598 F.3d 1336, 94 U.S.P.Q.2d 1161

United States Court of Appeals,

Federal Circuit.

ARIAD PHARMACEUTICALS, INC., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College, Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY, Defendant-Appellant.

No. 2008-1248.

March 22, 2010.

***1340** LOURIE, Circuit Judge.

Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively, "Ariad") brought suit against Eli Lilly & Company ("Lilly") in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516 ("the '516 patent"). After trial, at which a jury found infringement, but found none of the asserted claims invalid, a panel of this court reversed the district court's denial of Lilly's motion for judgment as a matter of law ("JMOL") and held the asserted claims invalid for lack of written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed.Cir.2009).

Ariad petitioned for rehearing *en banc*, challenging this court's interpretation of 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. Because of the importance of the issue, we granted Ariad's petition and directed the parties to address whether § 112, first paragraph, contains a written description requirement separate from the

enablement requirement and, if so, the scope and purpose of that requirement. We now reaffirm that § 112, first paragraph, contains a written description requirement separate from enablement, and we again reverse the district court's denial of JMOL and hold the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement.

BACKGROUND

The '516 patent relates to the regulation of gene expression by the transcription factor NF-KB. The inventors of the '516 patent were the first to identify NF-KB and to uncover the mechanism by which NF-KB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-KB normally exists in cells as an inactive complex with a protein inhibitor, named "IKB" ("Inhibitor of kappa B"), and is activated by extracellular stimuli, such as bacterial-produced lipopolysaccha rides, through a series of biochemical reactions that release it from IKB. Once free of its inhibitor, NF-KB travels into the cell nucleus where it binds to and activates the transcription of genes containing a NF-KB recognition site. The activated genes (*e.g.*, certain cytokines), in turn help the body to counteract the extracellular assault. The production of cytokines can, however, be harmful in excess. Thus the inventors recognized that artificially interfering with NF-KB activity could reduce the harmful symptoms of certain diseases, and they filed a patent application on April 21, 1989, disclosing their discoveries and claiming methods for regulating cellular responses to external stimuli by reducing NF-KB activity in a cell.

Ariad brought suit against Lilly on June 25, 2002, the day the '516 patent issued. Ariad alleged infringement of claims 80, 95, 144, and 145 by Lilly's Evista® and Xigris® pharmaceutical products. The asserted claims, rewritten to include the claims from which they depend, are as follows:

> 80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-KB-mediated intracellular signaling, the method comprising altering NF-KB activity in the cells such that NF-KB-mediated effects of external influences are modified, wherein NF-KB activity

in the cell is reduced] wherein reducing NF-KB activity comprises reducing binding of NF-KB to NF-KB recognition sites on genes which are transcriptionally regulated by NF-KB.

***1341** 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-KBmediated intracellular signaling, the method comprising reducing NF-KB activity in the cells such that expression of said genes is reduced], carried out on human cells.

144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-KB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-KB activity comprises reducing binding of NF-KB to NF-KB recognition sites on genes which are transcriptionally regulated by NF-KB.

145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-KB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

The claims are thus genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-KB to NF-KB recognition sites. Furthermore, the claims, although amended during prosecution, use language that corresponds to language present in the priority application. Specifically, the asserted claims recite methods of reducing NF-KB activity, and more specifically reducing binding of NF-KB to NF-KB recognition sites, in cells in response to external influences like bacterial lipopolysaccha rides. The specification filed on April 21, 1989, similarly recites the desired goal of reducing NF-KB activity and binding to NF-KB recognition sites in cells in response to such external influences. *See* ' 516 patent col.3 l.59-col.4 l.19; col.31 l.65-col.32 l.11; *see also id.* at col.2 ll.54-59. The specification also hypothesizes three types of molecules with the potential to reduce NF-KB activity in cells: decoy, dominantly interfering, and specific inhibitor molecules. *Id.* at col.37 l.43-col.38 l.22.

