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Patents and the Written Description Requirement

Implications of *Ariad v. Eli Lilly* and Best Practices to Meet Section 112 Requirements

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- *Ariad v. Lilly*
  - Overview of Federal Circuit's ruling
  - Implications of the decision
    - on patent prosecution
    - for predictable arts
    - for non-predictable arts
    - on patent litigation
  - Best practices to meet the written description requirement

Written description requirement: Purpose and Scope

- 35 U.S.C. § 112, ¶ 1:
  - 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.

Written description requirement: Purpose and Scope

- Purpose:
- Describe exactly what the grant covers:
  - "The specification shall contain a written description of the invention and the manner and process of making and using it, …"
  - Must "convey clearly to those skilled in the art the information that applicant has invented the specific subject matter claimed." (*Carnegie Melon v. Hoffman La Roche* quoting *Vas-Cath v. Mahurkar)*
- Requires more than a "hope" or a "plan." (*Fiers v. Revel*)
- The invention is defined by the claim(s) of the application. (*CFMT v. YieldUP International*)
- Sufficiency of disclosure is measured at the time of filing. (*Elan Pharmaceuticals v. Mayo Foundation*)

Written description requirement: Purpose and Scope

- Purposes of the Written Description Requirement:
  - Before the introduction of a claims requirement (1836), the written description served to define the metes and bounds of the patented invention.
  - This requirement kept the inventor from "pretending that his invention is more than what it really is." (*Evans v. Eaton, 20 U.S. 434-435 (1835))*

Written description requirement: Purpose and Scope

- Historical development:

  Courts have long held that paragraph 1 of 35 U.S.C. § 112 contains a separate written description requirement.

- The CCPA noted that:
  - the specification must provide sufficient guidance in identifying the invention, analogizing "blaze marks" to mark a trail in a forest. (*In re Ruschig)*
  - statutory interpretation supports existence of separate written description requirement. (*In re Barker)*
  - "[i]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe the invention." *(In re DiLeone)*

Written description requirement: Purpose and Scope

- Historical development:

- The Supreme Court recognized the distinction between the description requirement and enablement requirement. (*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*)

- The Federal Circuit has followed this precedent in several cases. (*Fiers v. Revel*; *Regents of the University of California v. Eli Lilly & Co.*; *Enzo Biochem v. Gen-Probe*; *University of Rochester v. G.D. Searle & Co*.)

Written description requirement: Purpose and Scope

- Historical development:

- The separate written description requirement prevents a patent grant from being "a hunting license." It rewards not the "search" but its "successful conclusion." (*University of Rochester, v. G.D. Searle & Co*)

- Two key aspects of the separate written description requirement are:
  - A showing that the inventor(s) had *possession* of the claimed subject matter to insure the quid pro quo (*Capon v. Eshhar);* and
  - Public notice of what the inventor(s) considered to be the invention. (*In re Ruschig)*

Written description requirement: What is Required

- The written description does not require:
  - examples (*Falkner v. Inglis)*;
  - actual reduction to practice (*Falkner v. Inglis);*
  - word for word disclosure (*Fujikawa v. Wattanasin*);
  - the same type of written description for every type of invention (*Capon v. Eshhar);* or
  - express disclosure of each and every species of a genus (*In re Robins*).

Written description requirement: What is Required

- The Written Description Requirement:
  - ensures that the inventor was in possession of the subject matter claimed by her patent;
  - defines the patent grant and what can or cannot be practiced;
  - ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing the invention during the life of the patent. (*Ariad*, 598 F.3d at 1354).

Written description requirement: What is Required

- Applying the Written Description Requirement:
  - Compliance is a question of fact.
  - Would the ordinary skilled artisan have understood that the inventor was in possession of the claimed invention at the time of filing?
  - Compare the patent claims with the patent disclosure.
  - The requirement is not met if the claimed invention lacks sufficient specificity in the disclosure.

Written description requirement: What is Required

- Applying the Written Description Requirement:

  The requisite level of detail to meet the requirement is based on factors:

  - the nature and scope of the claims;
  - the predictability of the relevant technology;
  - the existing knowledge in the field;
  - the prior art;
  - the maturity of the field.

