

2008-1248

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, and
THE PRESIDENTS AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellants,

v.

ELI LILLY & COMPANY,

Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT
OF MASSACHUSETTS IN 02-CV-11280, JUDGE RYA W. ZOBEL

BRIEF OF *AMICI CURIAE* MARK D. JANIS AND TIMOTHY R. HOLBROOK
IN SUPPORT OF NEITHER PARTY

MARK D. JANIS
INDIANA UNIVERSITY
MAURER SCHOOL OF LAW
211 South Indiana Avenue
Bloomington, IN 47405
(812) 855-1205

TIMOTHY R. HOLBROOK
EMORY UNIVERSITY
SCHOOL OF LAW
1301 Clifton Rd., NE
Atlanta, GA 30322
(404) 712-0353

October 14, 2009

CERTIFICATE OF INTEREST

Counsel for the *Amici Curiae* certifies the following:

1. The full name of every party or *amicus curiae* represented by me is: Mark D. Janis & Timothy R. Holbrook
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: same as above
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 names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or agency or are expected to appear in this court are:

Mark D. Janis
Professor of Law
Indiana University Maurer School of Law
211 South Indiana Ave
Bloomington, IN 47405
(812) 855-1205 (phone)
mdjanis@indiana.edu

Signed:

Date: October 14, 2009

TABLE OF CONTENTS

CERTIFICATE OF INTEREST.....ii

TABLE OF AUTHORITIES.....v

STATEMENT OF IDENTITY OF *AMICI CURIAE*.....x

SUMMARY OF THE ARGUMENT.....1

ARGUMENT.....2

I. THE LANGUAGE OF SECTION 112 ESTABLISHES AN
ENABLEMENT REQUIREMENT, BUT NOT A WRITTEN
DESCRIPTION REQUIREMENT.....2

 A. Section 112 Creates an Enablement Requirement and
 Specifies that the Requirement Must be Fulfilled by a Written
 Description.....2

 B. Alternative Interpretations of Section 112 Take Liberties
 With Section 112’s Language.....3

II. THE ENABLEMENT REQUIREMENT BEST EFFECTUATES
THE PURPOSES OF SECTION 112, FIRST PARAGRAPH.....4

 A. The Enablement Requirement Appropriately Correlates
 Claim Scope with the Scope of the Inventor’s Contribution.....6

 B. The Enablement Requirement Provides a Workable Rule
 for Determining Whether a Disclosure Supports
 Later-Added Claims.....11

III. THE COURT SHOULD NOT USE THE SECTION 132 NEW
MATTER PROHIBITION TO CRAFT A BACK-DOOR
WRITTEN DESCRIPTION REQUIREMENT.....13

 A. Section 132 and Section 112 Serve Related Purposes,
 but Do Not Together Establish a *Ruschig*-Style Written
 Description Requirement.....14

 B. Section 132 Should Not be Construed to Provide an
 Independent Basis for a *Ruschig*-Style Written
 Description Requirement.....16

CONCLUSION.....20

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

Cases

<i>Agilent Tech., Inc. v. Affymetrix, Inc.</i> , 567 F.3d 1366 (Fed. Cir. 2009)	5, 11
<i>AK Steel Corp. v. Sollac & Ugine</i> , 344 F.3d 1234 (Fed. Cir. 2003)	6
<i>Amgen, Inc. v. Hoechst Marion Roussel Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003)	5
<i>Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.</i> , 560 F.3d 1366 (Fed. Cir. 2009)	8
<i>Brooktree Corp. v. Advanced Micro Devices, Inc.</i> , 977 F.2d 1555 (Fed. Cir. 1992)	17
<i>Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.</i> , 541 F.3d 1115 (Fed. Cir. 2008)	4
<i>Dow Chem. Co. v. Astro-Valcour, Inc.</i> , 267 F.3d 1334 (Fed. Cir. 2001)	19
<i>Enzo Biochem, Inc. v. Gene-Probe Inc.</i> , 323 F.3d 956 (Fed. Cir. 2002)	6, 7, 14
<i>Fiers v. Revel</i> , 984 F.2d 1164 (Fed. Cir. 1993)	6
<i>Fromson v. Advance Offset Plate, Inc.</i> , 720 F.2d 1565 (Fed. Cir. 1983)	12
<i>Gentry Gallery, Inc. v. Berkline Corp.</i> ,	