In April 2006, the district court held a fourteen-day jury trial on the issues of infringement and validity. The jury rendered a special verdict finding infringement of claims 80 and 95 with respect to Evista® and claims 144 and 145 with respect to Xigris®. The jury also found that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description. The court denied without opinion Lilly's motions for JMOL and, in the alternative, a new trial. In August 2006, the court conducted a four-day bench trial on Lilly's additional defenses of unpatentable subject matter, inequitable conduct, and prosecution laches, ruling in favor of Ariad on all three issues. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F.Supp.2d 106 (D.Mass.2007).

Lilly timely appealed to this court, and on April 3, 2009, a panel affirmed in part and reversed in part. *Ariad*, 560 F.3d at 1369. The panel upheld the district court's finding of no inequitable conduct, *id.* at 1380, but reversed the jury's verdict on written description, holding the asserted claims invalid for lack of an adequate written description as required by 35 U.S.C. § 112, first paragraph, *id.* at 1376. Ariad petitioned for rehearing *en banc*, challenging the existence of a written description requirement in § 112, first paragraph, separate from the enablement requirement. Although not a new question, *see In re Barker*, 559 F.2d 588, 591-93 (CCPA 1977), its prominence has increased in recent years, *see Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373 (Fed.Cir.2005) (denying rehearing *en banc* on the question whether a separate written description requirement exists in § 112, first paragraph); ***1342***Univ. of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303 (Fed.Cir.2004) (same); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed.Cir.2002) (same). In light of the controversy concerning the distinctness and proper role of the written description requirement, we granted Ariad's petition, vacating the prior panel opinion and directing the parties to brief two questions:

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

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

In addition to the parties' briefs, the court received twenty-five amicus briefs. Of those, seventeen were filed in support of Lilly, one was filed in support of Ariad, and seven were filed in support of neither party. The majority, including a brief filed by the United States, were filed in support of this court's current written description doctrine. The court heard oral arguments on December 7, 2009.

DISCUSSION

I.

Although the parties differ in their answers to the court's questions, their positions converge more than they first appear. Ariad, in answering the court's first question, argues that § 112, first paragraph, does *not* contain a written description requirement separate from enablement. Yet, in response to this court's second question on the scope and purpose of a written description requirement, Ariad argues that the statute contains two description requirements: "Properly interpreted, the statute requires the specification to describe (i) what the invention is, and (ii) how to make and use it." Appellee Br. 1; *see also id.* at 43 ("[T]he written description requirement of § 112, ¶ 1 requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention."). Ariad reconciles this apparent contradiction by arguing that the legal sufficiency of its two-prong description requirement is judged by whether it enables one of skill in the art to make and use the claimed invention. Thus, according to Ariad, in order to enable the invention, the specification must first identify "*what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use." *Id.* at 30. Yet Ariad argues that this first step of "identifying" the invention applies only in the context of priority (*i.e.*, claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims "constitute their own description." *Id.* at 44.

Lilly, in contrast, answers the court's first question in the affirmative, arguing that two hundred years of precedent support the existence of a statutory written description requirement separate from enablement. Thus, Lilly argues

that the statute requires, first, a written description of the invention and, second, a written description of how to make and use the invention so as to enable one of skill in the art to make and use it. Finally, Lilly asserts that this separate written description requirement applies to all claims-both original and amended-to ensure that inventors have actually invented the subject matter claimed.

Thus, although the parties take diametrically opposed positions on the existence of a written description requirement separate from enablement, both agree that the specification must contain a written description of the invention to establish what the invention is. The dispute, therefore, centers on the standard to be applied and whether it applies to original claim language.

***1343** A.

As in any case involving statutory interpretation, we begin with the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108, 100 S.Ct. 2051, 64 L.Ed.2d 766 (1980). Section 112, first paragraph, reads 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.

According to Ariad, a plain reading of the statute reveals two components: a written description (i) of the invention, and (ii) of the manner and process of making and using it. Yet those two components, goes Ariad's argument, must be judged by the final prepositional phrase; both written descriptions must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." Specifically, Ariad parses the statute as follows:

> The specification shall contain
> [A] a written description
> [i] of the invention, and
> [ii] of the manner and process of making and using it,

> [B] 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 ...

