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§ 112 REQUIREMENTS

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IN THIS ISSUE:

This issue will focus on the requirements for patentability set forth in the first two paragraphs of 35 U.S.C. § 112. Section 112, paragraph 1 has been construed by the Federal Circuit to encompass three separate requirements relating to a patent's specification, commonly known as written description, enablement and best mode. Section 112, paragraph 2 addresses patent claims and provides the foundation for the definiteness requirement. This issue will analyze the pending Federal Circuit *en banc* rehearing of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, in which the court will consider whether written description and enablement are separate requirements. The issue will also examine other recent Federal Circuit decisions concerning the written description, enablement and definiteness requirements.

THE WRITTEN DESCRIPTION REQUIREMENT

Section 112, paragraph 1 provides:

> 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 . . . .

The Federal Circuit has interpreted that portion of the statute as imposing two separate requirements: (1) the specification must clearly convey to those skilled in the art that the inventor was in possession of the claimed invention, and (2) the specification must describe the invention in sufficient detail to enable one of ordinary skill in the art to make and use the invention. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963-64 (Fed. Cir. 2002); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-63 (Fed. Cir. 1991). The first requirement, known as the written description requirement, serves a "teaching function" to ensure that the disclosure provided to the public is commensurate with the exclusivity granted to the patentee. *See Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 921 (Fed. Cir. 2004). Federal Circuit decisions have made clear that a specification may fail to satisfy the written description requirement even though it enables an ordinarily skilled artisan to make and use the invention. *Id.*

The Federal Circuit's written description jurisprudence may, however, be upended following its *en banc* rehearing of *Ariad*. In its *en banc* order, the court presented the following questions: (a) "Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement," and (b) "[i]f a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?" *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 332 Fed. Appx. 636 (Fed. Cir. 2009).

In the panel decision that preceded the *en banc* order, a panel comprising Judges Linn, Prost and Moore found the patent-in-suit invalid for lack of written description, ruling that a jury verdict to the contrary was not supported by substantial evidence. 560 F.3d 1366 (Fed. Cir. 2009). The method claims at issue were directed to reducing the activity of a transcription factor named NF-κB. *Id.* at 1370. The patent specification hypothesized three classes of molecules potentially capable of reducing NF-κB activity, but the claims did not explicitly recite any compounds. *Id.* at 1370, 1373.

The Federal Circuit panel found the issues presented similar to those decided previously in *Rochester. Ariad*, 560 F.3d at 1373. In *Rochester*, the claims recited a method for inhibiting PGHS-2 activity by administering a nonsteroidal compound that selectively inhibits the activity of the PGHS-2 gene product. *Rochester*, 358 F.3d 926. The *Rochester* court found the claims invalid for lack of written description, citing the patent holder's failure to present "any evidence that the ordinarily skilled artisan would be able to identify any compound based on [the specification's] vague functional description." *Id.* In *Ariad*, the court rejected Ariad's attempt to distinguish *Rochester* on the basis that the patent claims in *Rochester* explicitly included the nondescribed compositions. The court explained that "[r]egardless of whether the asserted claims recite a compound, . . . the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-κB activity." *Ariad*, 560 F.3d at 1369.

The *Ariad* panel concluded that the specification failed to include any working or even prophetic examples of reducing NF-κB activity or any completed syntheses of the molecules hypothesized to reduce NF-κB activity. *Id.* Noting the "primitive" and "uncertain" state of the art at the time of filing, the panel held that the jury's written description finding lacked substantial evidence. *Id.* Writing for the panel, Judge Moore opined that the outcome largely resulted from Ariad's insistence on maintaining the "breadth" of its claims through claim construction and into trial. *Id.* at 1376-77. Quoting Judge Rader's dissent in the court's denial of petition for rehearing *en banc* in *Rochester,* Judge Moore stated that "the situation presented in this case should not often occur, because '[i]n simple terms, a court would properly interpret the claim[s] as limited.'" *Id.* (quoting *Rochester*, 375 F.3d at 1312 (Rader, J., dissenting from denial of rehearing *en banc*)).

