United States Court of Appeals for the Federal Circuit

03-1304

UNIVERSITY OF ROCHESTER,

Plaintiff-Appellant,

v.

G.D. SEARLE & CO., INC.,
MONSANTO COMPANY, PHARMACIA CORPORATION,
and PFIZER INC.,

Defendants-Appellees.

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Daniel J. Furniss, Townsend and Townsend and Crew LLP, of Palo Alto, California, for amici curiae The Regents of the University of California, et al. With him on the brief were Susan M. Spaeth and Madison C. Jellins.

James J. Kelley, Eli Lilly and Company, of Indianapolis, Indiana, for amicus curiae Eli Lilly and Company. With him on the brief were Steven P. Caltrider, Michael T. Bates, Robert A. Armitage, Gilbert T. Voy, and Gregory C. Cox.

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

Judge David G. Larimer

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Defendants-Appellees.

DECIDED: February 13, 2004

Before LOURIE, BRYSON, and DYK, Circuit Judges.

LOURIE, Circuit Judge.

The University of Rochester ("Rochester") appeals from the decision of the United States District Court for the Western District of New York granting summary judgment that United States Patent 6,048,850 is invalid. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216 (W.D.N.Y. 2003). Because we conclude that the court did not err in holding the '850 patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment on that ground, we affirm.

BACKGROUND

Traditional non-steroidal anti-inflammatory drugs ("NSAIDs") such as aspirin, ibuprofen, ketoprofen, and naproxen are believed to function by inhibiting the activity of enzymes called cyclooxygenases. Cyclooxygenases catalyze the production of a molecule called prostaglandin H_2, which is a precursor for other prostaglandins that perform various functions in the human body. Id. at 219.

In the early 1990s, scientists discovered the existence and separate functions of two distinct cyclooxygenases, referred to as "COX-1" and "COX-2."[1] COX-1 is expressed (i.e., produced biologically) in the gastrointestinal tract, where it is involved in the production of prostaglandins that serve a beneficial role by, for example, providing protection for the stomach lining. Id. COX-2 is expressed in response to inflammatory stimuli, and is thought to be responsible for the inflammation associated with diseases such as arthritis. Id. It is now known that the traditional NSAIDs inhibit both COX-1 and COX-2, and as a result they not only reduce inflammation, but also can cause undesirable side effects such as stomach upset, irritation, ulcers, and bleeding. Id.

After the separate functions of COX-1 and COX-2 were discovered, it was hypothesized that it would be possible to reduce inflammation without gastrointestinal side effects if a method could be found for selectively inhibiting the activity of COX-2 (i.e., inhibiting the activity of COX-2 without inhibiting COX-1 activity). Id. To that end, Rochester scientists developed a screening assay for use in determining whether a particular drug displayed such selectivity, and filed a U.S. patent application directed to their developments in 1992. After filing a series of continuation, continuation-in-part, and divisional applications derived from that 1992 application, the scientists eventually received United States Patent 5,837,479 in 1998, covering methods "for identifying a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2)."

From a division of the application that led to the '479 patent, the scientists also obtained, on April 11, 2000, the '850 patent. The '850 patent contains three independent claims and five dependent claims. The three independent claims read as follows:

> 1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

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[1] COX-1 and COX-2 are alternatively referred to as "PGHS-1" and "PGHS-2," respectively, where "PGHS" is an abbreviation for "prostaglandin H synthase."

5. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the activity of the non-steroidal compound does not result in significant toxic side effects in the human host.

6. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the ability of the non-steroidal compound to selectively inhibit the activity of the PGHS-2 gene product is determined by:

a) contacting a genetically engineered cell that expresses human PGHS-2, and not human PGHS-1, with the compound for 30 minutes, and exposing the cell to a pre-determined-amount of arachidonic acid;

b) contacting a genetically engineered cell that expresses human PGHS-1, and not human PGHS-2, with the compound for 30 minutes, and exposing the cell to a pre-determined amount of arachidonic acid;

c) measuring the conversion of arachidonic acid to its prostaglandin metabolite; and

d) comparing the amount of the converted arachidonic acid converted by each cell exposed to the compound to the amount of the arachidonic acid converted by control cells that were not exposed to the compound, so that the compounds that inhibit PGHS-2 and not PGHS-1 activity are identified.

