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A Brief Defense of the Written Description Requirement

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A Brief Defense of the Written Description Requirement

The Federal Circuit's December 7, 2009 hearing of oral argument in *Ariad v. Lilly*¹ has generated significant interest among those who follow patent policy. An en banc decision is expected within the next few months.

The dispute arises from the interpretation of 35 U.S.C. § 112, which states in relevant part:

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 same²

All agree that this language includes an “enablement” rule, which requires that the specification enable a person having ordinary skill in the art (PHOSITA) to make and use the invention.³ More controversial is the phrase “written description of the invention” and whether that phrase entails a separate requirement apart from enabling the PHOSITA to make and use the

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1. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir.), *reh'g granted*, 2009 U.S. App. LEXIS 18981 (Fed. Cir. Aug. 21, 2009).
 2. 35 U.S.C. § 112 (2006).
 3. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting) (“A straightforward reading of the text of section 112 suggests that the test . . . is whether it provides enough written information for others to make and use the invention.”).

invention.⁴ It appears that academics are split on the question, and most practitioners appear to disfavor a separate requirement.⁵

This Essay briefly describes the dispute and then raises an important but previously undertheorized argument in favor of a separate written description requirement. This Essay accepts the persuasive grammatical reading of the statute proposed by opponents of a separate written description requirement: a patent disclosure is sufficient so long as the PHOSITA can practice the invention.

However, this does not end the analysis. *Both* the written description *and* the “make and use” instructions must allow the PHOSITA to practice the invention. Thus, while enablement is a necessary prong of § 112, it is not the only prong. Even if the specification contains instructions sufficient to make and use the invention, the applicant is not relieved of the obligation to also identify the invention. In short, the specification must contain a “description of the invention,” even if such description would only serve to reinforce other parts of the disclosure.

This reading of the statute is consistent with the grammatical breakdown of § 112. It is also the normatively appropriate interpretation, because a description of the invention fulfills an important purpose in the patent system. Because it is possible to enable an invention without actually “inventing” the invention, the written description requirement ensures that the applicant actually invented the claimed subject matter. Reading description out of the statute would allow patent applicants to claim subject matter they did not invent and would effectively rewrite nearly 120 years of precedent about the conception of inventions.

This is certainly not the only argument in favor of a written description requirement; a strong written description requirement provides policy benefits

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4. See Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998) (“Recent developments . . . illustrate the difficulties of maintaining a clear demarcation between the written description and enablement requirements.”); see also Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1252 (2000) (“The role of the written description requirement under 35 U.S.C. § 112 has been the subject of much debate.”).
 5. See, e.g., Laurence H. Pretty, *The Recline and Fall of Mechanical Genus Claim Scope Under “Written Description” in the Sofa Case*, 80 J. PAT. & TRADEMARK OFF. SOC’Y 469, 471 (1998) (“This new requirement of the written description came without legislative hearings, without study or debate by the patent bar whether there was a need for construing the ‘written description’ of paragraph one in such a way, without case law precedent, and without even an exposition in the *Ruschig* case of the rationale for thus expanding paragraph one.”).

in clarifying claim scope and policing patentable subject matter.⁶ This Essay leaves such benefits to the side and focuses only on the statutory basis for the rule.

Finally, the Essay considers the *Ariad* case and concludes, perhaps surprisingly, that under the vision of written description presented in this Essay, the claims at issue may well be described.

I. WRITTEN DESCRIPTION AND ENABLEMENT

Understanding the debate requires understanding when and how the written description requirement operates. Most agree that there is a place for some sort of description requirement.⁷ When a patent claim is added or amended after the initial filing, the U.S. Patent and Trademark Office and courts look to the original specification to see whether the new claim was described in the initial application.⁸ The outside boundaries of the “invention” are set in stone on the date of the patent filing, and no “new matter” is allowed in later amendments.⁹ Thus, if a claim added later in the process is not described in the initial specification, it is considered new matter and disallowed. The policy is relatively straightforward—we do not like patentees