In a concurring opining, Judge Linn stated, "I write separately to emphasize, as I have before, my belief that our engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided." *Id.* at 1380 (Linn, J., concurring) (citing *Rochester*, 375 F.3d at 1325-27 (Linn, J., dissenting from denial of rehearing *en banc*)). According to Judge Linn, the court's "invention" of a separate written description requirement creates confusion as to where the courts and the public should look in determining the scope of a patent. *Id.* at 1381. Judge Linn also noted that the court's reliance on the written description requirement prevented it from reaching "the important enablement issue raised by Lilly." *Id.*

Ariad expanded on Judge Linn's sentiments in its principal brief for the rehearing *en banc*. Ariad responded to the questions presented by stating that "§ 112, ¶ 1, does not contain a written description requirement separate from an enablement requirement" and therefore "cannot have any scope or purpose as a separate written description requirement." Ariad Br. at 1 (available at http://patentdocs.typepad.com/files/ariads-principal-brief.pdf). Ariad argued that the statutory language is inconsistent with current Federal Circuit written description jurisprudence, and contended that the enablement clause in paragraph 1 is a prepositional phrase modifying the phrase "written description." Asserting that the Federal Circuit's interpretation ignores ordinary rules of grammar, Ariad claimed that by truncating the statutory language of paragraph 1, the court has substituted its own written description standard for the one set forth in the statute, namely enablement. Ariad Br. at 2-6.

Ariad further argued that Supreme Court and C.C.P.A. precedent cited by the Federal Circuit to support the existence of a separate written description requirement has been misconstrued. In addition, Ariad contended that by creating a basis for invalidating potentially enabled inventions and thus favoring companies whose commercial activities are downstream from the underlying research, the court has reduced the incentive to invest in innovation. Highlighting several dissenting and concurring opinions by Federal Circuit judges expressing frustration with the lack of clarity in the court's written description jurisprudence, Ariad suggests that the present rehearing "presents a long-sought opportunity for this Court to clarify and correct the law regarding the disclosure requirement of § 112, ¶ 1." Ariad Br. at 42.

Lilly answered the Federal Circuit's questions by stating that "there has always been a robust written description requirement separate from enablement that is supported by almost two hundred years of precedent," and that the requirement "applies to both original and amended claims and ensures that inventors have actually invented the subject matter claimed in their patents." Lilly Br. at 1 (available at http://patentdocs.typepad.com/files/lillys-principal-brief.pdf). Lilly devoted the bulk of its brief to Supreme Court, C.C.P.A. and Federal Circuit decisions that it contends support the existence of a separate written description requirement. Addressing Ariad's statutory construction argument, which Lilly characterized as advocating for the abandonment of "long-standing precedent . . . based on a fine grammatical parsing of the statute," Lilly argued that Ariad's proposed construction would render the statutory phrase "the manner and process of making and using" superfluous. Lilly Br. at 26.

Lilly further contended that even if the statute is construed without reference to precedent, the use of the word "and" between the description and the enablement phrases indicates two separate requirements. Lilly Br. at 27. And according to Lilly, the written description requirement ensures that incentive remains for the "true innovators" who actually make an invention by preventing premature preemption in areas such as biotechnology. Lilly Br. at 45-47. Finally, Lilly asserted that contrary to Ariad's assertions, the written description requirement is an objective test that is no more difficult to apply than enablement.

Twenty-five amicus briefs have been submitted, 16 of which were filed in support of Lilly. Although no briefs were specifically filed in support of Ariad, Novozymes (a biotechnology company) and a collection of research universities argued for the elimination of a separate written description requirement. Other amici, supporting neither party, argued for the existence of a separate written description requirement but offered a variety of arguments as to how the Federal Circuit has misapplied the standard in the leading written description cases.

The Federal Circuit heard oral argument on December 7, 2009 and the court's ultimate decision is likely to have a substantial impact on the application of section 112, paragraph 1. We will continue to monitor the case and report on developments.

The Federal Circuit addressed a more subtle aspect of the written description requirement in *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358 (Fed. Cir. 2009). In that case, the asserted patent, the '545 patent, was directed to an eyeglass frame designed to support an auxiliary frame. *Id.* at 1363. Such frame assemblies are typically used by prescription eyeglass wearers who wish to attach sunglass lenses to their prescription frames. The patent identified two problems with prior art frames, which contained embedded magnets to support the auxiliary frames. First, such auxiliary frames were likely to disengage during vigorous activity such as jogging due to the limited holding power of the magnets. Second, the prior art frames suffered a strength deficiency as a result of the cavities in which the magnets were embedded. *Id.* The '545 patent addressed the first problem with a "top-mounted" design in which the auxiliary frame is essentially hooked to the top of the primary frame. The invention purportedly avoided the decreased strength problem by adding projections to both the primary and the auxiliary frames to support the magnets, rather than imbedding them within the frames. *Id.*

Revolution argued at trial that one of the asserted claims, which was directed solely to a primary frame, was invalid for lack of written description. *Id.* at 1366. According to Revolution, the specification described an invention that addressed two deficiencies, but the asserted claim addressed only one of the two identified problems. The Federal Circuit agreed with the district court that Revolution's argument was without merit, noting that it had previously held "that when the specification sets out two different problems present in the prior art, it is unnecessary for each and every claim in the patent to address both problems." *Id.* at 1367. The panel made clear that inventors are free to "frame their claims to address one problem or several," and the written description requirement will be satisfied as to each claim as long as the description conveys that the inventor was in possession of the recited invention. *Id.*

