

Appeal No. 2008-1248

Before The  
United States Court of Appeals  
For the  
Federal Circuit

ARIAD PHARMACEUTICALS, INC., et al,  
Plaintiffs-Appellees,

- vs -

ELI LILLY CO.,  
Defendant-Appellant.

BRIEF OF AMICUS CURIAE IN SUPPORT OF NEITHER PARTY  
SUBMITTED ON BEHALF OF  
THE UNIVERSITY OF KENTUCKY INTELLECTUAL PROPERTY LAW SOCIETY,  
AND THE SMALL ENTITY BUSINESSES NAMED HEREIN.

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, Charles Lee Thomason, counsel, for amicus curiae, certifies the following:

1. The full name of every party or amicus represented by me is:

IP Law Society of the University of Kentucky College of Law, and Small entity businesses, Universal Support Systems LLC, Polymer Construction Products Ltd., and Safeteccs LLC.

2. The name of the real party in interest represented by me is:

Not applicable.


3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The named of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

None.

11 NOV 2009  
Date:

  
Signature of counsel  
Charles Lee Thomason

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## Interest of Amicus

The undersigned counsel for the Amicus Curiae named below respectfully submits this brief pursuant to Rule 29, FED. R. APP. PROC. The Order that granted review *en banc* expressly granted permission for amicus to file briefs.

No part of this brief was authored by counsel for any of the parties to the appeal. No person or entity, other than the amicus and amicus counsel listed here, made any financial contribution to the preparation or submission of this amicus brief.

This brief was authored and prepared by the undersigned counsel, with the assistance of student members of the Intellectual Property Law Society at the University of Kentucky College of Law.

### Identity of Amicus Curiae.

Amicus curiae represent the interests of small entity business concerns (as defined by 37 C.F.R. §1.27(a)(2)). These amicus have obtained one or a few patents to protect their core products and processes. All small entity businesses would be affected by a change in the interpretation of 35 U.S.C. §112, ¶1. Small entity businesses with one or few patents desire a clear and uncomplicated interpretation of

§112, ¶1, and of the USPTO regulations that implement the statutory requirement, 37 C.F.R. §1.71(a) & (b).

Small businesses with issued patents that protect their business interests are disserved by complicated patent requirements, and by uncertain interpretations of law, which add to the expense and uncertainties of obtaining and enforcing patents. A complicated written description inquiry, if assessed as a questions of fact and expert opinion, adds considerable cost to the actions of small entity businesses to enforce duly-issued, presumptively valid patents.

The small entity businesses, which appear through counsel as amicus curiae, are Universal Support Systems LLC, which makes and sells support apparatus and grounded equipment frames, Polymer Construction Products Ltd., which holds patent rights to apparatus and method for forming a barrier wall, and Safeteccs LLC, which makes and sells collapsible platforms for maintenance tasks.

The Intellectual Property Law Society is a student-run, voluntary organization of law students, which is moderated by faculty at the University of Kentucky, College of Law. The undersigned counsel for amicus serves as an adjunct professor of law, and the arguments set forth

herein are those of counsel and should not be attributed to any other person or organization.

## Statement of the Issues and Summary of Arguments.

The issues regard the statutory provision 35 U.S.C. §112, ¶1:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The *en banc* order specified two questions to be addressed:

a. Whether 35 U.S.C. §112, paragraph 1, contains a written description requirement separate from an enablement requirement?

Precedent and plain language instruct that the “written description” requirement is distinct from the requirement “to enable.”

b. If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

The “scope and purpose” inquiry should address the procedural context of this case, a JMOL, and beyond that, consider how the written description requirement arises in litigation and in application practice. A policy-driven interpretation should not alter the actual statute.

## INTRODUCTION.

Small entity business owners want the requirements for patent applications to be straightforward. They have no interest in the esoterics of statutory interpretation or in varying views of attorneys or courts about how the patent laws apply. Small businesses want a clear path charted for filing and prosecuting their patents.

For businesses of any size, debating whether §112, ¶1 has a written description requirement, separate from the rest of ¶1 may stimulate legal minds, but it complicates the patenting process and adds uncertainty to the result. The decades-long debate over parsing §112, ¶1 should end.

### **I. The Statute Plainly Requires a Written Description, Distinct From Having “to enable” the Invention.**

Each statute is written intending that its requirements are certain. Congress presumably enacts no statute with the thought that its effect is limited by, or premised on, judicial interpretation.

The express terms of a statute should be applied. Non-statutory or policy arguments should not unduly impact the interpretation.

The rules for interpreting a statute are hierarchical. The focus is on the statute as a whole, and as composed of express terms. “If Congressional intent must be sought, I would look to its primary source

the words of the statute itself.” C.J. Markey, concurring, *In re Application of Chakrabarty*, 571 F.2d 40, 44 (C.C.P.A. 1978) *aff’d*, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

Next, operative terms are read in the context of the provision, and then, more broadly read to achieve an interpretation consistent with the same terms used elsewhere in the statute.<sup>1</sup>

All terms in a statute add meaning, and presumably, none are mere ‘surplus’ or lack meaning. “Thus, our inquiry begins with the statutory text, and ends there as well if the text is unambiguous.” *BedRoc Ltd., LLC v. U.S.*, 541 U.S. 176, 183 (2004).