'850 patent, col. 71, l. 36 - col. 72, l. 51. Thus, all eight claims are directed to methods "for selectively inhibiting PGHS-2 activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment."

On the day the '850 patent issued, Rochester sued G.D. Searle & Co., Inc., Monsanto Co., Pharmacia Corp., and Pfizer Inc. (collectively, "Pfizer"), alleging that Pfizer's sale of its COX-2 inhibitors Celebrex® and Bextra® for treatment of inflammation infringed the '850 patent,[2] and seeking injunctive and monetary relief. Univ. of Rochester, 249 F. Supp. 2d at 220. In May 2002, Pfizer moved for summary judgment of invalidity of the '850 patent for failure to comply

[2] Celebrex® and Bextra®, generically known as celecoxib and valdecoxib, respectively, were both developed by Searle, which was purchased by Monsanto in 1985. In 2000, Monsanto merged with Pharmacia & Upjohn, Inc. to form Pharmacia Corp. In 2002,

with the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1. Rochester opposed the motion and filed a cross-motion for summary judgment with respect to the written description issue. Id.

In evaluating the parties' motions, the district court found that, although all of the claims require the use of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene," the '850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research. Id. at 224-25, 228-29. Indeed, the court found no evidence in the '850 patent that the inventors themselves knew of any such compound at the time their patent application was filed. Id. at 228. Accordingly, the court concluded that the patent's claims are invalid for lack of written description. Id. at 224.

The district court also found that practice of the claimed methods would require "a person of ordinary skill in the art . . . to engage in undue experimentation, with no assurance of success," and on that basis concluded that the claims are also invalid for lack of enablement. Id. at 232. The court considered, but rejected as conclusory, Rochester's experts' opinions that one of skill in the art would have known to start with existing NSAIDs and would have used routine methods to make structural changes to lead compounds to optimize them, citing a general failure to point to any language in the patent supporting those opinions. Id. at 233.

Finding no genuine issue of material fact concerning either written description or enablement, the district court accordingly granted Pfizer's motions for summary judgment of invalidity of the '850 patent for failure to meet the written description and enablement requirements, denied Rochester's cross-motion, and dismissed the complaint. Id. at 235-36.

Rochester now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Monsanto, sans Searle, was spun off from Pharmacia, and Pharmacia merged with Pfizer in

Rochester asserts three grounds of error on appeal. First, it argues that the district court erred by granting Pfizer's motion for summary judgment of invalidity for lack of written description. Second, it argues that the court erred by granting Pfizer's motion for summary judgment of invalidity for lack of enablement. Third, Rochester contends that the court erred by denying its cross-motion for summary judgment with regard to written description. Pfizer refutes each of those asserted grounds of error.

Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998). We review a district court's grant of summary judgment de novo, reapplying the summary judgment standard. Conroy v. Reebok Int'l, 14 F.3d 1570, 1575 (Fed. Cir. 1994). In contrast, "when a district court denies summary judgment, we review that decision with considerable deference to the court," and "will not disturb the trial court's denial . . . unless we find that the court has indeed abused its discretion in so denying." Suntiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1333 (Fed. Cir. 1999). Additionally, "[w]hen evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed. Cir. 2001) ("Barr"). In that process, we draw all justifiable inferences in the nonmovant's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

An issued patent enjoys a presumption of validity, 35 U.S.C. § 282, that can be overcome only through clear and convincing evidence, U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed. Cir. 1997). Accordingly, a party "seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity." Barr, 251 F.3d at 962.

