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Patents and the Written Description Requirement

Meeting Section 112 Disclosure Obligations After Ariad v. Lilly

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today's panel features:
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Thursday, June 10, 2010

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Written Description Requirement for Patents

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

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June 10, 2010

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I. Written description requirement

- Purpose and scope
- What is required by Section 112

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II. Ariad v. Lilly

- Overview
- Federal Circuit's ruling
- Dissents by Judges Rader and Linn
- Implications of the decision
  - on patent prosecution
  - for predictable arts
  - for non-predictable arts
  - on patent litigation

III. Best practices to meet the written description requirement

- Are provisionals vulnerable?
- Effect on pioneering inventions?
- Effect on patent application drafting and timing?

I. Written description requirement: Purpose and Scope

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General Policy:

The requirement of an adequate disclosure assures that the public receives *quid pro quo* for the limited monopoly which is granted to the inventor. (*Bonito Boats v. Thunder Craft Boats*)

I. Written description requirement: Purpose and Scope

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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.

I. Written description requirement: Purpose and Scope

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Written Description:

"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*)

I. Written description requirement: Purpose and Scope

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Enablement:

"…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 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*)

I. Written description requirement: Purpose and Scope

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Best Mode:

"… and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Must be the best mode at the time of filing – there is no requirement to "update" the best mode during prosecution of the application.

I. Written description requirement: Purpose and Scope

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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)*

I. Written description requirement: Purpose and Scope

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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.*)

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Historical development:

The purpose of the separate written description requirement is for the inventors to satisfy their portion of the quid pro quo by providing a meaningful disclosure of the invention. (*Bonito Boats Inc. v. Thunder Craft Boats*; *University of Rochester v. G.D. Searle & Co. citing Enzo Biochem v. Gen-Probe*)

The patent statute and policy behind the statute require more than simple conception of an idea defined by a "hoped-for-function." (*Fiers v. Revel*)

The policy is to promote disclosure of inventions, "not research plans." (*Fiers v. Revel*)

I. Written description requirement: Purpose and Scope

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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*)

Hence, 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)*

I. Written description requirement: What is Required

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The written description must describe that invention "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." (*University of California v. Eli Lilly & Co.)*

An inventor must be able to "describe [the] invention with particularity." (*Fiers v. Revel)*

An applicant describes the invention "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." (*Lockwood v. American Airlines, Inc.*)

I. Written description requirement: What is Required

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The written description requirement also can be satisfied by:

- "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics … *i.e.*,
  - complete or partial structure, other physical and/or chemical properties,
  - functional characteristics when coupled with a known or disclosed correlation between function and structure, or
  - some combination of such characteristics."

(Manual of Patent Examination and Procedure)

I. Written description requirement: What is Required

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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*).

II. *Ariad v Lilly*: Overview

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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)

II. *Ariad v Lilly*: Overview (cont.)

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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 being capable of reducing NF-κB activity and described them functionally: specific inhibitors, dominantly interfering molecules, and decoy molecules.

One example was provided of 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.

II. *Ariad v Lilly*: Overview (cont.)

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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.

II. *Ariad v Lilly*: Overview (cont.)

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A jury found the claims to be both valid and infringed and the district court ruled against Lilly's motion for judgment as a matter of law 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.

II. *Ariad v Lilly*: Overview (cont.)

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The Federal Circuit vacated the panel's decision and agreed to a rehearing of the appeal *en banc*, asking 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.

II. *Ariad v Lilly*: Overview (cont.)

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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."

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

II. *Ariad v Lilly* Parties' Arguments: Statutory Interpretation

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Ariad

The specification shall contain

[A] a written description

- [i] of the invention, and
- [ii] of the manner and process of making and using it,

[B] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same …

Lilly

(1) The specification shall contain a written description of the invention, and

(2) The specification shall contain a written description … of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...

II. *Ariad v Lilly* Majority Opinion

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

II. *Ariad v Lilly* Majority Opinion: Statutory Interpretation and Purpose

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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.

II. *Ariad v Lilly* Majority Opinion: Supreme Court Precedent

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"[W]e … read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims."

"[I]n Schriber-Schroth, … [t]he Court ascribed two purposes to [Section 112] of the statute, only the first of which involved enablement. … Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did."