134 F.3d 1473 (Fed. Cir. 1998)	11
<i>Glaxo Inc. v. Novopharm Ltd.</i> , 52 F.3d 1043 (Fed. Cir. 1995)	11
<i>Heard v. Burton</i> , 333 F.2d 239 (C.C.P.A. 1964)	19
<i>ICU Medical, Inc. v. Alaris Medical Sys., Inc.</i> , 558 F.3d 1368 (Fed. Cir. 2009)	5
<i>In re Alonso</i> , 545 F.3d 1015 (Fed. Cir. 2008)	3
<i>In re Amos</i> , 953 F.2d 613 (Fed. Cir. 1991)	13
<i>In re Barker</i> , 559 F.2d 588 (C.C.P.A. 1977)	3
<i>In re Gardner</i> , 480 F.2d 879 (C.C.P.A. 1973)	16
<i>In re Rasmussen</i> , 650 F.2d 1212 (C.C.P.A. 1981)	16
<i>In re Ruschig</i> , 379 F.2d 990 (C.C.P.A. 1967)	14
<i>In re Wands</i> , 858 F.2d 731 (Fed. Cir. 1988)	8, 17
<i>Invitrogen Corp. v. Clontech Labs., Inc.</i> , 429 F.3d 1052 (Fed. Cir. 2005)	18, 19

<i>LizardTech, Inc. v. Earth Resource Mapping, Inc.</i> , 433 F.3d 1373 (Fed. Cir. 2006)	11
<i>Martin v. Mayer</i> , 823 F.2d 500 (Fed. Cir. 1987)	18
<i>Moba v. Diamond Automation</i> , 325 F.3d 1306 (Fed. Cir. 2003)	14, 15
<i>Nat'l Recovery Tech., Inc. v. Magnetic Separation Sys., Inc.</i> , 166 F.3d 1190 (Fed. Cir. 1999)	6
<i>Pennwalt Corp. v. Akzona Inc.</i> , 740 F.2d 1573 (Fed. Cir. 1984)	16
<i>PowerOasis, Inc. v. T-Mobile USA, Inc.</i> , 522 F.3d 1299 (Fed. Cir. 2008)	18
<i>Prima Tek II, L.L.C. v. Polypap, S.A.R.L.</i> , 412 F.3d 1284 (Fed. Cir. 2005)	18
<i>Regents of the Univ. of Cal. v. Eli Lilly & Co.</i> , 119 F.3d 1559 (Fed. Cir. 1997)	13
<i>Schering Corp. v. Amgen Inc.</i> , 222 F.3d 1347 (Fed. Cir. 2000)	15, 18
<i>Schering Corp. v. Geneva Pharms., Inc.</i> , 339 F.3d 1373 (Fed. Cir. 2003)	18
<i>Sitrick v. Dreamworks, LLC</i> , 516 F.3d 993 (Fed. Cir. 2008)	11
<i>Univ. of Rochester v. G.D. Searle & Co.</i> , 249 F. Supp. 2d 216, 229 (W.D.N.Y. 2003).....	7

<i>Univ. of Rochester v. G.D. Searle & Co.</i> , 358 F.3d 916, 922 (Fed. Cir. 2004)	7
<i>Univ. of Rochester v. G.D. Searle & Co.</i> , 375 F.3d 1303 (Fed. Cir. 2004)	3
<i>Vas-Cath Inc. v. Mahurkar</i> , 935 F.2d 1555 (Fed. Cir. 1991)	6
<i>Warner-Lambert Co. v. Teva Pharm. USA, Inc.</i> , 418 F.3d 1326 (Fed. Cir. 2005)	6