Ariad argues that its interpretation best follows the rule of English grammar that prepositional phrases (here, "of the invention," "of the manner and process of making and using it," and "in such full, clear, concise, and exact terms") modify another word in the sentence (here, "written description"), and that it does not inexplicably ignore the comma after "making and using it" or sever the "description of the invention" from the requirement that it be in "full, clear, concise, and exact terms," leaving the description without a legal standard.

Ariad also argues that earlier versions of the Patent Act support its interpretation. Specifically, Ariad contends that the first Patent Act, adopted in 1790, and its immediate successor, adopted in 1793, required a written description of the invention that accomplished two purposes: (i) to distinguish the invention from the prior art, and (ii) to enable a person skilled in the art to make and use the invention.[FN1] Ariad then asserts that when Congress assigned the function of defining the invention to the claims in 1836, Congress amended the written description requirement so that it served a single purpose: enablement.[FN2]

> FN1. Section 3 of the 1793 Patent Act provided, in relevant part: "[E]very inventor, before he can receive a patent shall ... 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, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same."

FN2. Section 6 of the 1836 Patent Act provided, in relevant part: "[B]efore any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

***1344** Lilly disagrees, arguing that § 112, first paragraph, contains three separate requirements. Specifically, Lilly parses the statute as follows:

(1) "The specification shall contain a written description of the invention, *and* "
(2) "The specification shall contain a written description ... 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* "
(3) "The specification ... shall set forth the best mode contemplated by the inventor of carrying out the invention."

Lilly argues that Ariad's construction ignores a long line of judicial precedent interpreting the statute's predecessors to contain a separate written description requirement, an interpretation Congress adopted by reenacting the current language of § 112, first paragraph, without significant amendment.

[1] We agree with Lilly and read the statute to give effect to its language that the specification "shall contain a written description of the invention" and hold that § 112, first paragraph, contains two separate description requirements: a "written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention"]. 35 U.S.C. § 112, ¶ 1 (emphasis added). On this point, we do not read Ariad's position to be in disagreement as Ariad

concedes the existence of a written description requirement. *See* Appellee Br. 2 ("Under a plain reading of the statute, a patent specification ... must contain a description (i) of the invention, and (ii) of the manner and process of making and using it."). Instead Ariad contends that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement.

But, unlike Ariad, we see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the "written description of the invention" must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same" modifies only "the written description ... of the manner and process of making and using [the invention]," as Lilly argues, without violating the rules of grammar. That the adequacy of the description of the manner and process of *making* and *using* the invention is judged by whether that description enables one skilled in the art to *make* and *use* the same follows from the parallelism of the language.

While Ariad agrees there is a requirement to describe the invention, a few amici appear to suggest that the only description requirement is a requirement to describe enablement. If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently. Specifically, Congress could have written the statute to read, "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," or "The specification shall contain a written description of the manner and process of making and using 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." Under the amicis' construction a portion of the statute***1345** - either "and of the manner and process of making and using it" or "[a written description] of the invention"-becomes surplusage, violating the rule of statutory construction that Congress does not use unnecessary words. *See United States v. Menasche*, 348 U.S. 528, 538-39, 75 S.Ct. 513, 99 L.Ed. 615 (1955) ("It is our duty 'to

give effect, if possible, to every clause and word of a statute.' ") (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152, 2 S.Ct. 391, 27 L.Ed. 431 (1883)).

Furthermore, since 1793, the Patent Act has expressly stated that an applicant must provide a written description of the invention, and after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement. *See infra* Section I.B. Congress recodified this language in the 1952 Act, and nothing in the legislative history indicates that Congress intended to rid the Act of this requirement. On the contrary, "Congress is presumed to be aware of a[ ] ... judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change." *Forest Grove Sch. Dist. v. T.A.*, --- U.S. ----, 129 S.Ct. 2484, 2492, 174 L.Ed.2d 168 (2009) (quoting *Lorillard v. Pons*, 434 U.S. 575, 580, 98 S.Ct. 866, 55 L.Ed.2d 40 (1978)).

Finally, a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (*i.e.*, enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office ("PTO") to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.

B.