Cases referenced
Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009)
Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002)
Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358 (Fed. Cir. 2009)
Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004)
Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991)

Enablement

Although the panel did not reach the issue of enablement in *Ariad*, recent Federal Circuit cases illustrate that the enablement requirement continues to play an important role in litigation, especially in cases involving pharmaceutical patents. To satisfy the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1991). The court considers numerous factors in determining if undue experimentation is needed, including (1) the quantity of the experimentation required, (2) the level of guidance or direction provided in the disclosure, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art,

(6) the relative skill of those practicing the art, (7) the expectation of predictable results, and (8) the breadth of the claims at issue. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

When a patent specification relies heavily on prior art references for its disclosure of the alleged invention, a patentee may have difficulty arguing that the cited references do not anticipate or render the invention obvious without undermining enablement. In *Janssen Pharmaceutica N.V. v. Teva Pharmaceuticals USA, Inc.*, 2009 U.S. App. LEXIS 21166 (Fed. Cir. Sept. 30, 2009), the Federal Circuit affirmed a district court judgment that Janssen's patent-in-suit was invalid for lack of enablement. The patent claimed a method for treating Alzheimer's disease by administration of galantamine. *Id.* at *27. The brief patent specification provided summaries of six scientific studies in which galantamine had been administered to humans or animals. Though several of those studies provided some insight into the effects of galantamine on brain activity, none of them directly involved treating Alzheimer's disease. *Id.* at *4-7. During prosecution of the patent, the inventor responded to an obviousness rejection by explaining that because the brains of the animals in the cited galantamine studies were "normal" and had not undergone the physiological changes associated with Alzheimer's, those studies were conducted under "circumstances having no relevance to Alzheimer's disease," and that it would therefore be "baseless" to predict the efficacy of galantamine as an Alzheimer's treatment from such studies. *Id.* at *9-10.

The district court held that the patent claims were neither anticipated nor obvious, but that they were invalid for lack of enablement. First, the district court concluded that without any results from relevant animal testing, the specification provided only "minimal disclosure" of utility at the time the patent issued. *Id.* at *11. The district court also found that the specification and claims did not teach one of ordinary skill in the art how to use the invention because the application only "surmised" that galantamine could provide effective treatment of Alzheimer's symptoms without providing sufficient dosage information. *Id.*

On appeal, the Federal Circuit noted that "[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Id.* at *12. The court noted that, although animal tests or in vitro experiments may be sufficient in some cases to satisfy the utility requirement, no animal tests involving the use of galantamine to treat Alzheimer's were available when the application was filed. Moreover, Janssen's own expert had opined that the studies summarized in the patent specification would not have led one skilled in the art to reasonably expect success in treating Alzheimer's with galantamine. *Id.* at *18-19. The panel affirmed the district court's ruling, concluding that the patent specification did "no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis," and thus did not establish utility necessary to satisfy the enablement requirement. *Id.* at *24.

In *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), the Federal Circuit affirmed invalidity of a broad claim for lack of enablement but reversed a judgment of invalidity of narrower, dependent claims. The three patents at issue were directed to microorganisms useful in the production of docosahexaenoic acid ("DHA"). *Id.* at 1367. After a jury verdict that the asserted claims of all three patents were infringed and not invalid, the district court granted the defendants' motion for JMOL that claims 1, 4 and 5 of the '567 patent were invalid for lack of enablement. *Id.* at 1368. The Federal Circuit, however, ruled that in evaluating all three claims, the district court had improperly

focused on a single element of claim 1 of the patent, which was directed to growing euryhaline organisms with stated characteristics. *Id.* at 1378. Evidence produced at trial indicated that claim 1 likely covered as many as 10,000 euryhaline organisms, but the patent specification disclosed only one working example of such an organism. *Id.* at 1379. Expert testimony also suggested that the technology was unpredictable and that a tremendous amount of experimentation would be required to identify euryhaline organisms meeting the limitations of claim 1. *Id.* On that basis, the district court had ruled that all three of the asserted claims in the '567 patent were invalid for lack of enablement. *Id.*