Only when plain meaning, and intrinsic indicia of statutory meaning, leave the inquiry unanswered, might a court seek congressional intent in the legislative history. Courts “should prefer the plain meaning since that approach respects the words of Congress ... [and] avoid[s] the pitfalls that plague too quick a turn to the more controversial realm of legislative history.” *Lamie v. U.S. Trustee*, 540 U.S. 526, 536 (2004).

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<sup>1</sup> Statutory interpretation is not unlike the intrinsic evidence approach used for interpreting patent claims and contracts, which rely on “a hierarchy of analytical tools.” *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998).

A. The First Requirement of §112 ¶1  
Is A Written Description.

Three phrases comprise §112, ¶1. Plainly, each applicant’s specification must “contain a written description of the invention,” and of “making and using” it. Next, applicants must “enable any person skilled in the art ...to make and use” the described invention. “Section 112 requires that the application describe, enable, and set forth the best mode” and if not, then that “could lead to the issued patent being held invalid.”<sup>2</sup>

The first *en banc* question asks whether the “written description ... of making and using” the invention is separate from the requirement “to enable” persons of skill to “make and use” it.

Some find the two “shall” clauses in §112, ¶1 to indicate two requirements, not three. The specification “shall contain” a written description, and it “shall set forth” the best mode. The enablement clause begins with the imperative - so “as to” enable – but a third “shall” does not introduce that requirement.

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<sup>2</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 724, (2002). *Accord*: “The Three Requirements are Separate and Distinct From Each Other.” MPEP 2161.

In part, jurists’ “interpretive divide”<sup>3</sup> over how to parse the “Specification” statute devolves upon the phrase that conjoins the “written description” and “enable” clauses.

The directive of “such full, clear, concise, and exact terms” in §112, ¶1 modifies both the requirement to describe and to enable. This linking phrase makes “description and enablement ... distinct though commingled requirements.” *In re Application of Barker*, 559 F.2d 588 (C.C.P.A. 1977), J. Baldwin and J. Rich, dissenting but concurring in the result, *cert. denied*, *Barker v. Parker*, 434 U.S. 1064 (1978). Judicial debate over the separate-or-commingled requirements may trace back to *Barker*.<sup>4</sup>

B. Separateness of the §112, ¶1 Requirements  
Long Has Been Recognized.

Precedent holds that a written description and enablement are two, separate requirements. Some “argue that the ‘enablement’ requirement of the first paragraph of 35 U.S.C. §112 cannot be read separately from the ‘description’ requirement therein ...We do not agree.” *Barker, supra* at 591; accord, *Vas-Cath v. Mahukar*, 935 F.2d 1555 (Fed. Cir. 1991).

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<sup>3</sup> Borrowed from *Lamie, supra*, 540 U.S., at 536.

<sup>4</sup> “All before that comma prescribes what shall be described. The phrase following the comma prescribes how and for whom it shall be described.” *In re Barker, supra*, at 595, C.J. Markey, dissenting “heartily.”

Numerous cases conclude that the written description is a separate requirement.<sup>5</sup> §112's "first paragraph ...mandate[s] that 'the specification shall contain a written description of the invention ...[and so, mandates] a distinct *description* requirement.'" *Martin v. Johnson*, 454 F.2d 746, 750 (C.C.P.A. 1972), citing cases.

No text in the statute allows disregard of three score years of precedent. "Congress has not seen fit to amend the statute in this respect and we must assume that it has been satisfied with, and adopted, the construction given to its enactment by the courts." *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 14 (1939).

The 1952 statute, expressly requiring a "written description of the invention" containing specific information, has not changed. Precedent supporting a separate, written description requirement has not and should not be changed

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<sup>5</sup> *In re Application of Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984) (the "description requirement ... is separate from the enablement requirement"). "Paragraph 1 of § 112 ... means that there must be both a written description in full, clear, concise, and exact terms, and that it enable any person skilled in the art to make and use the invention." *In re Application of Ahlbrecht*, 435 F.2d 908, 909-10 (C.C.P.A. 1971).

C. The Plain Reading of §112, ¶1, Requiring  
A “written description of the invention...  
In “full, clear, concise and exact terms.””

In three clauses, §112 ¶1 tracks from the broad “description” requirement, to a narrow “best mode” instruction. A complete written description sets out all elements of the invention, and of its “making and using.”<sup>6</sup> Next, the specification must detail how the described elements interwork and are used, so “as to enable” it. Last, §112 requires disclosure of the best mode or preferred embodiments of the invention.

The broad to narrower requirements of §112 correspond with the convention of first, broadly claiming the invention, then adding working features in several claim sets, and ending with claims narrowly reciting the best and preferred embodiments.<sup>7</sup>

The statutory requirement is for a complete “written description,” contained in the application when filed. Plainly, a “description” of the “invention” entails a broader recitation than that necessary to enable persons to carry out the described invention.

