that the inventors had made a generic invention, i.e., that they had possession of the breadth of the genus, as opposed to merely one or two such species. Id. The PTO has included a hypothetical example based on the facts of Eli Lilly in its Synopsis of Application of Written Description Guidelines in which the description requirement is not met. See Application of Guidelines, Example 17, at 61-64. The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar. See id., Example 9, at 35-37. Whether the disclosure provided by the three deposits in this case, coupled with the skill of the art, describes the genera of claims 1-3 and 5 is a fact question the district court did not address. On remand, the district court should determine, consistently with the precedent of this court and the PTO's Guidelines, whether one skilled in the art would consider the subject matter of claims 1-3 and 5 to be adequately described, recognizing the significance of the deposits and the scope of the claims.

Enzo argues that all of the claims are adequately described on another basis, viz., by means of the disclosed correlation of the function of hybridization with the bacterial DNA. In its petition for rehearing, Enzo states as attorney argument that "[t]he description and claiming of biological materials by their affinity to other materials that are clearly identified in the specification and claims (the particular deposited strains of N. gonorrhoeae and N. meningitidis) inherently specifies structure, and is routine in this field." Claim 1 sets forth the deposit numbers of six strains of N. gonorrhoeae to which the claimed nucleotide sequences preferentially hybridize, as well as the deposit numbers of six strains of N. meningitidis that are thereby distinguished. Again, as with the claimed nucleotide sequences, the sequences of the genomic DNA of those bacteria are not disclosed, perhaps because such sequencing

would have been unduly burdensome at the time of Enzo's invention. '659 patent, col. 3, ll. 40-46 (noting that it would take 3,000 scientists one month to sequence the genome of one strain of N. gonorrhoeae and one strain of N. meningitidis). However, as those bacteria were deposited, their bacterial genome is accessible and, under our holding today, they are adequately described in the specification by their accession numbers. Because the claimed nucleotide sequences preferentially bind to the genomic DNA of the deposited strains of N. gonorrhoeae and have a complementary structural relationship with that DNA, those sequences, under the PTO Guidelines, may also be adequately described. Although the patent specification lacks description of the location along the bacterial DNA to which the claimed sequences bind, Enzo has at least raised a genuine issue of material fact as to whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public. Such hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate. That is a fact question. We therefore conclude that the district court erred in granting summary judgment that the claims are invalid for failure to meet the written description requirement. On remand, the court should consider whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridization function and an accessible structure, consistent with the PTO Guidelines. If so, the written description requirement would be met.

We next address Enzo's additional argument that the written description requirement for the generic claims is necessarily met as a matter of law because the claim language appears in ipsis verbis in the specification. We do not agree. Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. One may consider examples from the chemical arts. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. Similarly, the expression "an antibiotic

penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. A description of what a material does, rather than of what it is, usually does not suffice. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

In Eli Lilly, we were faced with a set of facts in which the words of the claim alone did not convey an adequate description of the invention. Id. at 1567, 43 USPQ2d at 1405. In such a situation, regardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, § 112, ¶ 1 is not necessarily met. See Guidelines at 1100 (noting Eli Lilly's clarification of the "original claim" doctrine in situations in which the name of the claimed material does not convey sufficient identifying information). If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.

Inasmuch as § 112, ¶ 1 requires such description, we are not persuaded by Enzo's argument that, because the specification indicated that Enzo "possessed" the claimed invention by reducing three sequences within the scope of the claims to practice, Enzo necessarily described the invention. It is true that in Vas-Cath, we stated: "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." Vas-Cath, 935 F.2d at 1563-64, 19 USPQ2d at 1117. That portion of the opinion in Vas-Cath, however, merely states a purpose of the written description requirement, viz., to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always sufficient to meet that requirement. Furthermore, in Lockwood v. American Airlines, Inc., we rejected Lockwood's argument that "all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention." 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Rather, we clarified that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the

claimed invention." Id.

The articulation of the written description requirement in terms of "possession" is especially meaningful 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 or more of the parties, and in ex parte applications in which a claim at issue was filed subsequent to the application. See Vas-Cath, 935 F.2d at 1560, 19 USPQ2d at 1114 (describing situations in which the written description requirement may arise); Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (noting, in the context of claiming entitlement to the priority date of an earlier application, that the written description requirement is met if "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"). Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the statutory mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

Similarly, we conclude that proof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, ¶ 1. As with "possession," proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification. We are thus not persuaded by Enzo's argument, relying on the PTO's Guidelines, that its disclosure of an actual reduction to practice is an important "safe haven" by which it has demonstrated compliance with the description requirement. The Guidelines state:

> Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming

> components and combining steps, in such a way as to distinguish the composition with particularity from all others.

Guidelines, 66 Fed. Reg. at 1101. For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material, as we have held today. That compliance is grounded on the fact of the deposit and the accession number in the specification, not because a reduction to practice has occurred. Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.

CONCLUSION

For the foregoing reasons, we conclude that the district court erred in granting summary judgment that the claims of the '659 patent are invalid for failure to meet the written description requirement of § 112, ¶ 1. While the district judge clearly understood and correctly applied this court's existing precedent, we nevertheless reverse because this case has taken us into new territory and we have held, as a matter of first impression, that reference in a patent specification to a deposit of genetic material may suffice to describe that material. We therefore remand for further resolution consistent with this opinion.

REVERSED and REMANDED

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[1] Amicus curiae briefs were filed by the United States Patent and Trademark Office and Fish & Richardson P.C.

[2] We do not address the issue whether the breadth of the claim may implicate other validity issues, such as enablement. Only written description is before us.