Statutes

35 U.S.C. § 112, 1 st ¶	<i>passim</i>
35 U.S.C. § 112, 2 nd ¶	17
35 U.S.C. § 119(e)	15
35 U.S.C. § 120	15
35 U.S.C. § 132	<i>passim</i>
35 U.S.C. § 251	15

Other Authorities

GATT-WTO Agreement on the Trade Related Aspects of Intellectual Property TRIPS art. 29(1)	6
<i>Guidelines for Examination of Patent Applications under the 35 U.S.C. 112,</i> <i>paragraph 1, “Written Description” Requirement</i> 66 Fed. Reg. 1103 (Jan. 5, 2001)	9

Timothy R. Holbrook, <i>Equivalency and Patent Law’s Possession Paradox</i> , 23 Harv. J.L. & Tech. 10-12 (forthcoming 2009)	12
Timothy R. Holbrook, <i>Possession in Patent Law</i> , 59 SMU L. Rev. 123, 162-63 (2006).....	10
Mark D. Janis, <i>On Courts Herding Cats: Contending with the “Written Description” Requirement (and Other Unruly Patent Disclosure Doctrines)</i> , 2 Wash. U. J.L. & Pol’y 55 (2000).....	9, 10, 13
<i>United States Patent & Trademark Office, Written Description Training Materials (2008)</i>	9

STATEMENT OF IDENTITY OF AMICI CURIAE

Amici curiae are professors who teach and write about patent law and policy. *Amici* have no personal interest in the outcome of this case. Our interest in this case is to contribute to the development of patent law and policy. No part of this brief was authored by counsel for any party, person, or organization besides *amici*. This brief is filed in response to the Court's invitation to file amicus briefs in this matter without leave of Court, as indicated in the Court's order in this matter dated August 21, 2009.

SUMMARY OF THE ARGUMENT

This Court's en banc order requests answers to two en banc questions. For the reasons set forth in this brief, *Amici* answer the questions as follows:

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

Amici's response: No. Section 112, paragraph 1, does not contain a written description requirement separate from an enablement requirement.

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

Amici's response: Neither Section 112, paragraph 1, nor any other provision in the statute, including the new matter prohibition of Section 132, supports a written description requirement separate from an enablement requirement. Accordingly, the Court need not reach the question of the scope and purpose of any such written description requirement.

Amici take no position as to whether the patent-in-suit satisfies the requirements of Section 112, paragraph 1, as properly construed.

ARGUMENT

I. THE LANGUAGE OF SECTION 112 ESTABLISHES AN ENABLEMENT REQUIREMENT, BUT NOT A WRITTEN DESCRIPTION REQUIREMENT

A. Section 112 Creates an Enablement Requirement and Specifies that the Requirement Must be Fulfilled by a Written Description

Section 112, 1st paragraph, requires that “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. . .”. 35 U.S.C. § 112, 1st ¶. That language is straightforward. It requires that the specification enable the making and using of the invention. It also specifies how the enablement requirement must be fulfilled: by “a written description (1) of the invention, and (2) of the manner and process of making and using it.” (numerals added). As Judge Markey put it,

Congress saved words by specifying, in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall both be in “such full, clear, concise, and exact terms as to enable.” Section 112, first paragraph, is a simple sentence, with a comma after “it,” making the phrase “in such full * * * the same” a modifier of both objects of the verb “contain.” 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, 559 F.2d 588, 594-95 (C.C.P.A. 1977) (Markey, J., dissenting) (calling the written description requirement “incongruous” and “illustrative of stare decisis rampant”). Judge Linn has read the statute in the same fashion:

The question presented by 35 U.S.C. § 112, paragraph 1, is not, “Does the written description disclose what the invention is?” The question is, “Does the written description describe the invention recited in the claims-themselves part of the specification-in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?” That is the mandate of the statute. . .

Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1325 (Fed. Cir. 2004) (Linn, J., dissenting from denial of rehearing en banc). The statutory language is not ambiguous. It creates an enablement requirement; it does not create a separate written description requirement.