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<sup>6</sup> “The written description requirement embodies the basic disclosure function of a patent,” *Alcon, Inc. v. Teva Pharm.*, \_\_\_ F.Supp.2d \_\_\_, 2009 WL 3363655 (D.Del. 2009), and “the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *Carnegie Mellon Univ. v. Hoffmann La Roche Inc.*, 541 F.3d 1115, 1122 (Fed.Cir.2008).

<sup>7</sup> “The usual practice is to begin with the broadest claim and proceed to the narrowest.” Landis, *MECHANICS OF PATENT CLAIM DRAFTING*, Chap. II, Sec. 5 (2<sup>nd</sup> Ed. 1974 PLI), (*citing*, MPEP §608.01(m), “Claims should preferably be arranged in order of scope so that the first claim presented is the least restrictive.”).

In its denial of reconsideration in *Behr v. Talbott*, 27 U.S.P.Q.2d 1401, 1992 WL 512237 (B.P.A.I. 1992), the Board dispatched the contention that its “decision misapprehends or overlooks the distinction between the enablement and written description requirements.” The separate questions that the two requirements raise were identified. Whether a copied claim was supported by the written description asked if one reading the disclosure “would have understood” that rollers were, as claimed, “necessarily positioned downstream,” *viz.*, did it describe that locational aspect of making and using the claimed invention. “An enablement inquiry, in contrast, would be whether one skilled in the art would have known how to mount the Behr et al. pinch rollers in the positions called for by these claims.”

*Behr v. Talbott* appropriately distinguishes between (i) describing claimed features, such as locating an element in the process path, and (ii) teaching persons of skill “how to” make and use it.<sup>8</sup>

Critics confine the written description to gauge the “possession” of, or the “priority” of inventions, in retrospect.<sup>9</sup> Such purposes,

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<sup>8</sup> In *Fields v. Conover*, 443 F.2d 1386 (C.C.P.A. 1971), at 1391, Judge Rich noted a “specification may provide adequate teachings of how to make and use subject matter which is subsequently claimed and yet fail to contain a written description thereof which complies with the first requirement of ... § 112.” This plainly suggests an independent, distinct, written description requirement. The case concludes that the written description “falls far short, ... of the ‘full, clear, concise, description requirement of § 112.’”

however, are unexpressed in §112, ¶1. Other statutes deal directly with the retrospective inquiries for priority and new matter, *e.g.*, §120 and §132(a). Those complement §112, but unexpressed purposes should not be read in ‘between its lines’. “A statutory interpretation that renders another statute superfluous is of course to be avoided.” *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 35 (2003).<sup>10</sup>

## II.

### **Statutory Interpretation Rules are Considered, But Should Not Change the Plain Meaning of §112.**

It is dogmatic that “[w]hen interpreting statutes, a court looks to the language of the statute and construes it according to the traditional tools of statutory construction.” *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560 (Fed. Cir. 1996), J. Rich.

First and foremost, paragraph 1 of §112 should be read within its ‘four corners.’ Statutory construction tools should not be agents for changing the statute, or serving unexpressed purposes or policies.

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<sup>9</sup> “A factfinder should be aware ... of the distortion caused by hindsight.” *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

<sup>10</sup> The written description “cannot be swept away by claiming that it relates only to priority issues or the prohibition on introduction of new matter.” J. Lourie, dissenting from denial of en banc review in *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1305 (Fed. Cir. 2004).

A. Internal Consistency, and  
Presumption Against Surplusage.

Paragraph 1 of §112 repeats ‘make and use’ conditions, first in the written description clause, and a second time in the enablement clause. The specification must contain a written description of the invention, and of the manner and process of “making and using” it. Next, the specification must contain terms as will “enable any person skilled in the art ...to make and use the same” described invention.

Repetitive inclusion of these conditions indicates that two, separate directives were intended; for, if not, one of those two provisos is meaningless surplusage. “As early as in Bacon’s Abridgment, sect. 2, it was said that ‘a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant’ .” *Market Co. v. Hoffman*, 101 U.S. 112, 115-16 (1879).

To construe the multiple use in §112, ¶1 of separately expressed conditions – “making and using” and then “to make and use” – to be meaningless, or surplusage, would invite error.

Critics of a separate written description requirement urge that it is unitary with the statutory instruction “to enable.” If written description

and enablement are unitary, then reciting the ‘make and use’ terms twice in §112, was needless. Both uses should be read meaningfully. Otherwise, one is deemed pointless, contrary to the presumption against surplusage.

The more logical reading of §112, ¶1 is two requirements: (1) to describe the invention and the “making and using” of it, and (2) to give details so as to enable persons of skill to “make and use” it.<sup>11</sup>

#### B. Legislative History, and Amendment History.

Based on how current 35 U.S.C. §112, ¶1 differs from the wording of former versions, dissenting opinions have railed against a separate written description requirement.<sup>12</sup>

Relevant amendments provide indicia of legislative intent. More to the point, however, is that the “starting point in discerning congressional intent is the existing statutory text, see *Hughes Aircraft ...*,

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<sup>11</sup> Add to the debate *In re Application of Chilowsky*, 306 F.2d 908, 909 (C.C.P.A. 1962), where J. Rich noted an "examiner's rejection, ... puts in issue all four requirements of paragraph 112, namely, that the specification shall contain, in such full, clear, concise and exact terms as to enable any person skilled in the art to which the invention pertains, ... to make and use it, a written description (1) of the invention; (2) the manner and process of making the invention; and (3) the manner and process of using the invention; and that (4) the best mode contemplated by the inventor of carrying out his invention shall be set forth." (*em. added*).