Ariad argues that Supreme Court precedent comports with its reading of the statute and provides no support for a written description requirement separate from enablement. Specifically, Ariad asserts that in *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34, 5 L.Ed. 472 (1822), the Supreme Court recognized just two requirements under § 3 of the 1793 Act, the requirements "to enable" the invention and "to distinguish" it from all things previously known. And, goes

Ariad's argument, since the 1836 Act, which removed the latter language and added the requirement for claims, the Court has consistently held that a patent applicant need fulfill but a single "written description" requirement, the measure of which is enablement.

Lilly disagrees and reads Evans as acknowledging a written description requirement separate from enablement. Lilly further contends that the Court has continually confirmed the existence of a separate written description requirement, including in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 14 L.Ed. 601 (1853) under the 1836 Act; *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 59 S.Ct. 8, 83 L.Ed. 34 (1938), under the 1870 Act; and more recently in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002).

Like Lilly, we also read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims. Specifically, in *Schriber-Schroth,* the Court held that a patent directed to pistons for a gas engine with ***1346** "extremely rigid" webs did not adequately describe amended claims that recited flexible webs under the then-in-force version of § 112, first paragraph.[FN3] 305 U.S. at 56-57, 59 S.Ct. 8. The Court ascribed two purposes to this portion of the statute, only the first of which involved enablement:

> FN3. Section 26 of the 1870 Patent Act provided, in relevant part: "[B]efore any inventor or discoverer shall receive a patent for his invention or discovery, he shall ... file in the patent office a written description of [his invention or discovery], and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

> [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the

public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

Id. at 57, 59 S.Ct. 8. The Court then concluded that even if the original specification enabled the use of a flexible web, the claim could derive no benefit from it because "that was not the invention which [the patentee] *described* by his references to an extremely rigid web." *Id.* at 58-59, 59 S.Ct. 8 (emphasis added); *see also* *MacKay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 98-102, 59 S.Ct. 427, 83 L.Ed. 506 (1939) (holding invalid claims amended to include structures "not within the invention described in the application" even though the variations were small). Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did. FN4

> FN4. *Morse,* decided under the 1836 Act, can also be interpreted as involving a separate written description inquiry. 56 U.S. (15 How.) 62, 14 L.Ed. 601. The patent at issue contained eight claims, only seven of which recited the specific instrumentalities of the telegraph developed by Morse. The eighth claim, in contrast, claimed every conceivable way of printing intelligible characters at a distance by the use of an electric or galvanic current. *Id.* at 112. The Court rejected the latter claim as too broad because Morse claimed "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." *Id.* at 113 (emphasis added). Such a rejection implies a distinct requirement for a description of the invention. Yet, in reaching its conclusion, the Court also detailed how the claim covered inventions not yet made, indicating the additional failure of the description to enable such a broad claim. *See id.* at 113-14.

Further, both before and after *Schriber-Schroth,* the Court has stated that the statute serves a purpose other than enablement. In *Gill v. Wells,* 89 U.S. (22 Wall.)

1, 22 L.Ed. 699 (1874), the Court held invalid a reissue patent for claiming a combination not described in the original application, but the Court also emphasized the need for all patents to meet the "three great ends" of § 26, only one of which was enablement. Specifically, the Court stated:

> (1) That the government may know what they have granted and what will become public property when the term of the monopoly expires. (2.) That licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention.(3.) That other inventors may know what part of the field of invention is unoccupied.

Id. at 25-26. Finally, most recently in *Festo*, the Court recited three requirements for § 112, first paragraph, and noted***1347** a written description requirement separate from the others:

> [T]he patent application must *describe, enable, and set forth the best mode* of carrying out the invention. 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. What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue. The patent also should not issue if the other requirements of § 112 are not satisfied....

535 U.S. at 736, 122 S.Ct. 1831 (emphasis added) (internal citations omitted). As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them. *See Stone Container Corp. v. United States*, 229 F.3d 1345, 1349-50 (Fed.Cir.2000). While Ariad points to statements in other cases that support its view, Appellee Br. 18-19, not one disavows the existence of a separate written description requirement.