B. Alternative Interpretations of Section 112 Take Liberties With Section 112’s Language

Alternative interpretations of Section 112 which purport to yield a written description requirement would not be faithful to the language of the statute. It would not be proper to read Section 112 as supporting a written description requirement simply because the words “written description” appear in the provision, without regard for the other words of the provision. *But cf. In re Alonso*, 545 F.3d 1015, 1019 (Fed. Cir. 2008) (identifying a separate written description requirement by quoting the phrase “The specification shall contain a written description of the invention....” and omitting the remainder of Section 112, first

paragraph); *Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.*, 541 F.3d 1115, 1121 (Fed. Cir. 2008) (merely italicizing the phrase “[t]he specification shall contain a written description of the invention,” without further statutory analysis).

Likewise, it would not be proper to read Section 112 in a way that renders it ungrammatical or stilted—for example, to read the statute as requiring that “the specification shall contain

(1) a written description of the invention, and

(2) *of* the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable . . .”. (numerals and emphasis added).

Finally, it would not be proper to endorse a Section 112 written description requirement while simply sidestepping Section 112, even in pursuit of the crucial policy goal of ensuring that patent applicants provide adequate disclosures.

II. THE ENABLEMENT REQUIREMENT BEST EFFECTUATES THE PURPOSES OF SECTION 112, FIRST PARAGRAPH

Even setting aside questions about Section 112’s language, the statutory enablement requirement better effectuates Section 112, first paragraph’s purposes than does the judicially-crafted written description requirement. Section 112, first paragraph serves a number of purposes, but two are paramount: (1) to ensure that the inventor’s claim scope is roughly commensurate with the scope of the

inventor's contribution to the art, evidenced through the disclosure; and (2) to ensure that the disclosure as originally filed provides support for claims which may be filed later. The decision to craft a separate written description requirement was a well-intentioned response to those concerns. *See, e.g., ICU Medical, Inc. v. Alaris Medical Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009) (asserting that the written description requirement seeks to “ensure that the scope of the right to exclude...does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification”); *Agilent Tech., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) (asserting that the written description requirement operates to “prevent an applicant from later asserting that he invented that which he did not. . .”) (quoting *Amgen, Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). However, experience with the written description requirement suggests that having two doctrines for achieving these goals is not always preferable to having one. On its own, the enablement doctrine provides the tools for regulating claim scope and ensuring against the claiming of afterthoughts. Combining enablement doctrine with a written description doctrine may actually be less effective in achieving these goals, as this Court's decisions have illustrated.

A. The Enablement Requirement Appropriately Correlates Claim Scope with the Scope of the Inventor’s Contribution

“Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention.” *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993). It is part of “the *quid pro quo* of the patent bargain.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). “The purpose of [the enablement] requirement is to ensure that ‘the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.’” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1336-37 (Fed. Cir. 2005), quoting *National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). Since the inception of the patent system, the enablement requirement has performed these functions, and it remains today the international benchmark for correlating claim scope with the scope of the inventor’s contribution. See GATT-WTO Agreement on the Trade Related Aspects of Intellectual Property TRIPS art. 29(1) (designating enablement as a minimum standard for TRIPS-compliant patent systems but not mandating a written description requirement).

Although this Court sometimes has employed a “possession” standard for the written description requirement, see *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); but see *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (“Application of the written description

requirement, however, is not subsumed by the ‘possession’ inquiry.”), the Court has not demonstrated that adding a “possession” analysis to the enablement analysis yields a more effective regime of rules for policing claim scope. Indeed, when analyzing possession, the Court has sometimes reverted to quasi-enablement reasoning in any event. For example, confronting a claim scope problem in *Rochester*, this Court invoked the written description requirement but framed it in the language of enablement, asserting that “[t]he ‘written description’ requirement serves a teaching function, as ‘quid pro quo’ in which the public is given ‘meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.’” *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922 (Fed. Cir. 2004) (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002)). The Court’s “written description” analysis then proceeded along enablement lines, inquiring whether one of ordinary skill in the art would have been able to predict which compounds would achieve the results recited in the claimed method, and concluding, as the trial court had noted, that one of skill in the art could not have arrived at the compounds ““except through trial and error.”” *Rochester*, 358 F.3d at 925 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216, 229 (W.D.N.Y. 2003)).