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6. See Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 609 (2008) (arguing that rigorous patentability alleviates patentable subject matter concerns, and that such rigor includes a written description requirement to ensure that the inventor “possesses” the full scope of invention); Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 226 (2007) (“Because the specification helps to clarify the meaning of the claims, a specification that fully describes the invention and provides enough detail for a PHOSITA to easily practice the invention will allow claims to be better understood.”).
 7. See, e.g., Mueller, *supra* note 4, at 618 (noting that “[a]ll United States patent statutes have required a ‘description’ of the applicant’s invention”).
 8. See, e.g., Brian William Higgins, Note, *Reiffin and the New Economy: Rethinking the Use of the Written Description Requirement To Curb Submarine Patent Tactics*, 11 FED. CIR. B.J. 23, 29 (2002) (“Written description problems usually arise where the original claims are subsequently amended during prosecution, and broadened in scope, such that the original specification may no longer support the new claims. . . . [A]n accused infringer may defend itself by attempting to invalidate a patent on grounds that the written description does not support the amended claims.”).
 9. See 35 U.S.C. § 132 (2006) (“No amendment shall introduce new matter into the disclosure of the invention.”); see also *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1247 (Fed. Cir. 2002) (“While it is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others, there must be support for such amendments or additions in the originally filed application.”).

looking at later developments and then claiming to have invented them when the initial application makes no mention of the subject matter.¹⁰

There is a second type of written description requirement—one that has become more popular in the case law within the last fifteen years. This form of the rule requires that the applicant describe the invention with sufficient particularity that the PHOSITA would understand that the inventor “possessed” the invention, even if the claim was made at the time of the initial application.¹¹ Possession is a word used in judicial opinions; its ambiguity is doctrinally and theoretically problematic. Instead, this Essay argues that this type of written description is important to show the applicant’s conception—not possession—of an invention.

The reason this second interpretation of § 112 becomes important is that there are certain inventions that might be enabled but not described.¹² Enablement does not require disclosure of every step required to make the invention; so long as the PHOSITA can fill in the gaps with background knowledge and without too much experimentation, then the invention will be enabled.¹³ Thus, inventions that have never been built can be patented, so long as the PHOSITA could build them.

However, just because a PHOSITA could practice the invention does not mean the patent applicant can do so. One example is *University of Rochester v. G.D. Searle & Co.*,¹⁴ in which the inventors discovered that certain drugs (non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin, ibuprofen, and

10. Gary C. Ganzi, *Patent Continuation Practice and Public Notice: Can They Coexist?*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 545, 559 (2007) (“As with other strict interpretations of the written description, the courts appear to be most concerned about applicants’ over-reaching in later filed claims, and in particular by applicants’ use of hindsight and later developed technology to attempt to claim more than what had originally been possessed by the inventor.”).

11. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (1991) (noting that the written description requires that the applicant “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention”).

12. See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); see also Robert A. Hodges, *Black Box Biotech Inventions: When a “Mere Wish or Plan” Should Be Considered an Adequate Description of the Invention*, 17 GA. ST. U. L. REV. 831, 834 (2001) (noting that the Federal Circuit’s standard for the description requirement in *Regents of the University of California v. Eli Lilly* “creates a disconnect between what is required to describe a biotech invention and the amount of information needed (by those in the art) to produce such an invention”).

13. See *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

14. 358 F.3d 916 (Fed. Cir. 2004).

naproxen) potentially affect two different enzymes in the body.¹⁵ They also invented a method to differentiate which NSAIDs work on which enzymes. This was an important discovery—some NSAIDs can be used long-term without the negative side effects caused by NSAIDs that affect both enzymes.¹⁶ Of course, there were other ways to tell which NSAIDs had the desired therapeutic effects and undesired side effects, such as extensive human testing and observation of changes in health.

The applicants did not stop at the process for differentiating NSAIDs, however. They also claimed the method of treating humans by administering NSAIDs identified by the differentiation process.¹⁷ The application did not name any such NSAIDs, but a PHOSITA could have discovered them after experimentation using the method described in the patent.¹⁸ Prior cases hold that a “considerable amount” of experimentation is acceptable depending on facts such as clarity of instructions and skill in the art.¹⁹ In *Rochester*, the skill level was high, the basic type of starting materials was known, and the direction was disclosed in the patent, so the claim for treating people was arguably enabled.²⁰

Rather than ruling on enablement, the court held that the claim was not described; even assuming a PHOSITA could find appropriate NSAIDs with reasonable experimentation, it was clear that the inventors had not completed any such reasonable experiments. Thus, they could not describe the invention of treating people with as yet unknown NSAIDs, even if they taught others how to do so.²¹

15. *Id.* at 917-18 (“It is now known that the traditional NSAIDs inhibit both COX-1 and COX-2, and as a result they not only reduce inflammation, but also can cause undesirable side effects such as stomach upset, irritation, ulcers, and bleeding.”).

16. *Id.* Note that even this differentiation has its problems, as experience with the drug VIOXX shows.