Ariad v Lilly: Overview

- *Ariad* sued Eli Lilly for alleged infringement of U.S. Patent 6,410,516 B1.
- The '516 patent claims methods for modifying cellular responses to external influences that comprise reducing the activity of a protein transcription factor called Nuclear Factor kappa B (NF-kB).
- *Ariad* alleged that Eli Lilly's sale of its Evista and Xigris drugs induced or contributed to infringement of the '516 patent by patients.
- At trial the defenses raised included invalidity under 35 U.S.C. §§ 101, 102, and 112 (enablement and WD)

Ariad v Lilly: Overview

- The ‘516 patent specification (Table 2) identified DNA sequences that were known to contain NF-kB binding sites.
- Specification included three classes of molecules described as capable of reducing NF-κB activity and described them functionally: specific inhibitors, dominantly interfering molecules, and decoy molecules.
- One example was a specific inhibitor (I- κB), a naturally occurring molecule, along with the sequence of DNA that encodes it.
- No other molecules were identified in the specification that were capable of providing desired reduction in NF- κB activity in cells.
- The specification prophetically stated that “decoy” molecules, comprising such DNA sequences, “would bind” to NF-kB and would thereby effect a negative regulation of NF-kB activity.

Ariad v Lilly: Overview

- A jury found the claims to be both valid and infringed and the district court ruled against Lilly's motion JMOL that the claims were not infringed and were invalid for anticipation, lack of enablement, or lack of written description.

- A panel of the Federal Circuit affirmed in part and reversed in part, finding that the claims were invalid for lack of written description because the disclosure was insufficient to establish that the inventors were in possession of the claimed invention.

Ariad v Lilly: Overview

- The Federal Circuit vacated the panel's decision and agreed to a rehearing of the appeal *en banc*,
- Asked the parties and patent community to provide additional briefing concerning two questions:
- 1. Whether 35 U.S.C. § 112, first paragraph contains a written description requirement separate from an enablement requirement?

  2. If a separate written description is set forth in the statute, what is the scope and purpose of that requirement?
- In addition to the parties' briefs, the court received 25 amicus briefs responding to the court's questions.

Ariad v Lilly: Overview

- An en banc majority of the Federal Circuit ultimately found the claims invalid as lacking written description.

- The majority held that, even if "the decoy-molecule hypothetical" might enable a skilled artisan to make and use the claimed methods, "the asserted claims [were] far broader" and so were "invalid for lack of written description."

- The majority reaffirmed that 35 U.S.C. § 112, first paragraph has a separate written description and enablement requirement.

Ariad v Lilly Majority Opinion: Statutory Interpretation and Purpose

- The majority opined that "[i]f Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently."

- The majority noted that the written description requirement is part of the quid pro quo of a patent and operates to:
  - allow the USPTO 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.

En Banc Majority Opinion

- Written description component requires that the patentee disclose in the specification conceptual "possession of the claimed subject matter as of the filing date," to prove that by the filing date she invented what the patent claims
- The patentee must disclose:
  - knowledge of the structure of the claimed invention
  - A functional description of the invention is not sufficient unless the correlation between structure and function is known

No New Ground Broken

- The Federal Circuit stayed the course on the written description requirement. The nine-judge majority opinion does not break new ground but removes any uncertainty that the written description requirement applies to original claims.

- The written description doctrine requires an inventor to demonstrate
  - conceptual "possession of the claimed subject matter as of the filing date" in her disclosure, i.e., to prove in her disclosure that she "invented what is claimed" as of the filing date.

- The possession test:
  - the inventor must disclose knowledge of the structure of the claimed invention
  - a functional description of what it does is insufficient (unless there is a known correlation between function and structure)

What Is Not Required

- A few broad principles hold true across all cases. The written description does not require:
  - actual reduction to practice ;
  - any particular form of disclosure;
  - word for word disclosure;
  - the same type of written description for every type of invention; or
  - express disclosure of each and every species of a genus.

Is Disclosure of One Species or Embodiment Enough?

- Some language in the opinion suggests that disclosure of a sufficient embodiment or example would satisfy WD. For example, the opinion describes one of the "few broad principles that hold true across all cases" as follows:

  - 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).

- This passage supports the view that examples are not *necessary* but that a specific example falling within a claim is *sufficient* to satisfy WD.

When Is More Disclosure of More Than One Species Or Embodiment Required?

- Other language in *Ariad* suggests that a single example may not always suffice:

  - 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 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).

What Problems Does *Ariad* Leave Behind?

- The *Ariad* opinion does not resolve the potential for confusion between the written description requirement and the enablement requirement as means to regulate the scope of the claims.
- The *Ariad* opinion does not develop the WD analysis of "possession of the invention" in terms of other patent law concepts regarding the invention.

  - Can a specification that expressly describes a genus and adequately discloses one or more species fail to satisfy WD because it does not show sufficient "possession" of the genus invention?
  - Is a description inadequate when it defines a generic class in terms of a desired result and what species of the genus *do* instead of what they *are*?