<sup>12</sup> “The attempt to create historical and current statutory support for a ‘separate description’ requirement, ...is mistaken.” *In re Barker, supra*, at 594, dissent of C.J. Markey.

525 U.S. 432, 438, ... (1999), and not the predecessor statutes.” *Lamie*, *supra*, 540 U.S., at 534.

Two differences between present §112 and predecessors versions are urged: the earliest patent statutes did not require “distinctly claiming” what the applicant-inventor “regards as his invention,” and the present statute omits having “to distinguish it from other inventions.”<sup>13</sup>

That first difference – adding “distinctly claiming” to §112 in ¶2 – is read (by some) to indicate that the original written description requirement served purposes now met by “distinctly claiming” the invention. Those readers imply that Congress intended to gut the purposes served by the written description.<sup>14</sup> The alternative view is that both a “written description,” and the “distinctly claiming” requirements, have stayed in older and newer versions of the “Specification” statute.<sup>15</sup>

The amendments may indicate simply that Congress edited, and broke the long provisions into several sentences, and retained each of the separate requirements in the “Specification” statute. “These competing

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<sup>13</sup> *Bramley v. Beese*, 132 F.2d 1001 (C.C.P.A. 1942) sets out the former statute.

<sup>14</sup> “When the Patent Act assigned the notice function to claims rather than the written description, enablement became the sole 35 U.S.C. § 112, ¶ 1 standard for adequate disclosure of an invention.” J. Rader, dissenting from denial of en banc review in *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1309 (Fed. Cir. 2004).

<sup>15</sup> “The Patent Act of 1793, [was] authored by Thomas Jefferson,” *Diamond v. Chakrabarty*, 447 U.S. at 309, and not by an anonymous legislative caucus.

interpretations of the legislative history make it difficult to say with assurance [who] lays better historical claim to the congressional intent.” *Lamie, supra*, 540 U.S., at 541.

The second difference – the former requirement “to distinguish” the invention – overlooks that the novelty and non-obviousness provisions deal with that. Also, the Patent Office rules, 37 C.F.R. §1.71(b) preserved the requirements that the “specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what it old.” (*em. added*).<sup>16</sup>

In sum, no pertinent legislative history exists.

### C. Consistency With Other, Related Provisions of Patent Act.

“Where Congress uses the same form of statutory language in different statutes having the same general purpose, courts presume that Congress intended the same interpretation to apply in both instances.” *Imazio Nursery*, at 1568. This tenet of consistency lends weight to some

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<sup>16</sup> “Rules of Practice in the Patent Office, when not inconsistent with the statutes from which they are derived, have the force and effect of law.” *In re Application of Newton*, 414 F.2d 1400, 1407, fn. 6 (C.C.P.A. 1969).

past dissents that argue for §112, ¶1 solely to police priority, or to align a disclosure with later-presented or interference claims.<sup>17</sup>

Another provision though, which refers to §112, implies that an *in*-complete description is ground to invalidate. Section 162 states that: “No plant patent shall be declared invalid for noncompliance with section §112 of this title if the description is as complete as is reasonably possible.”<sup>18</sup>

That provision should be read as an exception from the general rule that a patent can be “declared invalid ...if the description” is not as complete as §112, ¶1 requires. Also, §162 supports conclusions that: a complete written description is a separate requirement, and that incompleteness is a ground to invalidate.<sup>19</sup> Thus, completeness is the standard, not adequacy, sufficiency, or another non-statutory measure.<sup>20</sup>

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<sup>17</sup> Consider sections referring to description of inventions. The “invention ...was described in a printed publication,” or “in a patent,” §102; patents for an invention “not identically disclosed or described,” §103; “no patent ...for an invention ...described in a printed publication,” §119; priority for “an invention disclosed in the manner provided by the first paragraph of section 112,” §120; no “new matter into the disclosure of the invention,” §132; reissue of “any patent ...deemed wholly or partly inoperative or invalid, by reason of a defective specification,” §251.

<sup>18</sup> The “provisions of [the 1952 Patent Act] relating to patents for inventions shall apply to patents for plants, except as otherwise provided.” 35 U.S.C. §161.

<sup>19</sup> §112, ¶1 as a ground to invalidate has been questioned. “After all, *Eli Lilly* created a new validity doctrine.” J. Rader, dissenting from denial of en banc review in *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1309 (Fed. Cir. 2004).

