

VOLUME ONE | ISSUE THREE
NOVEMBER 2008

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Willkie Farr & Gallagher's *Federal Circuit Review* is a newsletter from the Intellectual Property Department on recent developments taking place in the Court of Appeals for the Federal Circuit. The *Federal Circuit Review* will present an annual synopsis of the most recent decisions and what they mean for today's intellectual property-focused businesses. Each issue will present recent developments and highlights concerning a specific area of patent law.

This issue will focus on the requirements for patentability set forth in 35 U.S.C. § 112. Section 112, paragraph 1 requires that the patent specification contain a written description of the claimed invention in "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." Section 112, paragraph 2 states that "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." Paragraph 1 is the underpinning for the written description, enablement and best mode requirements for a patent specification. Under paragraph 2, the claims of a patent must be definite. This issue will explore recent Federal Circuit cases that highlight trends concerning the requirements of written description, enablement and definiteness.

THE WRITTEN DESCRIPTION REQUIREMENT

The written description requirement of § 112 ensures that the patentee claims only what has been invented, as measured by the specification. The specification must give a "meaningful disclosure" to the public "in exchange for [the public] being excluded from practicing the invention for a limited period of time." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002). The written description requirement is separate from the enablement requirement. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); see also *In re Curtis*, 354 F.3d 1347, 1357 (Fed. Cir. 2004) ("We interpret 35 U.S.C. § 112, 1 to require a written description requirement separate and apart from the enablement requirement.").

The Federal Circuit recently has focused on the written description analysis for broad claims to a genus, allegedly supported by limited disclosure of a species. The Patent and Trademark Office's Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, 1,

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“Written Description” Requirement, 66 Fed. Reg. 10-99 (Jan. 5, 2001), which the Federal Circuit finds is persuasive authority, states that

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species ... A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

* * *

Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

66 Fed. Reg. at 1106.

In *Carnegie Mellon University v. Hoffman-La Roche*, 541 F.3d 1115 (Fed. Cir. 2008), *reh’g en banc denied* (Nov. 10, 2008), the court affirmed the district court ruling that the claims of the patents-in-suit failed to meet the written description requirement. Carnegie Mellon’s patents were directed to recombinant plasmids that enhance expression of an enzyme, DNA polymerase I. The prior art showed that there were “difficulties cloning polA into multicopy plasmids because the increase in expression of DNA polymerase I above the natural level of expression was found to be lethal to a host bacterium.” *Carnegie Mellon*, at 1118. According to the court, the patents overcame this problem “by constructing a novel plasmid containing the entire and undamaged polA gene coding region enzymatically excised from a DNA molecule, which contains essentially none of or at the most only a portion of the activity of its natural promoter.” *Id.* at 1118-19 (internal citations omitted). The claims were not limited to any particular bacterial species, but instead claimed a DNA coding sequence that was “broadly defined, and only by its function.” *Id.* at 1124. The record demonstrated that the polA gene varied among numerous bacterial species, but the specification only disclosed the *E. coli* polA gene sequence.

The district court found the claims of the patents-in-suit invalid based on *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In *Eli Lilly*, the Federal Circuit held that a specification disclosing only rat insulin cDNA did not meet the written description requirement when the claims covered recombinant prokaryotic microorganisms comprising any vertebrate and mammalian cDNA, stating that “[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the claimed invention, 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.” *Id.* at 1566 (internal quotations omitted).

Here, the Federal Circuit agreed with the district court and ruled that under *Eli Lilly* the narrow disclosure related to *E. coli* in the specification did not represent or support the generic claims to the entire genus of bacteria. *Carnegie Mellon*, at 1126. Therefore, “[t]o satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required. One must show that one has possession, as described in the application, of

sufficient species to show that he or she invented and disclosed the totality of the genus ... [W]e conclude that that requirement was not met here." *Id.*

The district court also had found the claims of one of the three patents-in-suit invalid for failure to meet the written description requirement under *Gentry Gallery v. Berklinc Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) because the specification allegedly disclosed a key feature that was not found in the claims, specifically "lethality." In *Gentry Gallery* the Federal Circuit had ruled a claim invalid for failure to meet the written description requirement because the claim failed to recite an "essential element" found in the specification.

In *Carnegie Mellon*, the Federal Circuit reiterated its prior stance that *Gentry Gallery* "'did not announce a new "essential element" test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.' Rather, 'we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.'" *Carnegie Mellon*, at 1127 (citing *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002).) The court ruled that "lethality" was simply a reason for the invention, not an element that needed to be defined in the claims. In any event, the patent was invalid under *Eli Lilly* because the specification's narrow disclosure did not support broad generic claims. *Carnegie Mellon*, at 1128.