Ariad v Lilly: The Practical Implications

- The law is the same for both the predictable and unpredictable arts.
- In practice, it generally is more difficult to satisfy the written description requirement in the unpredictable arts.
- *Ariad* may heighten attention to the separate written description requirement as it applies to litigation, opinion work, and patent prosecution.

The Practical Implications: Prosecution

- Existing PTO guidelines probably unaffected.

- Possible decrease in the scope of protection afforded to pioneering-type inventions, especially in unpredictable arts.

The Practical Implications: Prosecution

- An unpredictable impact on the number of patent applications being filed as it becomes more difficult to strike the right balance of when the written description is satisfied.

- Possible increase in rejections of all claims by Examiners in the U.S.P.T.O. for lack of written description (both original and amended).

The Practical Implications: Litigation and Opinion Work

- Possible increase in the ease with which a party may challenge a patent based on the written description in litigation and both clearance and freedom-to-operate opinions.

- Claims limited to subject matter actually reduced to practice are unaffected.

Impact of *Ariad*

- Possession = Description
  - "The hallmark of written description is disclosure. Thus, 'possession as shown in the disclosure' is a more complete formulation."

Ariad, 598 F. 3d at 1351.

- Inventors in the unpredictable arts have long faced substantial disclosure hurdles.
- Inventors in the predictable arts now face them, too.
  - Literally or graphically describe the invention with all its limitations.
- The heightened sensitivity to the written description requirement in U.S. patent applications may complicate the preparation and examination of foreign counterpart applications.

Cases Since *Ariad v. Lilly*

- ***Crown Packaging Tech., et al. v. Ball Metal Beverage Container Corp.***
- Asserted claims were directed to metal cans and methods for seaming them
- Parties disagreed about what the spec disclosed
- District Court granted SJ of invalidity for lack of written description
  - asserted claims cover two ways of construction – a "chuck" to save metal, but the spec only disclosed one
- Federal Circuit reversed
  - the spec teaches two separate solutions
- Predictable art
-

635 F.3d 1373 (Fed. Cir. 2011)

Cases Since *Ariad v. Lilly*

- ***LG Electronics v. Whirlpool Corp.***

- Whirlpool asserted that its 130 patent disclosed a refrigerator design that located the ice storage bin in the freezer compartment door
- Whirlpool sued LG for infringement and won at trial
- LG sought JMOL that the '130 patent failed the written description requirement
- The only disclosure of this design was a single drawing that depicted an ice storage bin on the inside of the freezer compartment door
- LG: the technical complications of this design were more than an ordinary skilled artisan could readily comprehend based only on the drawing
-

2001 U.S. Dist. Lexis 70963
(D. Del., July 1, 2011)

Cases Since *Ariad v. Lilly*

- ***LG Electronics v. Whirlpool Corp.***

- District court agreed and granted a new trial
  - The specification of Whirlpool's later '624 patent describes an ice maker on the compartment door in greater detail
  - Merely viewing the '130 patent drawing does not indicate how the specification disclosed the claimed invention to the ordinary-skilled artisan

2011 U.S. Dist. LEXIS 70963, *38-*40
(D. Del, July 1, 2011)

Cases Since *Ariad*: The Unpredictable Arts

- The description required to satisfy § 112 "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence."

Capon v. Eshhar, 48 F.3d 1349, 1357 (Fed. Cir 2005)

- "For inventions characterized by factors not reasonably predictable which are know to one of ordinary skill in the art, more evidence is required to show possession."

MPEP § 2163

Cases Since *Ariad*

- ***Billups-Rothenberg, Inc. v. Assoc. Regional and Univ. Pathologists***
- Billups asserted the '681 patent, directed to methods of diagnosing hemochromatosis by
  - obtaining a patient sample containing a non-classical MHC class 1 heavy chain
  - test the sample for a gene mutation that reduces the ability of the heavy chain to interact with beta-2 microglobulin
- People with the mutation (C282Y) have or are predisposed to hemochromatosis

2010 U.S. Dist. LEXIS 143170

(C.D. Ca. May 26, 2010)

Cases Since *Ariad*

- ***Billups-Rothenberg, Inc. v. Assoc. Regional and Univ. Pathologists***
- Defendants moved for SJ of invalidity for lack of written description
  - the asserted claim is a genus claim and the DNA sequence of the C282Y mutation and the hemochromatosis gene were not expressly disclosed
  - The '681 patent spec only disclosed the location of the histocompatibility complex gene (short arm of chromosome 6), where mutations linked to hemochromatosis were predicted to reside
- The '681 patent does not disclose any species of the claimed genus or structural features common to members of the genus