On appeal, the Federal Circuit noted that dependent claims 4 and 5, which included order and genus limitations, were narrower than claim 1, and that no evidence of undue experimentation had been presented regarding those limitations. *Id.* Indeed, expert testimony indicated that the claim to the genus encompassed only 22 known species. *Id.* That testimony and additional evidence led the court to conclude that "the evidence presented to the jury support[ed] an inference that there [were] relatively few potential species that may meet the limitations of claims 4 and 5, as compared to the large number of potential species that may meet the limitations of claim 1." *Id.* The court thus found that the evidence supported the jury's implicit finding that claims 4 and 5 were enabled. *Id.*

Cases referenced
Janssen Pharmaceutica N.V. v. Teva Pharmaceuticals USA, Inc., 2009 U.S. App. LEXIS 21166 (Fed. Cir. Sept. 30, 2009)
Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009)
In re Wands, 858 F.2d 731 (Fed. Cir. 1988)
In re Wright, 999 F.2d 1557 (Fed. Cir. 1991)

Definiteness

Section 112, paragraph 2 requires that the specification of every patent conclude with one or more claims that particularly and distinctly claim the invention such that it reasonably apprises one skilled in the art of the boundaries of the invention. *See Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). The claims must clearly define the scope of the invention when construed in light of the entire patent document. Additionally, when a claim includes means-plus-function limitations pursuant to section 112, paragraph 6, failure of the specification to adequately disclose the structure that corresponds to the claimed function will render the claim indefinite. *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994).

In *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008), the Federal Circuit reversed the district court's ruling that one of the patents-in-suit was invalid because it failed to adequately define the term "port body." *Id.* at 1321. The technology at issue was directed to pressurized storage containers and associated features that prevent accidental rapid discharge of hazardous gas. *Id.* at 1310. During claim construction proceedings, Praxair argued that embodiments pictured in the specification supported a construction of the term "port body" as "a structure that connects to the outlet of a pressurized tank and includes a path for the discharge of a fluid from the pressurized tank." *Id.* at 1319-20. But the district court rejected Praxair's proposed construction, finding that the term was not labeled or coherently discussed in the specification and that its meaning was not discernable from the patent.

The Federal Circuit disagreed with the district court's reasoning and determined that the specification's discussion of two embodiments of the invention provided ample definition of the term "port body." *Id.* at 1321. The court noted numerous references to a "port body" describing how such a component interacted with other elements of the invention. *Id.* The court concluded that while the discussion of the "port body" in the specification "may not be a model of clarity," it nevertheless "adequately explains that the port body is a housing that sealingly engages the outlet of the cylinder and defines the fluid discharge path." *Id.* And while the court acknowledged that expert testimony presented at trial supported ATMI's definiteness arguments, it pointed out that because definiteness is a legal rather than a factual question, such extrinsic evidence would not prove the patent invalid. *Id.*

The court addressed definiteness in the context of means-plus-function limitations in *Blackboard, Inc. v. Desire 2 Learn, Inc.*, 574 F.3d 1371 (Fed. Cir. 2009). In that case, the court affirmed the district court's decision that the specification contained insufficient structure to support one of the means-plus-function limitations in claim 1 of the patent-in-suit. *Id.* at 1385-86. The patent claimed an Internet-based educational support system that involved varying access levels for different users. *Id.* at 1373. Claim 1 of the patent included a limitation of a "means for assigning a level of access to and control of each data file based on a user of the system's predetermined role in a course." *Id.* at 1382. At trial and on appeal, Blackboard asserted that the structure that performs the "means for assigning function" is a "server computer with an access control manager and equivalents thereof." *Id.* Although the specification did describe certain functions performed by the access manager, like creating access control lists, it provided no details as to how such functions were implemented. *Id.*

The Federal Circuit thus agreed with the district court that the specification did not provide sufficient disclosure to satisfy section 112, paragraph 6. The court noted that Blackboard's attempts to explain the operation of the access control manager were simply abstractions of the access-assigning function, and that the component that actually performed that function was an undefined "black box." *Id.* at 1383. Referring to its prior decisions in *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 521 F.3d 1328 (Fed. Cir. 2008) and *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008), the court stated that in order to avoid purely functional claiming in cases involving computer-implemented inventions, it has "consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." *Id.* at 1384. Thus, to satisfy the definiteness requirement, a specification disclosing a general purpose computer as a structure for a means-plus-function limitation must also disclose an algorithm for performing the claimed function. *Id.* Complex descriptions of *what* functions are performed will not substitute for descriptions of *how* those functions are performed.

Cases referenced

Aristocrat Technologies Australia Pty Ltd. v. International Game Technology, 521 F.3d 1328 (Fed. Cir. 2008)
Blackboard, Inc. v. Desire 2 Learn, Inc., 574 F.3d 1371 (Fed. Cir. 2009)
In re Donaldson Co., 16 F.3d 1189 (Fed. Cir. 1994)
Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870 (Fed. Cir. 1993)
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