Following in the wake of *Carnegie Mellon*, in *In re Alonso*, No. 2007-1079 (Fed. Cir. Oct. 30, 2008), the court sustained rejection by the PTO Board of Patent Appeals and Interferences of one claim in a pending patent application for lack of written description. The claim at issue was directed to a "method of treating neurofibrosarcoma in a human by administering an effective amount of a monoclonal antibody idiotypic to the neurofibrosarcoma" of the patient where the "monoclonal antibody is secreted from a human-human hybridoma" derived from the tumor cells. *Id.* at 2. The specification described only one preparation of a monoclonal antibody. The examiner rejected the claim for lack of adequate written description because the claims encompassed a broad genus of antibodies not described in the specification, and the Board affirmed. *Id.* at 3-4.

The Federal Circuit affirmed the rejection for lack of adequate written description. The court stated that the specification was insufficient because it "teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method." *Id.* at 9. In addition, although the claim is a method claim, "the antibodies themselves are described in purely structural language." *Id.* The court held that, as in *Eli Lilly*, the specification "contains information about only one compound." *Id.* at 10.

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In *Technology Licensing Corporation v. Videotek, Inc.*, 2008 U.S. App. LEXIS 21380 (Fed. Cir. Oct. 10, 2008), the Federal Circuit dealt with the question of whether "the written description of the earlier application supports the later-claimed technology." *Id.* at *2. The technology at issue dealt with separation of a synchronization signal from a composite video signal so that images can be accurately reproduced on a television. The patent in question was issued from a continuation-in-part (CIP) application claiming priority to an earlier filed application. The record indicated anticipatory art had published after the filing date of the original application but more than one year before the filing date of the CIP. The issue was whether the original application provided an adequate written

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description of the CIP claim limitations at issue so that the CIP claim would be entitled to the original application's filing date.

The CIP claim at issue contained a limitation regarding a "capacitor or other circuit." The specification for the CIP contained a figure and specific references to two resistors that the court ruled support the "other circuit" limitation. The specification of the original application contained only a circuit diagram with two labeled resistors but no reference to the resistors in the text. TLC argued that since the figure in the CIP supported the "other circuit" limitation and the circuit diagram in the original application was similar to the CIP figure, then the original application provided an adequate written description to support the "other circuit" limitation.

The Federal Circuit disagreed, stating that "the issue is whether a person skilled in the art would understand from the earlier application alone, without consulting the new matter in the [CIP] patent, that the inventor had possession of the claimed 'other circuit'" when the original application was filed. *Id.* at *40. The court affirmed a judgment of invalidity based on the trial court's finding, after the trial, that the original application did not show that the inventor had possession of the "other circuit" limitation at the time of the original application. Therefore, the claim at issue was not entitled to the earlier filing date and therefore was invalid as anticipated.

Cases referenced

In re Alonso, No. 2007-1079 (Fed. Cir. Oct. 30, 2008)

Carnegie Mellon University v. Hoffman-La Roche, 541 F.3d 1115 (Fed. Cir. 2008), *reh'g en banc denied* (Nov. 10, 2008)

Gentry Gallery v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998)

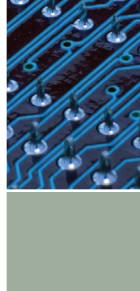
Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)

Technology Licensing Corporation v. Videotek, Inc., 2008 U.S. App. LEXIS 21380 (Fed. Cir. Oct. 10, 2008)

ENABLEMENT

Recent Federal Circuit cases also have addressed the enablement requirement and reaffirmed that the full scope of the claims must be enabled. "The scope of the claims must be less than or equal to the scope of the enablement" to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). Broad claims that could be construed to cover multiple embodiments must be supported by a specification that enables each of those embodiments. The challenge for patentees is to assert a claim construction that is not so overly broad that it is not fully enabled.

In *Sitrick v. Dreamworks*, 516 F.3d 993 (Fed. Cir. 2008), the Federal Circuit affirmed the district court ruling that, as construed, the claims of the patents-in-suit were not fully enabled. Sitrick sued Dreamworks and others over their use of a computer program called "ReVoice Studio," which allows users to add their own voice to movie images on DVDs. The district court construed the claims of the patents to cover a method for integrating user-generated audio and visual effects into both movies and video games. However, the court ruled that the patent specifications did not teach "how the substitution and integration of a user image would be accomplished in movies" because "movies and video games are technically different." *Id.* at 1000.



The court determined that the scope of the claims was broad enough to cover both movies and video games, though the specification enabled only video games. Thus, the court ruled that the claims were not fully enabled.