2003. The combined company has retained the name Pfizer Inc.

In its first argument, Rochester asserts that the district court effectively—but erroneously—held that a patent claiming a method of obtaining a biological effect in a human by administering a compound cannot, as a matter of law, satisfy the written description requirement without disclosing the identity of any such compound. Indeed, Rochester contends that "no written description requirement exists independent of enablement." In any event, Rochester argues that its patent met the requirements of § 112 and is not invalid.[3]

Pfizer responds to Rochester's argument by pointing out that we have "interpreted § 112 'as requiring a "written description" of an invention separate from enablement,'" (citing Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 963 (Fed. Cir. 2002)), and that "the many prior precedential decisions" contrary to Rochester's position "cannot be overruled except by an en banc decision." Pfizer also cites Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991), in which we explained that "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]," id. at 1563; and Reiffin v. Microsoft Corp., 214 F.3d 1342 (Fed. Cir. 2000), in which we stated that the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification," id. at 1345. Pfizer asserts that a patent fails to satisfy the written description requirement if it claims a method of achieving a biological effect, but discloses no compounds that can accomplish that result. It maintains that the district court correctly invalidated Rochester's '850 patent.[4]

We agree with Pfizer that our precedent recognizes a written description requirement and that the '850 patent does not satisfy that requirement. As in any case involving statutory

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[3] Rochester is supported by amici curiae the Regents of the University of California, the University of Texas Southwestern Medical Center at Dallas, and the University of Texas M.D. Anderson Cancer Center, which make essentially the same points.

[4] Pfizer is supported by amicus curiae Eli Lilly & Co., which makes similar arguments.

interpretation, we begin with the language of the statute itself. Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980). Section 112 provides, in relevant part, 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 (2000). Three separate requirements are contained in that provision: (1) "[t]he specification shall contain a written description of the invention"; (2) "[t]he specification shall contain a written description . . . of the manner and process of making and using it [i.e., the invention] 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 (3) "[t]he specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."

In common parlance, as well as in our and our predecessor court's case law, those three requirements are referred to as the "written description requirement," the "enablement requirement," and the "best mode requirement," respectively. See In re Moore, 439 F.2d 1232, 1235 (CCPA 1971) ("Robert Moore") ("This first paragraph analysis in itself contains several inquiries. Considering the language of the statute, it should be evident that these inquiries include determining whether the subject matter defined in the claims is described in the specification, whether the specification disclosure as a whole is such as to enable one skilled in the art to make and use the claimed invention, and whether the best mode contemplated by the inventor of carrying out that invention is set forth."). The United States Supreme Court also recently acknowledged written description as a statutory requirement distinct not only from the best mode requirement, but also from enablement. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) ("[A] number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not

obvious. 35 U.S.C. §§ 101-103 (1994 ed. and Supp. V). In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. § 112 (1994 ed.). These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public." (emphasis added)).

Although there is often significant overlap between the three requirements, they are nonetheless independent of each other. In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996). Thus, an invention may be described without an enabling disclosure of how to make and use it. A description of a chemical compound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described. See, e.g., In re DiLeone, 436 F.2d 1404, 1405 (CCPA 1971) ("[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention."). Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B if B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535 (Fed. Cir. 1987).

The "written description" requirement serves a teaching function, as a "quid pro quo" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." Enzo, 323 F.3d at 970. Rochester argues, however, that this teaching, or "public notice," function,[5] although "virtually unchanged since the 1793

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[5] We and the Supreme Court have frequently used the term "public notice" in connection with claims and discussion of the doctrine of equivalents, the point being that the public is entitled to notice of what the inventor has claimed and the Patent and Trademark Office has agreed should be the subject of a patent's limited right to exclude. However, while the role of the claims is to give public notice of the subject matter that is protected, the role of

Patent Act," in fact "became redundant with the advent of claims in 1870." We disagree. Statutory language does not become redundant unless repealed by Congress, in which case it no longer exists.

In addition, and most significantly, our precedent clearly recognizes a separate written description requirement. In In re Ruschig, 379 F.2d 990 (CCPA 1967), our predecessor court affirmed a rejection under 35 U.S.C. § 112 of a claim that was added to a patent application during prosecution to provoke an interference. That application had originally included a claim directed to a genus of chemical compounds, all having a central benzenesulphonylurea structure and two variable substituents attached at specified sites on that structure. Id. at 994. As a result of the way in which those substituents were defined in the claim, the genus defined by the claim included thousands of compounds, corresponding to all the possible permutations of the substituents. Id. at 993-94. The added claim, in contrast, was directed to a single member of that genus, N-(p-chlorobenzenesulfonyl)-N-propylurea. Id. at 991. Although that compound was within the literal scope of the originally filed claim, it was never "named or otherwise exemplified" in the appellants' original patent application. Id. at 992. The examiner rejected the added claim on the basis that the specific compound was not adequately supported by the specification as filed. Id.