<sup>20</sup> As the dissenting Justices stated in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 136 (1948), “we do not agree that the patent ...is invalid for want of a

CONCLUSION: In answer to the first *en banc* question, a complete written description is a plain and separate requirement of §112, ¶1, but it is “commingled” with the enablement requirement, and is complementary to the separate provisions dealing with new matter, priority, reissue and interference.

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clear, concise description of how the combinations were made and used ...[and the] completeness and character of the description” will vary.

**III.**  
**The Second *en banc* Question Should Distill Out  
Only Corollary Propositions That Follow  
From A Plain Language Reading of §112, ¶1.**

A “written description,” complete according to the statute, is what §112, ¶1 requires. Precedent that identifies and relies on *non*-statutory ‘purposes’ should not amend that requirement.<sup>21</sup>

Two questions, bound up in the second *en banc* question, are: whether the purpose of the written description requirement is met when reviewed as a fact question in a post-verdict JMOL motion; and, whether, in that context, the scope of the written description inquiry varies based on regional standards for Rule 50(a), FED. R. CIV. PROC.<sup>22</sup>

The scope and purpose of the complete written description requirement will be tested fully in litigation, and after the USPTO duly examines the specification. The “scope and purpose” inquiry should center upon the procedural context of a JMOL motion, as in the *Ariad* case or summary judgment as in the *Vas-Cath* case, rather than via searching abstractly for scope or purpose.

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<sup>21</sup> “Helpful insights, however, need not become rigid and mandatory formulas.” *KSR, supra*, 550 U.S. at 419.

<sup>22</sup> That rule in (a)(1) sets the standard of “no legally sufficient evidentiary basis for a reasonable jury to find” for a party on a controlling issue.

Jurors in the *Ariad* case determined the patents to be valid, *viz.*, described, enabled, etc.<sup>23</sup> Using a regional circuit standard, the appeal panel reviewed the lower court's denial of JMOL. Some may read that decision as a jury's verdict negated by judicial re-assessment of expert opinion and file wrapper evidence.<sup>24</sup>

The several Circuit Courts have articulated JMOL standards that may be outcome determinative of validity decided in jury trials.<sup>25</sup> A singular standard for patent determinations would reduce variation. The Circuits' JMOL standards range from review of the record for the absence of "substantial evidence" as in the *Ariad* panel decision,<sup>26</sup> to the more stringent affirmative inquiry whether "when viewing the evidence in a light most favorable to the non-moving party - giving that party the benefit of all reasonable inferences - there is no genuine issue of material

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<sup>23</sup> The jury "found that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description." *Ariad*, Slip op., pg. 4.

<sup>24</sup> Under more JMOL stringent standards, the substantiality of testimony that left "little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art" (*Ariad*, slip op., pg. 14) could not be re-weighed. A "court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence ...[and it] must disregard all evidence favorable to the moving party." *Reeves v. Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).

<sup>25</sup> Consider, *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006) reversing a JMOL ruling of the Federal Circuit that applied an erroneous Tenth Circuit standard. This Court acts "de novo to determine whether those [JMOL] standards are correct as a matter of law." *Markman, en banc* 52 F.3d at 967, citing S.Ct. cases.

<sup>26</sup> "We review the specification's disclosure ...to determine whether there is substantial evidence to support the jury's verdict that the written description evidenced that the inventor possessed the claimed invention." *Ariad*, slip op., pg. 11.

fact for the jury, and reasonable minds could come to but one conclusion.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1365 (Fed. Cir. 2008).

If issues about the written description are factual issues to be decided by juries, then a singular JMOL standard for that patent issue would accord a just result in keeping with the goals of 28 U.S.C. §1295.<sup>27</sup> The written description requirement should not be ‘balkanized’ by regional Circuit JMOL standards. A single standard, crafted consistent with Chief Judge Markey's remarks in *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1546 (Fed. Cir. 1983) would comport with the deference due jury verdicts under the Seventh Amendment. A “court ...cannot substitute its view for that of the jury when to do so would be an effective denial of the right to trial by jury.” *Id.*

- A. Whether Completeness of the “written description” is (i) a Question of Fact Susceptible to JMOL, or (ii) a Legal Decision for the Judge to Make  
As A Component of the Intrinsic Evidence Assessment.

Written description issues should be part of the judge’s *Markman* inquiry, rather than fact questions posed for jurors later to decide.

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<sup>27</sup> To promote stability, consistency, and predictability in the patent system. *See*, S. Rep. No. 275, 97th Cong., 1st Sess. 1, 5-6 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 15-16.

Allocating written description issues for decision as questions of fact has two effects. It essentially defeats the purposes served by summary judgment. Also, post-trial JMOL motions end up being the context in which any factual determinations actually are made final. Determination of a “JMOL requires careful distinction between fact and law,” because factual determinations deserve “substantial deference,” and rulings of law are reviewed de novo. *Markman*, 52 F.3d at 976.