Sitrick is similar to other recent Federal Circuit cases addressing the requirement that the specification enable the full scope of the claims. In *Liebel-Flarsheim v. Medrad*, 481 F.3d 1371 (Fed. Cir. 2007), the Federal Circuit construed the patents' claims to cover both a jacketed and a jacket-free needle holder during the first appeal of the case. On a second appeal, the Federal Circuit affirmed the district court's ruling that the patents were not enabled. The specification only enabled jacketed needle holders. Since the specification did not enable a jacketless needleholder, and actually taught away from it, the claims were not fully enabled. Judge Lourie stated that "[t]he irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, 'beware of what one asks for,' might be applicable here." *Id.* at 1380.

In *Automotive Technologies International v. BMW, et al.*, 501 F.3d 1274 (Fed. Cir. 2007), the court again ruled that the full scope of the claims were not enabled by the specification. The district court, based on arguments made by ATI, construed the claims to cover both mechanical and electronic sensor structures. On summary judgment, the court found that the patent was not fully enabled because the specification only described the electronic sensor in broad terms while describing the mechanical sensor in detail. In affirming the district court, the Federal Circuit noted that the electronic sensors are "distinctly different" from the mechanical sensors and therefore must be separately enabled. The court also rejected the argument that the broad disclosure of the electronic sensor was enabling when combined with the knowledge of one of ordinary skill in the art, finding that the statements in the specification that side impact sensing is a "new field" meant that the sensor was a novel aspect of the invention and therefore must be enabled by the specification.

Cases referenced

Automotive Technologies International v. BMW, et al., 501 F.3d 1274 (Fed. Cir. 2007)

Liebel-Flarsheim v. Medrad, 481 F.3d 1371 (Fed. Cir. 2007)

Sitrick v. Dreamworks, 516 F.3d 993 (Fed. Cir. 2008)

DEFINITENESS

Section 112, paragraph 2 requires that the claims particularly point out and distinctly claim the invention so that the public can determine what can and cannot be practiced without the patentee's permission. A claim is considered "definite" when the claim, when read in light of the specification, allows one of ordinary skill in the art to determine the scope of the invention. A claim is indefinite if it cannot be construed or it is ambiguous.

In *Halliburton Energy Servs., Inc. v. M-I, LLC*, 514 F.3d 1244 (Fed. Cir. 2008), *reh'g denied, reh'g en banc denied*, 2008 U.S. App. LEXIS 8526 (Fed. Cir. Mar. 18, 2008), the court held that the claims were "insolubly ambiguous," even though the claim term purportedly was defined in the specification. The patent related to oil field drilling fluids that are fragile gels, used for "removing drill cuttings from the wellbore, cooling and lubricating the drill bit, aiding in support of the drill pipe and drill bit, and providing a hydrostatic head to maintain the integrity of the wellbore walls and prevent well blowouts." *Id.* at 1246 (citations omitted).

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The district court had granted summary judgment, finding that the definition of the claim term “fragile gel” in the specification was too subjective and unclear because it was defined by terms such as “easily transitions,” “less gel-like,” and “more liquid-like.” The district court also found that the doctrine of claim differentiation could not resolve the ambiguity since “fragile gel” could not be limited to contain “no or only [a] low amount of organophilic clay or lignite” because dependent claims included this limitation. The district court therefore held that the claims were indefinite.

The Federal Circuit affirmed the finding of indefiniteness. The court detailed examples where it has held a claim to be indefinite under § 112, such as when a means-plus-function claim recites functional elements without disclosing any corresponding structure, when a term is based upon a person’s subjective opinion, or when a claim contains a term lacking proper antecedent basis. *Id.* at 1249. The examples were meant to illustrate cases where claims would not allow a person of ordinary skill in the art to determine the scope of the claims, such that the claims were “insolubly ambiguous.” *Id.*

Although Halliburton had provided a three-part proposed definition of “fragile gel,” the Federal Circuit first ruled that part three of the definition, which required that a fragile gel contain no organophilic clay or organophilic lignite or that it contain only low amounts of organophilic clay or lignite, was not supported either by the claims or the specification. The court then ruled that parts one and two of the definition (which required that the gel easily transition between a gel and a liquid state when force is applied, and that the gel at rest can suspend drill cuttings and weighting materials) even though they were supported by the specification, did not allow a person of ordinary skill in the art to “translate the definition into meaningfully precise claim scope” because “ambiguity as to the scope of ‘fragile gel’ cannot be resolved.” *Id.* at 1251.

The court also addressed claims with functional limitations, i.e., a term defined “by what it does rather than what it is.” *Id.* at 1255 (citations omitted). Although claims having these types of limitations are not inherently indefinite, the court stated that:

When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area). We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.