This is the enablement inquiry. Trial and error is the epitome of experimentation, and for decades courts have assessed enablement by inquiring

whether one of ordinary skill in the art would have needed to undertake undue experimentation to make and use the claimed invention in accord with the disclosure. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (setting forth the established multi-factor test for undue experimentation).

In theory, the fact that the enablement and written description analyses overlap is not alone an indictment, since it may be useful to have two doctrines that do essentially the same thing. In practice, however, courts have too often bypassed the enablement analysis in favor of the more amorphous written description analysis. This practice threatens to impede the evolution of the statutory enablement doctrine. Judge Linn has noted this “mischief”:

I note that the written description requirement does separate mischief in this case. Because the court relies upon this requirement to reverse the district court, it does not reach the important enablement issue raised by Lilly....To my knowledge, however, we have not specifically addressed this requirement in relation to the type of claims at issue here—that is, claims written broadly enough to cover any method for achieving a particular result....This is an important issue that we have left unresolved. It is an issue that we would have been compelled to reach had the case been decided on enablement grounds, a basis found in section 112, instead of on written description grounds, a separate basis not justified under that section or any other provision of the Patent Act.

Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1381 (Fed. Cir. 2009) (Linn, J., concurring), *rehearing en banc granted and judgment vacated*, No. 2008-1248, 2009 WL 2573004 (Fed. Cir. Aug 21, 2009). *See also* Mark D. Janis,

On Courts Herding Cats: Contending with the “Written Description” Requirement (and Other Unruly Patent Disclosure Doctrines), 2 WASH. U. J.L. & POL’Y 55, 107 (2000) (urging courts to “resist the narcotic of the written description requirement and redirect their energies towards refining the enablement concept, particularly as it correlates to claim scope.”). The use of dual doctrines does not provide double assurance that the disclosure is adequate. Instead, it results in a net loss, undercutting the development of the statutory enablement requirement and diverting resources towards an extra-statutory written description requirement which continues to defy ready explanation.

One need look no further than the U.S. Patent and Trademark Office (PTO) for evidence of this phenomenon. Over the past several years, in cooperation with industry experts, the PTO has made heroic efforts to translate the Court’s written description doctrine into a consistent and workable set of guidelines, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, paragraph 1, “Written Description” Requirement* 66 Fed. Reg. 1103 (Jan. 5, 2001), and (more recently), into an elaborate set of “training materials.” See *United States Patent & Trademark Office, Written Description Training Materials* (2008), available at <http://www.uspto.gov/web/menu/written.pdf> (last visited Oct. 10, 2009). Yet the “possession” standard enunciated in these documents is vaguely akin to an enablement requirement, and the examples, while faithful to this Court’s decisions,

do not collectively evince a coherent approach to conforming disclosure to claim scope. *See, e.g., PTO Training Materials* at 1 (suggesting that possession be evaluated by assessing the existence of an actual reduction to practice, a method for making the invention, predictability in the art, and the level of skill in the art, among other factors); *see also* Janis, 2 Wash. U. J.L. & Pol'y at 6 (noting that the 2001 Guidelines “do little to bring the written description requirement out from under the shadow of enablement”); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. Rev. 123, 162-63 (2006) (same). Meanwhile, the PTO has undertaken no comparable effort to articulate guidelines for applying the enablement requirement. The fault here does not lie primarily with the PTO; the problem is that any benefit of using the written description requirement to police claim scope is outweighed by the cost of attempting to make sense of that requirement, and the cost of the foregone opportunity to refine the law of enablement.