B. The “Words Used” in the Written Description  
Raises a Question of Law.

Early caselaw held that a judge decides whether the written description is complete as a matter of law. In *Hogg v. Emerson*, 47 U.S. 437, 484 (1848), the Court said that the description of the invention, “involves a question of law ...so far as it regards the construction of the words used.” There, it was contended that the “letters [patent], even when thus connected with the specification, are not sufficiently clear and certain in their description of the invention.” Again, the words used to describe the invention presented a “question of law.” That was separate from the factual inquiries into enablement, *e.g.*, a “degree of clearness ... to distinguish [from prior art] and to enable.” The statute considered in

*Hogg* required those matters of “degree” to be proven factually, in a manner comparable to the current standard for obviousness.

The general proposition of legal construction of patents was observed in *Brown v. Huger*, 62 U.S. 305, 318 (1859), as follows. The “patent itself must be taken as evidence of its meaning; that, like other written instruments, it must be interpreted as a whole ... and the legal deductions drawn therefrom must be conformable with the scope and purpose of the entire document.” This “construction and these deductions we hold to be within the exclusive province of the court.” *Id.*, quoted in *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 383 (1996).<sup>28</sup>

C. Weak Precedent for “written description”  
Being a Fact Issue.

The Ariad panel decision held that whether a “patent is invalid for failure to meet the written description requirement ...is a question of fact.” Ariad, slip op., pg. 10. Tracing back through the caselaw cited for that proposition did not yield precedent that squarely addresses why, or

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<sup>28</sup> Judges determining the meaning of the claims, as a matter of law, also would interpret the “words used” in the applicant’s specification. *Hogg, supra*. The judge, not a jury, should decide if the claimed invention is, or is not, “the invention” in the written description. As the Ariad panel observed, “a court would properly interpret the claim[s] as limited” to the invention described in the specification. Slip op., pg. 16. The completeness of the written description, as assessed by a district judge or a patent examiner, would determine what was the applicant “the invention,” per §112. If “the invention” contained in the written description is not that set out in the claims, then invalidating those claims serves one purpose of the written description requirement.

why not, to decide completeness of the written description as a matter of law.

Assigning the “written description” for factual evaluation appears to trace back to, essentially, Judge Rich’s passing remark in *Ruschig*, that the “issue here is in no wise a question of its compliance with section 112, it is a question of fact.” That opinion took on the applicant’s argument that assumed there had been a §112 rejection.

Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that ‘The specification shall contain a written description of the invention\*\*\* \* \*.’ (Emphasis ours.) We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of fact: Is the compound of claim 13 described therein? Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound?  
*In re Application of Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967).<sup>29</sup>

The next decision, often cited, merely observed that the “primary consideration is factual.” *In re Application of Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976).<sup>30</sup> *Wertheim* holds that written description issues should be “determined on a case by case basis,” which courts later applied to

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<sup>29</sup> Cf., a case a decade later noted that for a “question of compliance with the description requirement of §112 that each case must be decided on its own facts.” *In re Application of Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977). J. Rich and C.J. Markey.

<sup>30</sup> The *Wertheim* decision was precedent for statements in *Enzo, Vas-Cath*, as well as for the Ariad panel’s holding that the written description raises issues of fact.

mean “determined on” the facts, rather than against a legal standard.<sup>31</sup>

Many recent cases hold, without discussion, that the written description requirement raises questions of fact, which leads necessarily to a jury deciding the matter.<sup>32</sup>

Here, the Ariad panel reviewed the “jury’s determinations of fact relating to compliance with the written description requirement for substantial evidence.” Slip op., pg. 10. Dividing the analysis between compliance with the written description requirement, on the one hand, and sufficiency, on the other, has engendered an odd division of labor between the judge and the factfinders, across the demarcation noted in *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988).

“Although the question of whether Hiraga's Japanese specification contains a sufficient disclosure under 35 U.S.C. § 112 ¶ 1 is one of law, *Kennecott Corp. v. Kyocera International Inc.*, 835 F.2d 1419, 1420, 5 USPQ2d 1194, 1195 (Fed.Cir.1987), *cert. denied*, 486 U.S. 1008, 108 S.Ct. 1735, 100 L.Ed.2d 198 (1988), compliance with the written description aspect of that requirement is a question of fact. *Ralston Purina Co.*, 772 F.2d at 1575, 227 USPQ at 179.”

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<sup>31</sup> *Vas-Cath Inc.*, *supra*, 935 F.2d at 1560 (whether specification supports claims, so as to satisfy written description requirement of 35 U.S.C. § 112 ¶ 1, is question of fact).

<sup>32</sup> *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984), *citing*, *In re Smith*, 458 F.2d 1389, 1395 & fn. 3 (C.C.P.A. 1972) *citing* to *Wertheim* and *Ruschig*, *supra*, decisions. See later decisions, *Tronzo v. Biomet*, 156 F.3d 1154, 1158 (Fed. Cir. 1998), and *Total Containment, Inc. v. Intelpro Corp.*, 217 F.3d 853 (Table) 1999 WL 717946 (Fed. Cir. 1999) (remanding summary judgment declaration to resolve fact questions); “Whether an applicant has complied with the written description requirement is a finding of fact, to be analyzed from the perspective of one of ordinary skill in the art as of the date of the filing of the application.” *In re Alonso*, 545 F.3d 1015, 1018 (Fed. Cir. 2008).

