Written Description, Claim Definiteness, and Best Mode

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Disclosure Requirements: §112(a)

- Specification Requirements of §112(a)
- Written Description
- Enablement
  - Ordinary Artisan
  - “Undue Experimentation” Test
- Best Mode

Uses of the Written Description Requirement

- Determining Priority Date
  - Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981): Need “to recount ... invention in such detail that ... future claims can be determined to be encompassed within ... original creation”
- Determining Validity
  - Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003): Need for “sufficient information in the original disclosure to show [the ordinary artisan] that the inventor possessed the invention at the time of the original filing”

Gentry Gallery (Fed. Cir. 1998)

Background

- Specification described “sectional sofa” with “console” between 2 “reclining seats” for which console had “controls.”
- Claim required:
  - “fixed console” between ... reclining seats”; and
  - 2 “control means ... mounted on the double reclining ... section.”

Gentry Gallery (Fed. Cir. 1998)

Claim 1

A sectional sofa comprising:

- a pair of reclining seats disposed in parallel relationship with one another in a double reclining seat sectional sofa section being without an arm at one end ... each of said reclining seats having a backrest and seat cushions and movable between upright and reclined positions...
Claim 1, continued

- a fixed console disposed in the double reclining seat sofa section between the pair of reclining seats and with the console and reclining seats together comprising a unitary structure,
- said console including an armrest portion for each of the reclining seats, said armrests remaining fixed when the reclining seats move from one to another of their positions,
- and a pair of control means, one for each reclining seat, mounted on the double reclining seat sofa section and each readily accessible to an occupant of its respective reclining seat and when actuated causing the respective reclining seat to move from the upright to the reclined position.
Gentry Gallery (Fed. Cir. 1998)

J. Lourie’s opinion for the Court

- “[C]laims may be no broader than the supporting disclosure.”
- “Sproule’s disclosure unambiguously limited the location of the controls to the console.”
- “[L]ocating the controls” elsewhere “is outside the stated purposes of the invention.”

- “In this case, the original disclosure clearly identifies the console as the only possible location for the controls. It provides for only the most minor variation in the location of the controls, noting that the control ‘may be mounted on top or side surfaces of the console rather than on the front wall ... without departing from this invention.’”
- “[T]he only discernible purpose for the console is to house the controls. As the disclosure states, identifying the only purpose relevant to the console, ‘[a]nother object of the present invention is to provide ... a console positioned between [the reclining seats] that accommodates the controls for both of the reclining seats.’”
- Thus, locating the controls anywhere but on the console is outside the stated purpose of the invention.

Gentry Gallery (Fed. Cir. 1998)

- “Sproule considered the location of ... controls on the console to be an essential element of his invention.”
- “[A]lthough not dispositive, because one can add claims to a pending application directed to adequately described subject matter, Sproule [the inventor] admitted at trial that he did not consider placing the controls outside the console until he became aware that some of Gentry’s competitors were so locating the recliner controls.”

What is the relationship between enablement and written description?

If the inventor re-files the specification at a later date, she cannot claim what the first filing enabled but failed to describe.
Claim 1

Enabled: 2 reclining seats in a sectional sofa; controls not located on arms of chair

Described: pair of reclining seats in a sectional sofa with a fixed console that houses the control means

Claimed: pair of reclining seats in a sectional sofa, a fixed console, and a pair of controls.

Regents of the University of California v. Eli Lilly (Fed. Cir. 1997)

- UC researchers discovered the cDNA sequence that codes for rat insulin
- Patent claimed microorganisms containing the sequence for human insulin, mammalian insulin, or vertebrate insulin
- Court held that the researchers had to wait until they had isolated the cDNA coding for human insulin before patenting it, and if they had, there would be no written description problem
- Court invalidated generic claims for mammalian and vertebrate insulin
- Commentator: Rush to patent during “recombinant DNA revolution” may have resulted in many patents being issued without a sufficiently enabling disclosure.

Ariad v. Eli Lilly (Fed. Cir. 2010)

Background
- NF-κB: gene expression stimulator
  - Nuclear Factor kappa B exists in cells bound to an inhibitor (IκB)
  - Messages outside the cell stimulate activity that removes the inhibitor
  - NF-κB then travels to nucleus and initiates gene expression
  - Blocking the receptor sites on NF-κB can help offset the effects of diseases caused by unwanted gene expression

133 Pages, 203 Claims

SD. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-κB-mediated intracellular signaling, the method comprising altering NF-κB activity in the cell; such that NF-κB-mediated effects of external influences are modified, wherein NF-κB activity in the cell is reduced] wherein reducing NF-κB activity comprises reducing binding of NF-κB to NF-κB recognition sites on genes which are transcriptionally regulated by NF-κB.
Ariad v. Eli Lilly (Fed. Cir. 2010)

- The claims are 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. 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.