The costs associated with the written description requirement extend beyond those affecting the enablement doctrine. The use of a separate written description requirement also has a pernicious affect on the claim construction analysis. It invites invalidity arguments whenever claims are interpreted to be broader than the scope of the disclosed embodiment. *See LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373, 1376-78 (Fed. Cir. 2006) (Rader, J., dissenting from

denial of en banc review) (critiquing the use of the written description requirement on this ground). Moreover, this Court has designated the written description requirement a question of fact. *Agilent Tech., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009). By contrast, enablement, like claim construction, is a question of law. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Accordingly, the written description requirement may provide a vehicle for injecting fact disputes into issues which otherwise might be more amenable to resolution as a matter of law.

B. The Enablement Requirement Provides a Workable Rule for Determining Whether a Disclosure Supports Later-Added Claims

“[T]he enablement requirement. . . looks to the *objective* knowledge of one of ordinary skill in the art.” *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1050 (Fed. Cir. 1995) (emphasis supplied). The enablement inquiry thus describes an objective baseline from which to measure whether a disclosure provides support for later-added or later-amended claims. By contrast, the possession standard for written description, while framed as an objective inquiry, invites courts to place undue emphasis on the inventor’s subjective perceptions about the scope of his or her contribution. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) (citing, as part of the basis for a written description violation, the inventor’s testimony about elements of the invention that he considered “essential”).

Adding a subjective tinge to the enablement requirement in the form of a written description “possession” test does more harm than good, especially in the context of policing later-added claims. The patent law has long contemplated the possibility that inventors may not appreciate subjectively the full extent of their objective contributions to the art. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983) (“[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.”) Yet the possession test may be used to punish inventors for just such a shortcoming. An inventor who did not grasp subjectively the scientific principles underlying his or her invention as of the priority date may be declared not to have possessed a later-claimed invention, even where the inventor provided a disclosure on the priority date which fully enabled the later-claimed invention. When it operates in this manner, the written description requirement reduces patent incentives without a concomitant gain in the form of meaningful teachings. See Timothy R. Holbrook, *Equivalency and Patent Law’s Possession Paradox*, 23 Harv. J.L. & Tech. 10-12 (forthcoming 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1330688 (arguing that this argument may even extend to unforeseeable alternative embodiments). Nor does the addition of a written description requirement offer a worthwhile gain in the form of notice to the public as to what the inventor may subsequently claim. The

possession standard is too amorphous, and its application too idiosyncratic, to enhance appreciably the notice that an enabled specification already provides.

Finally, the subjective character of the possession standard is also problematic because, in applying it to later-added claims, courts may in effect be requiring that patent applicants file perfect claims with the original application. But there is no prohibition against “late claiming” in U.S. patent law, nor should there be given the complexity of modern patent prosecution. *See In re Amos*, 953 F.2d 613 (Fed. Cir. 1991) (discussing and rejecting the “late claiming” doctrine in the context of reissue proceedings); *Janis*, 2 Wash. U. J.L. & Pol’y at 65-6.

Enablement provides a workable and balanced rule for policing later-added claims. Patent applicants should be regarded as possessing all that the specification objectively enables and should therefore be entitled to file claims later in prosecution that are commensurate with that specification.

III. THE COURT SHOULD NOT USE THE SECTION 132 NEW MATTER PROHIBITION TO CRAFT A BACK-DOOR WRITTEN DESCRIPTION REQUIREMENT

While the panel opinion in this case applied a Section 112 written description analysis under the authority of *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and progeny, the Court’s en banc questions extend to the more common use of a written description requirement for policing

the priority date of claims, which commonly cite *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), and progeny. As Judge Bryson anticipated, “the real question. . . is not whether *Lilly* was an unwarranted departure from the *Ruschig* line of cases, but whether that entire line of cases is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1.” *Moba v. Diamond Automation*, 325 F.3d 1306, 1327 (Fed. Cir. 2003) (Bryson, J., concurring). In taking this rare opportunity to speak en banc as to the proper analysis for adequate disclosure, this Court should make clear that neither Section 112, nor other provisions in the statute, support the recognition of an independent written description requirement, whether that requirement is applied in the manner of the *Lilly* line of cases, or for the purpose of policing “new matter” as in the *Ruschig* line of cases.