A separate written description requirement also does not conflict with the function of the claims. 35 U.S.C. § 112, ¶ 2. Claims define the subject matter that,

after examination, has been found to meet the statutory requirements for a patent. *See* *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 n. 5 (Fed.Cir.1985). Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches.

C.

In addition to the statutory language and Supreme Court precedent supporting the existence of a written description requirement separate from enablement, *stare decisis* impels us to uphold it now. Ariad acknowledges that this has been the law for over forty years, *see* Appellee Br. 24, and to change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions. As the Supreme Court stated in admonishing this court, we "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 535 U.S. at 739, 122 S.Ct. 1831; *see also* *Watson v. United States*, 552 U.S. 74, 82, 128 S.Ct. 579, 169 L.Ed.2d 472 (2007) ("A difference of opinion within the Court ... does not keep the door open for another try at statutory construction, where *stare decisis* has special force [since] the legislative power is implicated, and Congress remains free to alter what we have done." (internal quotations omitted)). If the law of written description is to be changed, contrary to sound policy and the uniform holdings of this court, the settled expectations of the inventing and investing communities, and PTO practice, such a decision would require good reason and would rest with Congress.

D.

Ariad next argues that an incorrect reading of *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990 (1967), by our predecessor court, the Court of Customs and Patent Appeals ("CCPA"), and then by this court, created the first written description requirement separate from enablement. Yet Ariad also asserts, in

response to Lilly's argument that *In re Moore*, 33 C.C.P.A. 1083, 155 F.2d 379 (1946); *In re Sus*, 49 C.C.P.A. 1301, 306 F.2d 494 (1962); and *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533 (1963), applied a separate written description requirement pre- ***1348***Ruschig*, that those cases "merely tested whether the specification *identified* the same invention that was defined by later-added or amended claims-which is an aspect of enablement-and did not interpret § 112, ¶ 1 as containing an independent description-possession requirement." Appellee Br. 22-23. Thus, according to Ariad, a written description of the invention is required but is not separate from enablement because it identifies the invention that must be enabled, and this, in Ariad's view, differs from first requiring the invention to be described and then separately requiring it to be enabled.

We view this argument as a distinction without a practical difference insofar as both approaches require a written description of the invention in the specification. In either case the analysis compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification, both Ariad and Lilly agree that the claim-whether in *Schriber-Schroth* or *Ruschig*-fails regardless whether one of skill in the art could make or use the claimed invention. *Ruschig* involved a claim amended during prosecution to recite a specific chemical compound, chlorpropamide. 379 F.2d at 991. The specification as filed disclosed a genus encompassing about "half a million possible compounds," but it did not disclose chlorpropamide specifically. *Id.* at 993. The CCPA affirmed the PTO's rejection of the compound claim because the specification provided no guides or "blaze marks" to single out chlorpropamide from all the other compounds, and thus did not support the later-added claim. *Id.* at 994-95. The court also rejected the argument that one of skill in the art would be enabled to make chlorpropamide as "beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented," which, the court held, it did not. *Id.* at 995-96.

According to Ariad, the court properly rejected Ruschig's claim based on enablement because the specification did not identify the later-claimed compound, leaving the skilled artisan with no guide to select that compound from the myriad of other compounds encompassed by the broad disclosure.

According to Lilly, the court properly rejected the claim under a written description requirement separate from enablement because the specification did not disclose the later-claimed compound to one of skill in the art as something the inventors actually invented out of the myriad of other compounds encompassed by the broad disclosure. Again, this difference amounts to little more than semantics as the parties agree that the court properly affirmed the rejection because the original application did not disclose the specific claimed invention, chlorpropamide, even if one of skill in the art could, based on the disclosure with respect to related compounds, make and use it.

Ariad also argues that the court properly rejected Ruschig's claim as violating 35 U.S.C. § 132's prohibition on "new matter." But § 132 is an examiner's instruction, and unlike § 282 of the Patent Act, which makes the failure to comply with § 112 a defense to infringement, § 132 provides no statutory penalty for a breach. Express statutory invalidity defenses carry more weight than examiner's instructions, and prohibiting adding new matter to the claims has properly been held enforceable under § 112, first paragraph. *See In re Rasmussen*, 650 F.2d 1212, 1214-15 (CCPA 1981). Regardless, one can fail to meet the requirements of the statute in more than one manner, and the prohibition on new matter does not negate the need to provide a written description of one's invention.