17. *Id.* at 918 (“Thus, all eight claims are directed to methods ‘for . . . administering a non-steroidal compound that selectively inhibits activity . . . to [or in] a human host in need of such treatment.’” (quoting U.S. Patent No. 6,048,850 (filed June 7, 1995))).

18. *Id.* at 918-19.

19. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) (stating that a claim may be enabled even if a “considerable amount” of experimentation is required, if the experimentation is the type a PHOSITA would expect in the relevant technology).

20. *See, e.g., Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) (noting that enablement was provided despite experimentation among thousands of different combinations where “one skilled in the art would know how to select a salt and fuel and then apply ‘Bancroft’s Rule’ to determine the proper emulsifier”).

21. *Rochester*, 358 F.3d at 929-30.

Rochester is not universally viewed as an enabled but undescribed claim. The district court ruled,²² and many argue,²³ that the failure to identify any NSAIDs means that the claim was not enabled. Nonetheless, the assumption of enablement provides a crisp example of the difference between description and enablement, even if the case might have been resolved in another manner.²⁴ As discussed further below, a written description requirement is important because it fills voids left by the easing of enablement standards and properly rejects patent challenges where enablement is indisputably present.²⁵

II. OPPOSITION TO A STRONG DESCRIPTION REQUIREMENT

Those who oppose a strong written description requirement do so for a variety of reasons. Ariad's opening brief²⁶ does an outstanding job of laying most of them out. In short, they argue that the proper grammatical reading of § 112 of the Patent Act requires (1) an identification of what the invention is, and (2) a description of how to make and use it.²⁷ Indeed, virtually all interested parties agree on this much. But opponents further argue that the description requirement is satisfied if a PHOSITA knows what the invention is to sufficiently make and use the claim; if the enablement prong is satisfied then the description prong is unnecessary beyond mere "identification" of the invention.

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22. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216, 232 (W.D.N.Y. 2003). The court did not cite *Wands*, *Atlas Powder*, or any other case that found enablement despite the need for extensive experimentation.
 23. Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 62 (2007) (arguing that the *Rochester* claim was described but not enabled).
 24. See also Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997). There, the claims covered a plasmid containing the gene that encodes insulin in vertebrates without ever identifying what the gene looked like. Arguably, however, the claim was enabled because the gene could have been found by other researchers based on the disclosure. *Id.* at 1562-63. Enablement is more questionable in *Lilly* because the disclosure was made in 1977, when it was far more difficult and costly to isolate gene sequences, but the case is still illustrative.
 25. See also Holman, *supra* note 23, at 63 (citing *In re Wallach*, 378 F.3d 1330 (Fed. Cir. 2004)) (describing a case in which disclosure quite likely enabled a claim, but where the court held that the claim was not described).
 26. Principal Brief for Plaintiffs-Appellees on Rehearing En Banc, Ariad Pharm., Inc. v. Eli Lilly & Co., No. 2008-1248 (Fed. Cir. Oct. 5, 2009) [hereinafter Brief for Plaintiffs-Appellees], available at http://www.patentlyo.com/ariad_20v._20lilly_20plaintiffs_20appellees_20principal_20brief.pdf.
 27. *Id.* at 2-7.

According to this argument, a patent claim is sufficient identification because it is part of the specification and stakes out the metes and bounds of the patent sufficiently for others to know what the invention is—and thus to practice it.²⁸ Opponents are quick to note that this does not mean an invention “identified” only by its boundaries is necessarily valid, because such claims may not be enabled.

A single enablement standard for all of § 112 makes good policy sense, opponents argue, because it is clearly applied and also saves inventors the cost of carrying out the necessary experiments to more fully describe an invention.²⁹ If the PHOSITA can practice the invention without excessive experimentation, then mere identification of the metes and bounds through a patent claim is sufficient, and the inventor need not understand why or how the invention works.

III. RECONCILING A STRONG DESCRIPTION REQUIREMENT WITH THE STATUTE

This Essay takes the perhaps novel approach of agreeing with the opponents’ persuasive grammatical reading of the statute that the proper test under both prongs of § 112 is whether the PHOSITA can make and use the invention. The Essay then shows why even under that reading, written description must require more than mere identification of the boundaries of the invention to ensure that the applicant has claimed boundaries that she has actually invented.

A. Importance of Invention and Conception

It is a bedrock principle that the patent applicant actually invent the subject matter claimed.³⁰ Section 101 states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter”³¹ is entitled to a patent, and § 102(f) bars patents if “he did not himself invent the subject matter sought to be patented.”³²

28. *Id.* at 56–59.

29. *Id.* at 38–40 (noting the likelihood of “prejudic[ing] university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention” (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 983 (Fed. Cir. 2002))).