A. Section 132 and Section 112 Serve Related Purposes, but Do Not Together Establish a *Ruschig*-Style Written Description Requirement

Neither Section 112 itself, nor other provisions in the statute, provide support for the written description requirement articulated in the *Ruschig* line of cases. First, as we have shown, Section 112’s language does not support a written description requirement at all, much less a written description requirement limited to the context of new matter. *Enzo Biochem, Inc. v. Gene-Probe Inc.*, 323 F.3d 956, 972 (Fed. Cir. 2002) (Lourie, J., concurring in the denial of rehearing en banc) (“The statute does not say ‘a written description of the invention for purposes of policing priority.’”); cf. *Moba v. Diamond Automation*, 325 F.3d 1306, 1327-28

(Fed. Cir. 2003) (Bryson, J., concurring) (“[I]f it is correct to read section 112 as containing a separate written description requirement, it is difficult to find a principled basis for restricting that requirement to cases involving priority disputes.”).

Second, the priority provisions establish a relationship with Section 112, first paragraph, but they do not call for a *Ruschig*-style written description requirement. Section 120 merely provides that claims are entitled to the filing date of an earlier domestic application if the earlier application disclosed the claimed invention “in the manner provided for by the first paragraph of section 112. . .” 35 U.S.C. § 120; *see also* 35 U.S.C. § 119(e) (using the same language to specify when claims in a regular application are entitled to the filing date of a provisional application).

Third, the new matter proscription of Section 132 makes no express reference to Section 112 at all, much less a Section 112, first paragraph written description requirement. 35 U.S.C. § 132 (specifying that “[n]o amendment shall introduce new matter into the disclosure of the invention.”); *see also* 35 U.S.C. § 251 (prohibiting the insertion of new matter in reissue applications, but making no reference to a written description requirement). To be sure, it has become customary in patent practice to recognize a connection between Section 132’s new matter prohibition and Section 112, first paragraph’s requirements for an adequate

disclosure. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000) (“[t]he new matter prohibition is closely related to the adequate disclosure requirements of 35 U.S.C. § 112”); *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1579 n. 11 (Fed. Cir. 1984) (“Claims which are amended with limitations unsupported by the original disclosure are rejected under 35 U.S.C. § 112 (first paragraph) as lacking support in the specification, while such amendments to the abstract, specification, and drawings are objected to as being drawn to *new matter*.”); *In re Rasmussen*, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981) (same). To the extent that this customary analysis insists that the claims must be “supported” by the remainder of the patent document in the sense of Section 112, first paragraph, this Court should continue to embrace it. But “support” in the Section 112 sense calls for a showing of enablement, not for an independent, additional showing of compliance with a written description requirement.

B. Section 132 Should Not be Construed to Provide an Independent Basis for a *Ruschig*-Style Written Description Requirement

In answering the en banc questions in this case, this Court should not only restore the proper analysis to Section 112, first paragraph, by discarding the written description requirement, but also should make clear that Section 132 does not independently create a written description requirement. Section 132 refers to amendments to the “disclosure,” and claims are deemed to be part of the

disclosure. *In re Gardner*, 480 F.2d 879 (C.C.P.A. 1973); 35 U.S.C. § 112, second paragraph (“The specification shall conclude with one or more claims. . .”). Hence, it is possible to find in Section 132 a prohibition against adding “new matter” to the claims. The court should rule that the Section 112, first paragraph enablement requirement provides the metric for determining whether amended or later-filed claims incorporate “new matter,” as we have demonstrated *supra*, Part II.B.

The Court has sometimes hinted at this analysis, but should make the rule explicit. In *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992), the Court concluded that “[w]hether particular technological information is ‘new matter’ depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter.” This set of factors is reminiscent of the undue experimentation inquiry employed in the law of enablement. *Wands*, 858 F.2d at 737.