The Patent Office Board of Appeals, and subsequently the Court of Customs and Patent Appeals, affirmed that rejection. In reaching its decision, the court observed that the claimed compound was not described in the specification and would not "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound." Id. at 996. It did not teach the specific compound. Although the appellants had argued that the rejection was improper because one skilled in the art would be enabled by the specification to make the specific compound, the court explained that it was

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the specification is to teach, both what the invention is (written description) and how to make

"doubt[ful] that the rejection [was] truly based on section 112, at least on the parts relied on by appellants [i.e., the 'language therein about enabling one skilled in the art to make the invention']. If based on section 112, it is on the requirement thereof that 'The specification shall contain a written description of the invention.'" Id. at 995-96.

While it is true that this court and its predecessor have repeatedly held that claimed subject matter "need not be described in haec verba" in the specification to satisfy the written description requirement, e.g., In re Smith, 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." Enzo, 323 F.3d at 968. We have further explained that:

> [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . 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. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] . . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

Enzo, 323 F.3d at 968. Similarly, for example, in the nineteenth century, use of the word "automobile" would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, viz., a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect.

Rochester is also factually incorrect in its assertion that a written description requirement separate from the enablement requirement was not recognized prior to Ruschig in 1967. For example, in Jepson v. Coleman, 314 F.2d 533 (CCPA 1963), our predecessor court explicitly

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and use it (enablement).

rejected the notion that an enabling disclosure necessarily satisfies the written description requirement: "It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device." Id. at 536. Still earlier, that court affirmed a decision of the Board of Appeals of the Patent Office affirming the rejection of an applicant's claims on the basis that those claims were "broader than the disclosure in appellant's application and . . . were properly rejected for that reason." In re Moore, 155 F.2d 379, 382 (CCPA 1946) ("Wm. Moore"). The court stated that it "is well settled that claims in an application which are broader than the applicant's disclosure are not allowable." Id.

Similarly, in 1962 the court affirmed the Board's rejection of the original claims in a patent application, based on, inter alia, the rejected claims' "fail[ure] to meet the requirements of 35 U.S.C. § 112 in that they are broader than the invention described in the written description thereof as set forth in the specification." In re Sus, 306 F.2d 494, 497 (CCPA 1962). In that case, the court specifically identified the "pertinent portions of 35 U.S.C. § 112 to be here considered" as the following: "'The specification shall contain a written description of the invention * * *. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.'" Id. at 494 n.1 (ellipsis in original). According to the court, "one skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals would be suitable for such purposes." Id. at 504.[6] The issues in Jepson, Wm. Moore, and Sus were clearly not confined to a

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[6] In Sus, the claims at issue were rejected by the patent examiner under 35 U.S.C. § 112, ¶ 2. However, the Court of Customs and Patent Appeals pointed out in subsequent

determination whether the enablement requirement was met. They were independent written description issues.

Rochester's suggestion in its brief that Lilly "compounded Ruschig's error" by "invoking the written description requirement in a case without priority issues" is similarly deficient. Neither Wm. Moore nor Sus, for example, involved any priority issues. Moreover, even if the court had never had occasion to apply the written description requirement to original claims prior to the 1987 Lilly decision, that requirement was nonetheless always present. As explained in Enzo:

> It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time. . . .
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> . . . As for the lack of earlier cases on this issue, it regularly happens in adjudication that issues do not arise until counsel raise them, and, when that occurs, courts are then required to decide them.

323 F.3d at 971-72 (Lourie, J., concurring in Denial of Petition for Rehearing En Banc). In any event, the basic requirement of a written description of an invention exists whether a question of priority has arisen or not. The statute does not limit the requirement to cases in which a priority question arises.