Denominating what is a “question of compliance” with §112, as distinct from ‘sufficiency’ or ‘adequacy’ of the written description, adds to confusion over whether factfinders or a judge appropriately should decide the issues.<sup>33</sup> Indeed, it may be a distinction so fine that the Patent Office mistakes its boundaries.

“Therefore, the examiner was in error when he stated that the Wall declaration, which attempted to shed light on whether the '451 specification adequately described the subject matter of claim 70, addressed a legal issue.”

*In re Application of Alton*, 76 F.3d 1168, 1174 (Fed. Cir. 1996) (“examiner's dismissal of the declaration on the grounds that ‘[l]ittle weight is given an opinion affidavit on the ultimate legal question at issue’ was error”).

The threshold concern should not be whether those skilled as patent attorneys might grasp fine distinctions between law and fact - the statute was not written for them. It should be asked whether small businesses, who are skilled in the product lines they make and sell, whether they can understand these distinctions. “The true rule of construction in respect to patents and specifications, and the doings generally of inventors, is to apply to them plain and ordinary principles, ... and not ... to yield to subtilties and technicalities ... likely to prove ruinous to a class of the community.” *Hogg, supra*, at 485-86.

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<sup>33</sup> It is to be noted that §112, ¶1 never mentions ‘adequacy’ or ‘sufficiency.’

Having a judge, at the *Markman* stage, decide written description issues as a matter of law is consonant with the scope and purpose of that §112, ¶1 requirement.<sup>34</sup> Again, small businesses that rely on patents will benefit from clarity in the rules of law for patent applications and in the procedures to be followed in litigation.

D. Factual Inquiries About Complete  
Compliance with the Written Description Requirement  
Should Not Merge with the *Wands* Factors.

Even when the written description is treated as a factual inquiry, elements of that analysis cross over with those for enablement. The Ariad panel decision evinces some of the confusion about how to assess the completeness of the written description, with how to evaluate whether the specification is enabling to persons skilled in the art.

The Ariad panel decision instructs, on page 8, that “what is adequate” in the written description depends on a “variety of factors.” The listed “factors to evaluate the adequacy of the disclosure” overlap with, or are redundant of, the *Wands* factors used to assess enablement. The *Wands* factors flow from the statutory standard for enablement, *i.e.*, whether as a matter of fact, “persons of skill” reading the original

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<sup>34</sup> *Markman* “decided as a matter of *policy* that judges, not juries, are better able to perform this task given the complexity of evidence and documentation.” J. Mayer and J. Newman, concurring, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1464 (Fed. Cir. 1998), *en banc*.

specification are able to practice the invention. The same factors do not flow from what §112, ¶1's requires for a complete written description.<sup>35</sup>

The factors used by the Ariad panel, which overlap necessarily with *Wands*, include “the existing knowledge in the particular field, the extent and content of the prior art, ...[and] the predictability of the aspect at issue.” Slip op., pg. 8. These three factors correspond to the “undue experimentation” factors of “(3) the presence or absence of working examples; ...(5) the state of the prior art; ...[and] (7) the predictability or unpredictability of the art” from *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988). Those should not be asked twice.

Ascertaining whether the applicant's specification contains a complete written description of the invention and the making and using of it should be subsumed in the *Markman*, inquiry. To instead posit factors for evaluating the written description, which overlap the *Wands* factors for enablement, disserves the scope and purpose of the written description requirement in §112, ¶1.

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<sup>35</sup> The statute does not use “adequate” to modify “written description” or enablement. J. Rader, dissent from en banc order in *Univ. of Rochester*, 375 F.2d at 1314.

**IV.**  
**The Policies Furthered by §112, ¶1,  
Are Relevant, but Nonstatutory Considerations  
Cannot Supplant or Redefine the Statutory Terms.**

The second *en banc* question asks about the scope and purpose that a written description requirement fulfills, or could fulfill. That might provoke discussion of competing legislative rationales – not what the statute requires, but what *un*-stated policies it might serve.<sup>36</sup>

Amicus small businesses, which are less likely to engage in priority contests, prefer that here, statutory considerations drive how §112, ¶1 is interpreted. This Court’s task “is the narrow one of determining what Congress meant by the words it used in the statute; once that is done [its] powers are exhausted.” *Diamond v. Chakrabarty*, 447 U.S., at 318.

A. The Constitutional  
“Quid Pro Quo.”

“The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’ *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 ... (1974).” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 534 U.S. 124, 142 (2001). The Ariad panel dealt with Lilly’s “conten[tion] that

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<sup>36</sup> “Congress may ...select[] the policy which in its judgment best effectuates the constitutional aim.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966).

[Ariad's] disclosure ...does not satisfy the patentee's quid pro quo as described in Rochester." Slip op., pg. 9.<sup>37</sup>

The *quid pro quo* assessment was equated with the enablement requirement in *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). "Patent protection is granted in return for an enabling disclosure of an invention."<sup>38</sup> Some view that as assigning supremacy to enablement, and impliedly, relegating the written description in §112, ¶1 to insignificance.