2010 U.S. Dist. LEXIS 143170

(C.D. Ca. May 26, 2010)

Cases Since *Ariad*

- ***Billups-Rothenberg, Inc. v. Assoc. Regional and Univ. Pathologists***
- Billups responded
  - the asserted claim is not a genus claim because only one known DNA mutation (C282Y) satisfies the claim limitations
  - the spec discloses sufficient function and structure to satisfy the written description requirement

2010 U.S. Dist. LEXIS 143170

(C.D. Ca. May 26, 2010)

Cases Since *Ariad*

- ***Billups-Rothenberg, Inc. v. Assoc. Regional and Univ. Pathologists***
- The district court's decision:
  - the asserted claim is a genus claim because its scope includes undiscovered mutation
  - the parties agreed that the '681 spec did not disclose any species of the disclosed genus of DNA mutations
  - the '681 patent did not disclose the DNA structure of the hemochromatosis gene or its mutations
- SJ of invalidity granted
- 2010 U.S. Dist. LEXIS 143170
- (C.D. Ca. May 26, 2010)

Cases Since *Ariad*: *Boston Scientific v. Johnson & Johnson*

- Johnson & Johnson asserted patents directed to drug-eluting stents using either rapamycin or a macrocyclic lactone analog of rapamycin as the therapeutic drug
- Boston Scientific filed for a DJ of invalidity for inadequate written description of a representative number of species of the claimed genus
- FYI: Rapamycin is a macrocyclic lactone

- 647 F.3d 1353 (Fed. Cir. 2011)

Cases Since *Ariad*: *Boston Scientific v. Johnson & Johnson*

- The patent spec did not disclose chemical structure or formulas for any analog contemplated by the inventors
- At the time of filing, many macrocyclic lactone analogs of rapamycin were possible, but only a few were known
- The patentees' expert opened that
  - the structure and mechanism of action of rapamycin were known
  - correlation between the structure and function of rapamycin was known
  - dozens of rapamycin analogs were known
- 647 F.3d 1353 (Fed. Cir. 2011)

Cases Since *Ariad*: *Boston Scientific v. Johnson & Johnson*

- The Federal Circuit affirmed summary judgment for lack of written description
  - The patent disclosed four experimental methods to deliver the therapeutic drug, all with rapamycin
  - The patent spec did not disclose any macrocyclic lactone analogs of rapamycin, let alone delivery of them
  - The spec did not describe the claimed analogs except to indicate vaguely that they must be structurally similar to rapamycin
- Inadequate written description support for broad genus claim to the analogs
- 647 F.3d at 1364

Cases Since *Ariad v. Lilly:* *Centocor Ortho Biotech, Inc. v. Abbott*

- Centocor sued Abbott for patent infringement
  - Humira® antibody to combat arthritis
- Jury found patent valid and infringed
- Abbott filed JMOL on § 112
  - Centocor patent allegedly failed the written description requirement

636 F.3d 1341 (Fed. Cir. 2011)

Centocor Ortho Biotech v. Abbott

- Technology:
- Overproduction of TNF is implicated in several auto-immune diseases
- Humira® is a monoclonal antibody that binds to TNF-α and thus prevents the activation of TNF receptors
  - This inhibits production of TNF
- The antibodies have constant and variable regions

636 F.3d at 1344-45

Centocor Ortho Biotech v. Abbott

- Centocor and Abbott each developed anti-TNF-α antibodies
- Two strategies
  - mouse and human: chimera
    - Centocor used a mouse antibody to human TNF-α
      - To reduce the human patient's immune response to the mouse antibody, Centocor replaced the mouse constant region with a human constant region
  - all human:
    - Abbott screened for human variable regions that bind human TNF-α and then improved the binding affinity
      - Abbott combined the improved human variable region with a human constant region
      - Humira®

636 F.3d at 1345 and 1346

Centocor Ortho Biotech v. Abbott

- 1991: Centocor filed patent application claiming chimeric antibody
  - CIPs 1993 and 1994
- 2002: Centocor added claims for human variable regions
  - Issued as '775 patent
- 1996: Abbott filed patent application claiming all-human antibodies to TNF-α
  - Claims cover Humira®
- 2000: Patent issued