"Further, both before and after Schriber-Schroth, the Court has stated that the statute serves a purpose other than enablement. … [M]ost recently in Festo, the Court recited three requirements for § 112, first paragraph, and noted a written description requirement separate from the others …. As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them."

II. *Ariad v Lilly* Majority Opinion: Other Precedent

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Stare decisis - "[T]his has been the law for over forty years, and to change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding license agreements, and rendering validity and infringement opinions."

"If the law of the written description is to be changed … such a decision would require good reason and would rest with Congress."

II. *Ariad v Lilly* Majority Opinion: Scope of the W.D.

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"Claims define and circumscribe, the written description discloses and teaches."

"[T]he [written description] analysis compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification, … the claim … fails regardless whether one of skill in the art could make or use the claimed invention."

II. *Ariad v Lilly* Majority Opinion: Scope of the W.D., cont'd.

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"[W]hile it is true that original claims are part of the original specification, that truisim fails to address whether the original claim language necessarily discloses the subject matter that it claims. … Although many original claims will satisfy the written description requirement, certain claims may not."

The written description analysis applies to both original claims and amended claims, nothing in the language of § 112, first paragraph supports restricting the requirement for purposes of determining priority.

"Although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we."

II. *Ariad v Lilly* Majority Opinion: Scope of the W.D., cont'd.

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"[G]eneric language in the application as filed does not automatically satisfy the written description requirement."

"[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species."

II. *Ariad v Lilly* Majority Opinion: Evaluating the W.D.

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"[T]he 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."

II. *Ariad v Lilly* Majority Opinion: Evaluating the W.D.

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The en banc court characterized the asserted claims as "**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" (emphasis added).

II. *Ariad v Lilly* Majority Opinion: Evaluating the W.D.

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"[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."

"The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges."

II. *Ariad v Lilly* Majority Opinion: Evaluating the W.D.

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For generic claims, there are a number of factors for evaluating the adequacy of the disclosure, including the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.

Thus, there are no bright-line rules governing the number of species that must be disclosed to describe a genus claim, as the number necessarily changes with each invention and with progress in the field.

Accordingly, an adequate written description of a genus may be provided by a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials.

II. *Ariad v Lilly* Newman's Concurring Opinion

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"[T]he overriding policy of patent systems requires both written description and enablement, and it is less critical to decide which statutory clause applies in a particular case, than to assure that both requirements are met."

"Although the content varies, the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility.

II. *Ariad v Lilly* Gajarsa's Concurring Opinion

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"In my judgment, the text of § 112, ¶ 1 is a model of legislative ambiguity. The interpretation of the statute, therefore, is one over which reasonable people can disagree …. While not entirely free from doubt, the majority's interpretation … is reasonable."

Yet, this [written description] thicket is the result of our best efforts to construe an ambiguous statute; only Congress wields the machete to clear it."

Summary: No New Ground Broken

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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

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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.

Unanswered Questions: Is Disclosure Of One Species or Embodiment Enough?

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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?

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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 Are On The Horizon?

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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*?

When Is The WD Adequate?

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The Ariad Court's explanation of when a written description is inadequate never gets to the heart of the matter. The opinion simply reiterates generalities from its *Eli Lilly*, *Fiers*, and *Enzo* decisions:

- sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so a POSA can "visualize or recognize" the members of the genus
- an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials
- functional claim language can meet the written description requirement when the art has established a correlation between structure and function

No Specific Guidance Is Provided

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The majority opinion provides only a vague directive:

"But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species."

II. *Ariad v Lilly* Rader's Dissenting Opinion

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"[T]he separate written description requirement that the court petrifies today has no statutory support. … [The] language, while cumbersome, is unambiguous."

"The reason for the description doctrine is clear: to ensure that the inventor fully discloses the invention in exchange for an exclusive right. The test for the adequacy of the specification that describes the invention also is clear: Is the description sufficient to enable a person of ordinary skill in the art to make and use the claimed invention? Nowhere does the paragraph require that the inventor satisfy some quixotic possession requirement."