Indeed, as early as 1822 the Supreme Court recognized the existence of separate written description and enablement requirements:

> [T]he patent act requires . . . that the party [i.e., the inventor] "shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before know[n], and to enable any person skilled in the art or science, &c. &c. to make, compound, and use the same." The specification, then has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is

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cases that that rejection was "more properly considered under the first paragraph of that section." In re Robins, 429 F.2d 452, 457 n. 8 (CCPA 1970).

> already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34 (1822). The Patent Act of 1793, 1 Stat. 318, which was in force at the time Evans was decided, required, in relevant part, that every inventor "deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same . . . ." In re Barker, 559 F.2d 588, 592 (CCPA 1977) (ellipses in original). Although the patent statutes have been extensively revised since 1822, most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement. Id. at 592-94.

Rochester also argues that Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993), Lilly, and Enzo are all distinguishable because they were limited to DNA-based inventions. Rochester asserts that undisputed evidence shows that, based on the '850 patent's teachings, skilled artisans would be able to recognize COX-2-selective inhibitors.

We agree with Rochester that Fiers, Lilly, and Enzo differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue; in fact, where there might be some basis for finding a written description requirement to be satisfied in a genetics case based on the complementariness of a nucleic acid and, for example, a protein, that correspondence might be less clear in a non-genetic situation. In Enzo, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such

characteristics." 323 F.3d at 964 (quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106). DNA and RNA are each made up of just four building blocks that interact with each other in a highly predictable manner. Each of those building blocks, or "nucleotides," is characterized by a unique "base": In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or "hybridizes," to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a "complementary" strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993-1995 period in which the applications that led to the '850 patent were filed. Rochester and its experts do not offer any persuasive evidence to the contrary. As the district court pointed out:

> Tellingly, . . . what plaintiff's experts' [sic] do not say is that one of skill in the art would, from reading the patent, understand what compound or compounds—which, as the patent makes clear, are necessary to practice the claimed method—would be suitable, nor would one know how to find such a compound except through trial and error . . . . Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method—a compound that selectively inhibits PGHS-2 activity—was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Univ. of Rochester, 249 F. Supp. 2d at 229.

Rochester also attempts to distinguish Fiers, Lilly, and Enzo by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." Univ. of Rochester, 249 F. Supp. 2d at 228. Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment." Id.

We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless "describe 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." Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998). But see Enzo, 323 F.3d at 969 ("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 invention."). The specification must teach the invention by describing it.

Rochester also contends that "[t]he patent-in-suit cannot be per se invalid," because written description is a question of fact. Rochester further argues that:

> [C]onsistent with written description's fact-intensive nature, this Court has recognized diverse forms of description, including description primarily (if not entirely) based on functional characteristics. In Union Oil [Co. v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000) ("Unocal")], for example, the Court rejected the

> argument that the patent-in-suit was invalid because it described claimed gasoline mixtures by their "desired characteristics," rather than by their "exact chemical component[s]."

In response, Pfizer argues that the district court did not apply a per se rule, and that written description of a method of selectively inhibiting the activity of an enzyme by administering a chemical compound is insufficient unless a skilled artisan can recognize the identity of the compound, and the description must convey what the compound is, not just what it does. Pfizer points out that the district court found that the '850 patent does not disclose the structure or physical properties of any of the compounds required to practice the claimed methods, and that the structure of such compounds cannot be deduced from any known structure-function correlation. Pfizer agrees with the district court that the '850 patent discloses nothing more than a hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it.

We agree with Pfizer that the '850 patent is deficient in failing to adequately describe the claimed invention. First, although compliance with the written description requirement is a question of fact, Vas-Cath, 935 F.2d at 1116, Rochester's argument that a patent may not be held invalid on its face is contrary to our case law. In PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235 (Fed. Cir. 2002), for example, we held that a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met. Similarly, in TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001), we held that "[n]o reasonable juror could find that [an appellant's] original disclosure was sufficiently detailed to enable one of skill in the art to recognize that [the appellant] invented what is claimed," and accordingly upheld a grant of summary judgment. Id. at 1119.