636 F.3d at 1346

Centocor Ortho Biotech v. Abbott

- Abbott argued on appeal that the '775 patent lacked adequate written description for the "human variable region" claimed in the asserted claim
- Centocor relied on the 1994 CIP as its priority date and that application was the focus of the written description analysis
  - The 1994 CIP application disclosed only a single mouse variable region
- The court concluded that the mouse variable region disclosure did not identify a human variable region as claimed

- 636 F.3d at 1348-50 and 1353

Centocor Ortho Biotech v. Abbott

- Centocor also relied on the "antibody exception," *e.g.*, the written description requirement was met because the '775 patent disclosed an antibody that binds to human TNF-α antigen (protein)
- PTO guidelines: An antibody which binds to a protein is sufficiently disclosed:
  - the application fully discloses the novel protein; and
  - generating the claimed antibody is so routine that once the protein is possessed, so is the antibody
- The Federal Circuit disagreed:
  - TNF-α was not novel
  - in 1994, obtaining the human form of the TNF-α antibody was not routine for a skilled artisan

636 F.3d at 1348-1353

Impact of *Ariad* on Patent Litigation

- Too soon to have reliable empirical data
- Prior to *Ariad*: A.B. Rabinowitz, "Ending the Invalidity Shell Game: Stabilizing the Application of the Written Description Requirement in Patent Litigation," 12 Minn. J.L. Sci. & Tech., 127, 141 (2011)

Year	Written Description Challenge Prevails
2000-2004	52%
2005	35%
2006	43%
2007	25%
2008	39%
2009	37%
Average	43%

Ariad: Impact on Patent Prosecution

- Dennis Crouch's 2010 study: 2,858 BPAI patent opinions in 2009
- Written description issues were decided in 123 decisions (4.3%)
  - None of the 123 outcomes would have ultimately changed if the written description requirement had been eliminated
  - New-matter written description rejections determined the outcome in 20 of the 2,858 cases (1%)
  - Chief Judge Michel comment during oral argument: it is "exceedingly rare that the patent office hands its hat on written description."

Crouch, Dennis D., "An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution" (February 18, 2010); Northwestern Law Review Colloquy, Vol. 104, 2010

Ariad: Impact on Patent Prosecution

- *Ariad* did not change the law or written description, but drew more attention to it
  - PTO guidelines have not changed
- Biotechnology patents and pioneer inventions may face greater scrutiny and limited scope

Ariad: Impact on Patent Prosecution

- Inventors may delay filing to further develop inventions
  - Weigh risk of losing rights in first-to-file system against written description requirement
- The increased attention may encourage examiners to reject on written description grounds
  - Mapping the claims (37 CFR 1.105; MPEP § 704.11(b)):
    - Provide a side-by-side chart comparing claims and written description support in specification

Best Practices

- Likely sources of written description problems:
  - broad claim with little support in the spec, *i.e.*, genus claim with few of no species described in the spec
  - overly narrow claims based on selecting certain elements in the original disclosure not previously combined in practice
  - substantial claim amendments during prosecution
  - reliance on early priority date for provisional applications

Best Practices

- There is a presumption there is a sufficient written description. Thus, the Examiner must have a reasonable basis for challenging the adequacy of the description.

- When claiming a genus, describe the structure of the genus and structures of as many species as necessary to reasonably allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed.

- Attempt to identify relationship between structure and function of useful materials.

- To avoid issues with written description upon amending the claims, draft the specification with potential future claim amendments and “fall back” positions in mind.

Best Practices

- Be wary of adequacy of written description when preparing all patent applications, **but especially provisional applications** – they are a trap, a prior disclosure or offer for sale may be enough to render claimed invention obvious, but not satisfy written description.

- Draft claims for provisional patent applications.

- Err on side of disclosing a lot of detail and alternative claim language in priority application – invest more now for future value of valid patent, rather than less now for zero future value or worse.

- Consider keeping invention trade secret rather than file inadequate written description.

Best Practices

- Ways to minimize the problems:
  - describe the structure of the genus and as many species as possible
  - identify relationship between structure and function
  - draft the specification with potential future claim amendments and positions in mind
  - disclose more rather than less detail
  - consider filing separate applications if structurally diverse means of attaining the desired result are discovered

Best Practices

- Strategy for responding to rejections of the written description:
  - The Examiner has failed to establish by a preponderance of the evidence why a skilled person would not recognize in the disclosure a description of the invention defined in the claims.
  - Present claim chart with the claim language and written description support in a side-by-side comparison referencing specific portions in the specification.
  - The claimed subject matter need not have literal support.
    - There is no requirement that the specification support the claim word for word.
    - The applicant needs to show identity of “that which is described” and that the applicant had possession of what is claimed within the four corners of the specification.