An alternative perspective is that the *quid pro quo* encompasses decidedly more than a complete written description. Patent protection is granted for distinctly claiming a novel and nonobvious invention, and for having met all conditions for patentability, including a specification as complete as §112, ¶1 requires.<sup>39</sup>

Long-standing in the patenting process are purposes advanced by applicants providing fair notice, and disclosing an antecedent basis for the invention that they have described, enabled and claimed.

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<sup>37</sup> Citing *Rochester*, the Ariad panel said the "requirement 'serves a teaching function, as a quid pro quo'" for giving the public "a meaningful disclosure in exchange for" the right to exclude others "for a limited time." Slip op., pg. 6.

<sup>38</sup> *Accord*: to "disclose[] an invention in such 'clear, concise and exact terms' (enablement) as to enable its practice, [is] the very purpose and quid pro quo of the patent system." *In re Barker, supra*, at 594, dissent of C.J. Markey.

<sup>39</sup> "The patent monopoly ... was a reward, an inducement, to bring forth new knowledge." *Graham, supra*, 383 U.S. at 8.

B.  
Proving Later that an Inventor  
Earlier Was “in possession” Of  
The Claimed Invention  
Is Not Expressed in §112, ¶1.

The earliest cited statement of the “in possession” purpose, *Evans v. Eaton*, 20 U.S. 356, 433-34 (1822) identified one “object of the specification [being], to put the public in possession of the what the party claimed as his own invention.” Possession could prove novelty, and provide notice to avoid infringements. The Ariad panel, at page 6 citing *Capon v. Eshar*, said the written description “demonstrate[s] that the patentee was in possession of the invention that is claimed.”

One criticism of reading into §112, ¶1 ‘proving possession’ of later-made claims, is that it effectively adds to, rather than construes the actual statutory wording. The ‘in possession’ construct makes §112, ¶1 be read as if requiring a “written description of the invention” *as claimed*; or as *claimed at any time* before issuance; or, of the manner and process of making the *claimed invention*.

The statute does not state, or imply, adding those terms to ¶1. “The preeminent canon of statutory interpretation requires [courts] to ‘presume that [the] legislature says in a statute what it means and means in a statute what it says there.’” *Connecticut Nat. Bank v. Germain*, 503

U.S. 249, 253-254 (1992), *cited in BedRoc Ltd., LLC v. U.S.*, *supra*, 541 U.S. at 183.<sup>40</sup> A policy should not re-interpret a statute.

C. Preventing “new matter”  
Or To ‘police priority’ Are  
Not Objectives Expressed in §112, ¶1.

Two of the policies asserted against a separate written description requirement are that §112, ¶1 prevents “adding new matter to an older disclosure” and serves “only to police priority.”<sup>41</sup> The counterpoint to that is that §112, ¶1 never mentions “new matter” or “priority,” and to ‘read those in’ invites error.

“We have also cautioned that courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.’” *Diamond, supra*, 447 U.S. at 308, *citing, U. S. v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 53 S.Ct. 554, 561, 77 L.Ed. 1114 (1933). The plain meaning of §112, ¶1 is a separate written description requirement, complete as that statute requires. To infuse policy goals to interpret, or to constrict, the express requirements of the statute would continue the debate over the scope and purpose of the requirement.

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<sup>40</sup> The “particular usefulness of the ‘possession’ inquiry” is coupled with a “caution[] that the written description requirement ‘is not subsumed by the ‘possession’ inquiry.’” *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295-96 (Fed. Cir. 2002).

<sup>41</sup> J. Rader, dissent from en banc order in *Univ. of Rochester*, 375 F.2d at 1307 and 1311 fn. 6.

## CONCLUSION

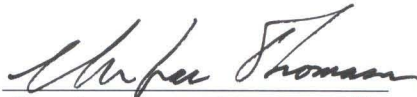
Small entity businesses with issued patents that protect their business interests are disserved by complicated patent requirements, and by rules that add to the litigation expense of enforcing patents.

Clarity in statutory interpretation is supportive of businesses. An uncertain or policy-driven construction of the patent laws, or an open-ended debate over patentability requirements can be harmful to business, and to patents that previously issued after being examined.

A complete written description is required by §112, ¶1, and policy goals should not diminish or change that.

If a small business must act to enforce its patents, then a pretrial, judicial evaluation of the written description as part of the *Markman* claims interpretation would be less costly and provide more certainty than having the issue decided as a fact question.

Respectfully submitted,



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11 NOV 2009

Date:

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<sup>42</sup> The diligent efforts of UK law students Jerrad Howard, Erin Sparks, Abigail Sheehan, Christine de Briffault, Alex J. Buschermohle, Gwen Jonge and Dan Hancock, who helped with the research and writing of this brief, are acknowledged.

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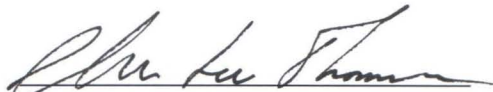
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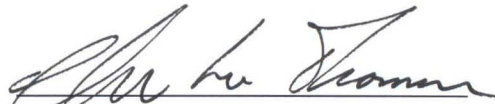
  
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- I. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).
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