Id. The Federal Circuit enumerated possibilities for a patent drafter to resolve ambiguities in functional limitations. Examples included using quantitative metrics or providing a formula in the specification for calculating the property and examples that both do and do not meet the limitation. A footnote suggests that if quantitative metrics or examples had been included in the specification in Halliburton, the definiteness issue might have been resolved differently. *Id.* at n.6.

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In *Aristocrat Technologies Australia (ATA) v. International Gaming Technology (IGT)*, 521 F.3d 1328 (Fed. Cir. 2008), *reh’g denied, reh’g en banc denied*, 2008 U.S. App. LEXIS 12719 (Fed. Cir. May 6,

2008), the Federal Circuit affirmed the district court ruling that all of the claims of the patent-in-suit were invalid as indefinite, in a case involving both § 112, paragraph 2, and § 112, paragraph 6, which requires that “the scope of [the means-plus-function] claim limitation had to be defined by the structure disclosed in the specification plus any equivalents of that structure.” *Id.* at 1331.

The patent covered an electronic slot machine where players can pre-select the symbol locations that will determine if the player is a winner. The district court found the means-plus-function claims invalid because the specification failed to provide a structure to perform the functions covered by the “game control means,” as required by § 112, paragraph 6. The specification only stated that the “game control means” could be a microprocessor-based gaming machine with “appropriate programming,” but, as the lower court pointed out, the specification did not provide a “specific algorithm” or “step-by-step process for performing the claimed functions.” *Id.* at 1332. As such, “in the absence of structure [sic] disclosed in the specification to perform those functions, the claim limitation would lack specificity, rendering the claim as a whole invalid for indefiniteness under 35 U.S.C. § 112 P 2.” *Id.* at 1331.

The Federal Circuit, affirming the district court ruling, stated that computer-implemented means-plus-function claims must include “more than simply a general purpose computer or microprocessor.” *Id.* at 1333. The court ruled that a microprocessor, without more, cannot be a sufficiently specific structural disclosure. “For a patentee to claim a means for performing a particular function and then to disclose only a general purpose computer as the structure designed to perform that function amounts to pure functional claiming.” *Id.* Because the means-plus-function claim limitation was not supported by a sufficient disclosure under § 112, paragraph 6, the claims were indefinite under § 112, paragraph 2.

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Similarly, in *Net MoneyIN, Inc. v. Verisign, Inc. et al.*, 2008 U.S. App. LEXIS 21827 (Fed. Cir. Oct. 20, 2008), the Federal Circuit affirmed the district court ruling that certain claims of the patents-in-suit were invalid under § 112, paragraph 2 as indefinite. The patents covered systems to process Internet credit card transactions. The district court construed the claims to include means-plus-function elements.

In the first patent, the district court construed the phrase “means for generating an authorization index” as a means-plus-function claim and found that there was no corresponding structure in the specification. On appeal, NMI argued that the element was not a means-plus-function element because the claim sufficiently disclosed the structure. The Federal Circuit held that the “bank computer” disclosed in the claims did not sufficiently disclose the required structure and the claim term was properly construed as a means-plus-function element under § 112, paragraph 6.

NMI argued that, in the alternative, the specification recited the structure such that the claims were definite. However, the Federal Circuit, relying on *Aristocrat*, held that, since there was no dispute “that the specification fails to disclose an algorithm by which a general purpose bank computer ‘generat[es] an authorization indicia,’” the claims were invalid as indefinite under § 112, paragraph 2. *Id.* at *16.

For the second patent-in-suit, NMI argued that the district court construed the function of the claim element too narrowly. The Federal Circuit, however, ruled that the “construction comports with and is fully supported by the language of the claim itself” and that NMI’s construction was “different from,

and broader in scope than, the construction it asserted in the district court.” *Id.* at *18. The district court’s construction was therefore affirmed. Since NMI had conceded that “under the district court’s construction, no structure is disclosed in the specification to perform the claimed function,” the patent was invalid as indefinite. *Id.* at *19.

Cases referenced

Aristocrat Technologies Australia (ATA) v. International Gaming Technology (IGT), 521 F.3d 1328 (Fed. Cir. 2008), reh’g denied, reh’g en banc denied, 2008 U.S. App. LEXIS 12719 (Fed. Cir. May 6, 2008)

Halliburton Energy Servs., Inc. v. M-I, LLC, 514 F.3d 1244 (Fed. Cir. 2008), reh’g denied, reh’g en banc denied, 2008 U.S. App. LEXIS 8526 (Fed. Cir. Mar. 18, 2008)

Net MoneyIN, Inc. v. Verisign, Inc. et al., 2008 U.S. App. LEXIS 21827 (Fed. Cir. Oct. 20, 2008)

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