Second, it is undisputed that the '850 patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known. The '850 patent does contain substantial description of the cyclooxygenases, including the nucleotide sequences of coding and promoter regions of the genes that encode human COX-1 and COX-2 and a comparison of those sequences. See, e.g., '850 patent, figs. 6A-6B, 10A-10D, and 11A-11C. The patent also describes in detail how to make cells that express either COX-1 or COX-2, but not both, id. § 5.2, at cols. 8-20, as well as "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds," id. at col. 8, ll. 2-7; see also id. § 5.6, at cols. 24-25. Such assay methods are in fact claimed in the '479 patent, i.e., Rochester's other patent based on the same disclosure. The '850 patent specification also describes what can be done with any compounds that may potentially be identified through those assays, including formulation into pharmaceuticals, routes of administration, estimation of effective dosage, and suitable dosage forms. Id. § 5.8, at cols. 27-34. As pointed out by the district court, however, the '850 patent does not disclose just "which 'peptides, polynucleotides, and small organic molecules' have the desired characteristic of selectively inhibiting PGHS-2." Univ. of Rochester, 249 F. Supp. 2d at 224. Without such disclosure, the claimed methods cannot be said to have been described. As we held in Lilly, "[a]n adequate written description of a DNA . . . '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." 119 F.3d at 1566 (quoting Fiers, 984 F.2d at 1171). For

reasons stated above, that requirement applies just as well to non-DNA (or -RNA) chemical inventions.

Third, Rochester's reliance on Unocal is unavailing. Although we held in that case that a "descri[ption] of the exact chemical component of each combination that falls within the range claims of the . . . patent" is not necessary to comply with § 112, we explained that the patentee is nonetheless required to provide sufficient description to show one of skill in the art that the inventor possessed the claimed invention at the time of filing. Unocal, 208 F.3d at 997. Evidence was adduced in that case that artisans skilled in petroleum refining were aware of the properties of raw petroleum sources and knew how to mix streams of such sources to achieve a final product with desired characteristics. Accordingly, we held that the written description requirement was satisfied in that case by specifying the ranges of properties of the claimed gasolines, reflecting the way that oil refiners actually formulate gasoline, such that one skilled in the art could recognize what was being claimed. Id. at 992. The present case is not analogous. Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description as "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product."[7]

Rochester also cites In re Edwards, 568 F.2d 1349 (CCPA 1978), and In re Herschler, 591 F.2d 693 (CCPA 1979), in support of its arguments. Those cases are also inapposite. In Edwards, the court held that the written description requirement was satisfied by a specification that described a claimed compound by the process by which it was made, rather than by its structure, because the court found that Edwards' application, "taken as a whole, reasonably leads persons skilled in the art to the [recited reactions] and, concomitantly, to the claimed

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[7] Indeed, if compounds that selectively inhibit activity of the PGHS-2 gene product had been known in the art, it is difficult to see how the claims of the '850 patent would have satisfied the novelty requirement of 35 U.S.C. § 102. After all, the novelty of those claims, if any, would appear to reside in the fact that COX-2-selective inhibitors were previously unknown.

compound." 568 F.2d at 1354. In marked contrast to the Edwards application, the specification of the '850 patent contains no disclosure of any method for making even a single "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product." In Herschler, the court found adequate written description support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent and dimethyl sulfoxide ("DMSO"), even though the specification disclosed only one example of a "physiologically active steroidal agent." Critically, however, there was no question in that case that, unlike "non-steroidal compound[s] that selectively inhibit[ ] activity of the PGHS-2 gene product," numerous physiologically active steroidal agents were known to those of ordinary skill in the art. As the court there noted, "[w]ere this application drawn to novel 'steroidal agents,' a different question would be posed." 591 F.2d at 701. The novelty in that invention was the DMSO solvent, not the steroids.

Although cases such as Unocal, Enzo, Edwards, and Herschler demonstrate that patent applicants have some flexibility in the "mode selected for compliance" with the written description requirement, neither those cases nor any other cases cited by Rochester eliminate the requirement that the patent specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. The only claims that appear to be supported by the specification are claims to assay methods, but those claims were already issued in the '479 patent.