***1349** E.

[2] In contrast to amended claims, the parties have more divergent views on the application of a written description requirement to original claims. Ariad argues that *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed.Cir.1997), extended the requirement beyond its proper role of policing priority as part of enablement and transformed it into a heightened and unpredictable general disclosure requirement in place of enablement. Rather, Ariad argues, the requirement to describe what the invention is does not apply to original claims because original claims, as part of the original disclosure, constitute their own written description of the invention. Thus, according to Ariad, as long as the claim language appears *in ipsis verbis* in the specification as

filed, the applicant has satisfied the requirement to provide a written description of the invention.

Lilly responds that the written description requirement applies to all claims and requires that the specification objectively demonstrate that the applicant actually invented-was in possession of-the claimed subject matter. Lilly argues that § 112 contains no basis for applying a different standard to amended versus original claims and that applying a separate written description requirement to original claims keeps inventors from claiming beyond their inventions and thus encourages innovation in new technological areas by preserving patent protection for actual inventions.

Again we agree with Lilly. If it is correct to read § 112, first paragraph, as containing a requirement to provide a separate written description of the invention, as we hold here, Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of § 112 supports such a restriction; the statute does not say "The specification shall contain a written description of the invention *for purposes of determining priority*." And although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we.

Furthermore, while it is true that original claims are part of the original specification, *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973), that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims. Ariad believes so, arguing that original claims identify whatever they state, *e.g.*, a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention. Oral Argument 37:26-38:00. We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that

achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Recognizing this, we held in *Eli Lilly* that an adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. ***1350** 119 F.3d at 1568. The patent at issue in *Eli Lilly* claimed a broad genus of cDNAs purporting to encode many different insulin molecules, and we held that its generic claim language to "vertebrate insulin cDNA" or "mammalian insulin cDNA" failed to describe the claimed genus because it did not distinguish the genus from other materials in any way except by function, *i.e.*, by what the genes do, and thus provided "only a definition of a useful result rather than a definition of what achieves that result." *Id.*

We held that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus. *Id.* at 1568-69. We explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials. *Id.* at 1568 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed.Cir.1993)). We have also held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function. *See Enzo*, 323 F.3d at 964 (quoting 66 Fed.Reg. 1099 (Jan. 5, 2001)). But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.

In fact, this case similarly illustrates the problem of generic claims. The claims here recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-KB binding to NF-KB recognition sites in response

to external influences. But the specification does not disclose a variety of species that accomplish the result. *See* *Eli Lilly,* 119 F.3d at 1568 ("The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention."). Thus, as indicated *infra,* that specification fails to meet the written description requirement by describing only a generic invention that it purports to claim.

We also specifically addressed and rejected Ariad's argument regarding original claims in *Fiers,* 984 F.2d at 1170, and again in *Enzo,* 323 F.3d at 968. In *Fiers,* we rejected the argument that "only similar language in the specification *or original claim* is necessary to satisfy the written description requirement." 984 F.2d at 1170 (emphasis added). Rather, we held that original claim language to "a DNA coding for interferon activity" failed to provide an adequate written description as it amounted to no more than a "wish" or "plan" for obtaining the claimed DNA rather than a description of the DNA itself. *Id.* at 1170-71. That *Fiers* applied § 112, first paragraph, during an interference is irrelevant for, as we stated above, the statute contains no basis for ignoring the description requirement outside of this context. And again in *Enzo* we held that generic claim language appearing *in ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed. 323 F.3d at 968. We concluded that "[a] claim does not become more descriptive by its repetition, or its longevity." *Id.* at 969.