By explicitly ruling that enablement is the metric for determining whether claims incorporate new matter, the court would avoid a new round of litigation over newly-minted analogs to the written description requirement. Unfortunately, some of this Court’s relatively few decisions on the new matter inquiry may have inadvertently sown the seeds for written description controversies under a new

name. For example, this Court has sometimes suggested that the new matter inquiry incorporates concepts from the doctrine of anticipation by inherency. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000) (“The fundamental inquiry [under the new matter prohibition] is whether the material added by amendment was inherently contained in the original application.”); *cf.* *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (under the written description requirement, the written description must “actually or inherently disclose” the subject matter at issue); *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (compliance with the written description requirement requires that the application “necessarily” disclose the subject matter in question). This resort to inherency opens the door to further litigation over whether an inventor must evince “appreciation” of his or her invention in order to make an adequate disclosure in a patent application. There is authority for the argument that no such showing is required in the context of inherent anticipation. *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1289-90 (Fed. Cir. 2005) (“Inherent anticipation does not require an appreciation of the inherent limitation by those of skill in the art before the critical date of the patents in issue.”); *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (same). On the other hand, in the context of establishing priority of invention, this Court has held that “conception requires that the inventor appreciate that which he has invented.”

Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1063 (Fed. Cir. 2005); *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001) (inventor must appreciate the fact of what he or she made, not the patentability of what he or she made); *Heard v. Burton*, 333 F.2d 239 (C.C.P.A. 1964).

In turn, the appreciation inquiry is complex. Whereas adequacy of disclosure inquiries (such as enablement) have turned on objective evidence, the appreciation inquiry has turned on a more complex mixture of the inventor's subjective understanding and objective corroboration of that understanding. *Invitrogen*, 429 F.3d at 1064 (appreciation analysis calls for inventor's "emerging recognition of something new," and courts require objective corroboration of the inventor's subjective beliefs in this analysis); *id.* at 1065 ("[O]bjective evidence is also an important part of the appreciation inquiry.")

The Court should preempt the growth of such doctrinal thickets. While the Court need not, and should not, anticipate every argument or resolve every dispute in the course of one en banc ruling, the Court should speak to the parameters of Section 132 in this case to avoid the need for a future en banc ruling on the very point.

CONCLUSION

For the reasons stated in this brief, this Court should answer en banc question no. 1 “no,” and should decline to reach en banc question no. 2.

Mark D. Janis
211 South Indiana Avenue
Bloomington, IN 47405
(812) 855-1205
Counsel of Record for Amici Curiae
Mark D. Janis and
Timothy R. Holbrook

**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE
REQUIREMENTS**

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Fed. Cir. Rule 32(b). The brief contains 4,574 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14-point Times New Roman font.

Mark D. Janis
211 South Indiana Avenue
Bloomington, IN 47405
(812) 855-1205
Counsel of Record for Amici Curiae
Mark D. Janis and
Timothy R. Holbrook

Dated: October 14, 2009

CERTIFICATE OF SERVICE

I, Mark D. Janis, hereby certify that I caused two copies of the foregoing Brief of *Amici Curiae* Mark D. Janis and Timothy R. Holbrook in Support of Neither Party to be served this 14th of October, 2009, by first class mail, postage prepaid, upon each of the following sets of Counsel:

Charles E. Lipsey
Finnegan, Henderson, Farabow, Garrett &
Dunner, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
(571) 203-2399

Attorney for Defendant-Appellant

James W. Dabney
Fried Frank Harris Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004
(212) 859-8000

John F. Duffy
Fried Frank Harris Shriver & Jacobson LLP
1001 Pennsylvania Avenue, N.W.
Washington, DC 20004
(202) 639-7000

John M. Whealan
12 Sunnyside Road
Silver Spring, MD 20910
(202) 994-2195

Attorneys for Plaintiffs-Appellees

Mark D. Janis