Rochester argues that "[t]he appealed decision vitiates universities' ability to bring pioneering innovations to the public," and that:

> Congress has determined that licensing of academia's inventions to industry is the best way to bring groundbreaking inventions to the public. See 35 U.S.C. § 200. By vesting in universities the patent rights to their federally funded research, the Bayh-Dole Act of 1980 encouraged "private industry to utilize government funded inventions through the commitment of the risk capital

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The issue of patentability under § 102, however, was not decided by the district court, and we do not address it further.

necessary to develop such inventions to the point of commercial application." H.R. Rep. No. 96-1307, pt. 1, at 3 (1980).

Further, amici the University of California and the University of Texas assert that "[t]his Court's decision will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector."

That argument is unsound. The Bayh-Dole Act was intended to enable universities to profit from their federally-funded research. It was not intended to relax the statutory requirements for patentability. As pointed out by amicus Eli Lilly, "no connection exists between the Bayh-Dole Act and the legal standards that courts employ to assess patentability. Furthermore, none of the eight policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities. See 35 U.S.C. § 200."[8]

In sum, because the '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such

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[8] Section 200, entitled "Policy and objective," provides that:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

compounds were otherwise within the knowledge of a person of ordinary skill in the art[9] at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention. Accordingly, we affirm the district court's grant of Pfizer's motion for summary judgment.

In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.

With respect to the third asserted error, relating to the denial of Rochester's cross-motion for summary judgment, Rochester argues that because Pfizer adduced no evidence, other than the patent in suit, to support its written description defense, Rochester was entitled to summary judgment on that issue. Rochester contends that, because all issued patents are presumed to be valid, the district court was wrong to conclude that the '850 patent constitutes clear and convincing proof of its own invalidity.

Pfizer responds by arguing that there is no issue of material fact in dispute and that the '850 patent is invalid as a matter of law. Pfizer argues further that the district court properly found that Rochester's experts' declarations did not raise any issue of material fact, because they focused only on the use and function of the screening assay, rather than on the disclosure in the specification of a suitable compound. According to Pfizer, common sense dictates that one has not described a method of treating a disease with a drug if he has not disclosed any such drug or even if one exists, and there is accordingly no need for any evidence of invalidity beyond the '850 patent itself.

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35 U.S.C. § 200 (2000).

[9] In O'Reilly v. Morse, 56 U.S. 62 (1853), the Supreme Court stated "[Morse] claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law." Id. at 113. Likewise, Rochester has claimed a method that could not be adequately described at the time its application was filed. As we explained in Fiers, "one cannot describe what one has not conceived." 984 F.2d at 1171.

Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity, see, e.g., PIN/NIP, 304 F.3d at 1235; TurboCare, 264 F.3d at 1111, and as detailed in section I above, we conclude that the '850 patent clearly and convincingly does just that. The patent's claims all require a COX-2-selective compound, but no COX-2-selective compound is disclosed in the patent, and it is undisputed that there was no pre-existing awareness in the art of any compound having COX-2-selective activity. Accordingly, we hold that the district court did not abuse its discretion by denying Rochester's cross-motion for summary judgment.[10]

CONCLUSION

Because the court did not err in holding the '850 patent to be invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment in favor of Pfizer on that ground, the decision of the district court is

AFFIRMED.

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[10] Although we have treated the issue in this case as one of written description, as it was argued and decided below, underlying that question is the fundamental issue whether Rochester actually invented the subject matter it claimed in the '850 patent as required by 35 U.S.C. § 102(f). As the Supreme Court has cautioned, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Brenner v. Manson, 383 U.S. 519, 536 (1966). Here the patentee has done no more than invent a search method, i.e., a method of identifying a selective COX-2 inhibitor, much less did it invent, as claimed in the '850 patent, a method of using any such compound to selectively inhibit COX-2 in humans. Under these circumstances, it might appear that the patentee also failed to satisfy the requirements of section 102(f).