Ariad argues that *Eli Lilly* constituted a change in the law, imposing new requirements on biotechnology inventions. We disagree. Applying the written description requirement outside of the priority ***1351** context in our 1997 *Eli Lilly* decision merely faithfully applied the statute, consistent with Supreme Court precedent and our case law dating back at least to our predecessor court's *Ruschig* decision. Neither the statute nor legal precedent limits the written description requirement to cases of priority or distinguishes between original and amended claims. The application of the written description requirement to original language was raised in *Fiers*, *Eli Lilly*, and *Enzo,* and is raised again by the parties here. Once again we reject Ariad's argument and hold that generic language in the application as filed does not automatically satisfy the written description requirement.

F.

[3] Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a "fairly uniform standard," which we now affirm. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed.Cir.1991). Specifically, the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* at 1563 (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed.Cir.1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed.Cir.1985)); *see also* *In re Kaslow*, 707 F.2d 1366, 1375 (Fed.Cir.1983).

The term "possession," however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, "possession as shown in the disclosure" is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

This inquiry, as we have long held, is a question of fact. *Ralston Purina*, 772 F.2d at 1575. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed.Cir.2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Id.* For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent

and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* at 1359.

The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. *Compare* *Eli Lilly*, 119 F.3d at 1567 (holding an ***1352** amino acid sequence did not describe the DNA sequence encoding it), *with* *In re Wallach*, 378 F.3d 1330, 1334 (Fed.Cir.2004) (discussing how it is now a "routine matter" to convert an amino acid sequence into all the DNA sequences that can encode it). Thus, whatever inconsistencies may appear to some to exist in the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.

[4][5] There are, however, a few broad principles that hold true across all cases. We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed.Cir.2006). Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed.Cir.2008), or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed.Cir.1997).

We also reject the characterization, cited by Ariad, of the court's written description doctrine as a "super enablement" standard for chemical and biotechnology inventions. The doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus. *Eli Lilly*, 119 F.3d at 1569; *see also* *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed.Cir.2005) (holding the written description requirement satisfied by a representative number of sequences of the claimed genus of enzymes). It also has not just been applied to chemical and biological inventions. *See* *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1343-47 (Fed.Cir.2005).

Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent. *See* *In re DiLeone*, 58 C.C.P.A. 925, 436 F.2d 1404, 1405 n. 1 (1971) ("[C]onsider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.").

The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function-a problem that is ***1353** particularly acute in the biological arts.[FN5] *See* *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement*, 66 Fed.Reg. 1099, 1105-1106 (Jan. 5, 2001). This situation arose not only in *Eli Lilly* but again in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed.Cir.2004). In *Rochester*, we

held invalid claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound that selectively inhibits the COX-2 enzyme. *Id.* at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. *Id.* at 927-28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in Eli *Lilly* and Ariad's claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries-leaving it to the pharmaceutical industry to complete an unfinished invention.

> FN5. The record does not reflect how often the PTO rejects claims as enabled but not described, but the government believes the number to be high. Oral Argument at 23:17-23:53. At least one example has made it to this court in recent years, *In re Alonso*, in which the PTO found claims to a method of treating a tumor by administering an effective amount of an antibody that recognizes the tumor enabled but, as we affirmed, not adequately described. 545 F.3d 1015, 1021-22, 1022 n. 6. (Fed.Cir.2008).

Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, *see* *Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g.*, *Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable

inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 930 n. 10 (quoting *Brenner*, 383 U.S. at 536, 86 S.Ct. 1033). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"-that is, conceive of the complete and final invention with all its claimed limitations-and disclose the fruits of that effort to the public.

That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not "attempt[s] to preempt the future before it has arrived." *Fiers*, 984 F.2d at 1171. As this court has repeatedly stated, 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***1354** contribution to the field of art as described in the patent specification." *Rochester*, 358 F.3d at 920 (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed.Cir.2000)). It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time. *Enzo*, 323 F.3d at 970.

II.

Because we reaffirm our written description doctrine, we see no reason to deviate from the panel's application of that requirement to the facts of this case. As such, we adopt that analysis, as follows, as the decision of the *en banc* court….

CONCLUSION

For the foregoing reasons, we hold that the asserted claims of the '516 patent are invalid for lack of written description, and we do not address the other validity issues that were before the panel. The judgment below is *REVERSED IN PART* AND *AFFIRMED IN PART*.