Evista tablets contain the active ingredient raloxifene hydrochloride, which is a type of medicine called a selective estrogen receptor modulator (SERM).
- Evista is used to both prevent and treat osteoporosis in postmenopausal women. It works by acting on estrogen receptors in the bone tissue, where it mimics the natural effects of estrogen.

Ariad’s reading of §112

The specification shall contain
(1) A written description
   (a) of the invention, and
   (b) of the manner and process of making and using it,
   (c) 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 ...

Lilly’s reading of §112

The specification shall contain
(1) A written description
   (a) of the invention, and
   (b) of the manner and process of making and using it,
   (c) 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 ...
J. Lourie’s opinion for the Court

- 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: (i) a “written description of the invention,” and (ii) of the manner and process of making and using the invention.” 35 U.S.C. § 112(a)

- “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.

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.

More on Written Description

- Capon v. Eshlar, 418 F.3d 1349, 1357 (Fed. Cir. 2005): what is required to meet the written description requirement “varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.”
- TurboCare v. General Elec. Co., 264 F.3d 1111, 1118 (Fed Cir. 2001): “When the applicant adds a claim or otherwise amends his specification after the original filing date, … the new claims or other added material must find support in the original specification.”

Claim Definiteness, § 112(b)

- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his [or her] invention.
Nautilus v. Biosig Instruments,
134 S.Ct. 2120 (2014)

Background

- The invention at issue is a heart-rate monitor used with exercise machines.
- Biosig alleged that after disclosure of the patented technology to StairMaster, StairMaster sold exercise machines incorporating the invention without a license. Nautilus continued to do so after acquiring StairMaster.

Claim 1

1. A heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures, comprising:
   - an elongate member comprising a first half and a second half;
   - a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other;
   - a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other.
**Cert Question Presented**

- “Does the Federal Circuit’s acceptance of ambiguous patent claims with multiple reasonable interpretations—so long as the ambiguity is not ‘insoluble’ by a court—defeat the statutory requirement of particular and distinct patent claiming?”

**J. Ginsburg’s opinion for the Court**

- “To tolerate imprecision just short of that rendering a claim ‘insolubly ambiguous’ would diminish the definiteness requirement’s public-notice function and foster the innovation-discouraging ‘zone of uncertainty,’ United Carbon, 317 U. S., at 236, against which this Court has warned.”
- “The expressions ‘insolubly ambiguous’ and ‘amenable to construction,’ which permeate the Federal Circuit’s recent decisions concerning §112(b) [do not satisfy the statute’s requirements]… and can leave courts and the patent bar at sea without a reliable compass.”

**Decision on remand to the Federal Circuit**

- Nautilus won at the Supreme Court, but it lost once again on remand at the Federal Circuit
- "The court ‘may now steer by the bright star of reasonable certainty,’ rather than the unreliable compass of ‘insoluble ambiguity.’"
- "[The] term ‘spaced relationship’ does not run afoul of the ‘innovation-discouraging’ ‘zone of uncertainty’ against which the Supreme Court has warned, and to the contrary, informs a skilled artisan with reasonable certainty of the scope of the claim.”

**Written Description and Definiteness**

- *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014):
  - “We do not understand the Supreme Court to have implied in [Nautilus], and we do not hold today, that terms of degree [e.g., ‘substantial’ or ‘about’] are inherently indefinite.”
  - “[The written description requirement was a part of the patent statutes at a time before claims were required]…
  - "The written description requirement guards against the inventor’s overreaching by insisting that he recount his invention in such detail that future claims can be determined to be encompassed within his original creation.”
  - "The definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.”
Best Mode

• Two part test: (1) whether at the time of filing the inventor knew of a mode of making and using his invention that he considered best, and (2) if so, is the disclosure adequate to enable one of ordinary skill in the art to practice the best mode, or has the inventor concealed his preferred mode?
• More detailed disclosure was not necessary to inform one of skill in the art about the inventor’s best mode
  • Young Dental Manufacturing Company, Inc. v. Q3 Special Products, Inc., 112 F.3d 1137 (Fed. Cir. 1997)
• The best mode requirement does not apply to “production details”
  • Wahl Instruments, Inc. v. Accuvas, Inc., 950 F.2d 1575 (Fed. Cir. 1991)

Any questions?