II. *Ariad v Lilly* Rader's Dissenting Opinion, cont'd.

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The cases recited by the majority "stand only for the unremarkable proposition that an application cannot add new matter to an original disclosure. Thus Supreme Court precedent is fully consistent with the logical reading of the statute and impeaches this court's ultra vires imposition of a new written description requirement for original claims."

"Eli Lilly was not only new law, it also is in tension with other areas of long-established law: claim construction and blocking patents."

II. *Ariad v Lilly* Rader's Dissenting Opinion, cont'd.

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Claim Construction:

"This court essentially claims unfettered power to err twice – both in construing the claim so broad as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to 'support' this court's own broad conception of the claimed subject matter."

Blocking Patents:

"The Supreme Court has long acknowledged the 'well established' rule that 'an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such.' … Unfortunately the new Eli Lilly doctrine effectively prevents this long-standing precept of patent law. … Under the new regime, mere improvements will likely invalidate genus patents. The principle of unintended consequences once again counsels against judicial adventurism."

II. *Ariad v Lilly* Linn's Dissenting Opinion

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"The statutory arguments that the majority today enshrines fail to justify establishing a separate written description requirement apart from enablement and beyond the priority context, and fail to tether that written description requirement to a workable legal standard."

"[T]he only reasonable interpretation [of § 112, paragraph 1] is the one offered by Ariad, both because it conforms to the long-recognized purpose of the statute in policing new matter violations and because it tethers the written description of the invention to an understood standard."

"The enablement requirement provides an established standard for the propriety of the written description offered to support a set of claims."

II. *Ariad v Lilly* Linn's Dissenting Opinion, cont'd.

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"I cannot accept the majority's conclusion that the current written description doctrine adopted [by this court] was created not by the Federal Circuit in 1997, but by the Supreme Court as early as the 19th century, and therefore carries weighty stare decisis effect. … Only since Lilly have we forced original claims over a description hurdle extending beyond enablement."

"It is inconsistent to say that on its filing date, a patent does not show that the inventor 'possessed' subject matter that the claims actually encompass and the specification fully enables. Doing so perpetuates an unnecessary tension between the claims and the written description of a patented invention."

"In my view, the question before the en banc court should have been answered in the negative and the appeal returned to the panel for resolution of the enablement question and Lilly's remaining invalidity and noninfringement defenses."

II. *Ariad v Lilly:* The Practical Implications

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Practically speaking, the law remains the same for both the predictable and unpredictable arts.

In practice, however, it generally is more difficult to satisfy the written description requirement in the unpredictable arts.

Although the law remains unchanged, *Ariad* may draw attention to the separate written description requirement as it applies to litigation, opinion work, and patent prosecution.

II. *Ariad v Lilly* The Practical Implications: Prosecution

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Existing PTO guidelines probably unaffected.

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

II. *Ariad v Lilly* The Practical Implications: Prosecution

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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).

II. *Ariad v Lilly* The Practical Implications: Litigation and Opinion Work

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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 invented are unaffected.

III. Best Practices, cont'd

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Written description problems typically appear in these circumstances:

- broad claim with little support in specification such as a genus claim or functionally described structure with few or no species described in specification;
- attempts to cherry pick the original disclosure to specifically claim narrow subject matter later discovered to be valuable;
- substantial claim amendments made during prosecution; and
- reliance on earliest priority date, often when priority application is a provisional.

III. Best Practices, cont'd

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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.

III. Best Practices, cont'd

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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.

III. Best Practices, cont'd

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Consider filing separate applications as structurally diverse means of attaining the desired result are discovered.

Consider including means plus function claims in addition to other claims.

III. Best Practices, cont'd

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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.

Precedent Cited

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Supreme Court

Bonito Boats Inc. v. Thunder Craft Boats Inc., 489 U.S. 141, 150-51 (1989).

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd. 535 U.S. 722, 736 (2002).

Federal Circuit/Court of Customs & Patent Appeals

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Precedent Cited

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Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research, 346 F.3d 1051 (Fed. Cir. 2003).

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Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996).

In re Barker, 559 F.2d 588 (C.C.P.A. 1977).

In re DiLeone, 436 F.2d 1404 (C.C.P.A. 1971).

In re Robins, 429 F.2d 452, 456-57 (C.C.P.A. 1970).

In re Ruschig, 379 F.2d 990 (C.C.P.A. 1967).

Precedent Cited

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