30. *See Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993).

31. 35 U.S.C. § 101 (2006).

32. *Id.* § 102(f).

Intimately tied to the notion of invention is the date of invention. Invention dates determine what prior knowledge might invalidate the patent.³³ It determines who wins as between two inventors who claim the same thing.³⁴ It also determines when a patent is barred because it is on sale,³⁵ because one cannot sell an invention that has yet to be invented.

Finally, invention and the date of invention depend on two separate events: the “conception” of the invention and the “reduction to practice” of the invention.³⁶ Indeed, the Supreme Court has stated that conception is really all that matters to determine an invention: “The primary meaning of the word ‘invention’ in the Patent Act unquestionably refers to the inventor’s conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented.”³⁷ The Court goes on to note that “[t]he word ‘invention’ must refer to a concept that is complete, rather than merely one that is ‘substantially complete.’”³⁸ Finally, the Court notes in a footnote that “[s]everal of this Court’s early decisions stating that an invention is not complete until it has been reduced to practice are best understood as indicating that the invention’s reduction to practice demonstrated that the concept was no longer in an experimental phase.”³⁹

How do we know that a concept is complete and no longer in an experimental phase? Those opposing a strong description requirement would say a description that enables the PHOSITA to reduce the invention to practice is sufficient evidence. *Pfaff v. Wells Electronics* lends some support to this view, saying that an invention is ready for patenting “by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.”⁴⁰

33. *Id.* § 102(a).

34. *Id.* § 102(g).

35. Patents are disallowed if someone (often the applicant) has attempted to sell an invention more than one year prior to the filing date. *Id.* § 102(b); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 55 (1998) (“Under § 102(b) of the Patent Act of 1952, no one can patent an ‘invention’ that has been ‘on sale’ more than one year before filing a patent application.”).

36. *Rex Chainbelt, Inc. v. Borg-Warner Corp.*, 477 F.2d 481, 487 (7th Cir. 1973) (stating that “invention has not occurred until the subject of the invention has been both conceived and reduced to practice”).

37. *Pfaff*, 525 U.S. at 60.

38. *Id.* at 66.

39. *Id.* at 66 n.12.

40. *Id.* at 67-68.

However, conception has long had a much more nuanced definition than attributed in the *Pfaff* case.⁴¹ It is true that some cases make clear that enablement is key, but where there is a question about a particular date that an invention was rendered operable, or the date the inventor understood the invention, then conception, completion, and operability are given much more fine-grained consideration.⁴² Neither *Pfaff* nor any of the others cases that imply that enablement is sufficient were confronted with the issue of whether an invention was fully conceived.

B. Description and Conception

This is where the description requirement comes in. Courts and the PTO have long determined that one need not actually build an invention if a patent application is filed that conforms to the specification requirements. This is often called “constructive reduction to practice,”⁴³ and courts, practitioners, and observers usually take for granted that enablement is enough to constructively show that the inventor conceived of all the steps necessary for invention because an enabling specification usually includes a description of the invention.

Those opposing strong written description go a step further and argue that enablement will *always* be sufficient. However, as the *Rochester* case shows, it is possible to have enablement without a complete conception. In such cases, describing the invention serves an important purpose—it serves to show not only that a PHOSITA can reduce the invention to practice, but also that the applicant had the precursor conception that indicates a completed invention. Consider two patent applications filed on the same day. One says, “I am close to conceiving the invention, but my experiments are not done. A PHOSITA

41. See, e.g., 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 532 (1890) (“[Conception is the] formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”). This definition is still used today in difficult questions about when an invention was conceived. See, e.g., Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc., 333 F.3d 1330, 1338 (Fed. Cir. 2003); Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

42. See, e.g., Clark Thread Co. v. Willimantic Linen Co., 140 U.S. 481, 489 (1891) (discussing the point at which conception becomes completed invention).

43. See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1377 (Fed. Cir. 2003) (“‘Constructive reduction to practice’ is a legal status unique to the patent art. Unlike the rules for scientific publications, which require actual performance of every experimental detail, patent law and practice are directed to teaching the invention so that it can be practiced.”).

can easily finish those experiments.” The second says, “I have conceived of the invention; the following is a description of the results of my experiments.” The described conception will win a priority battle every time.⁴⁴ The question then becomes why the first application should get rights against the world (including those who actually complete the experiments) when there is no second patent application to compete for priority.

Thus, there are times when the PTO or courts must determine whether the applicant actually conceived of the invention that is being claimed. The only place to look to make this determination is the specification, which is the applicant’s statement of the invention. And the portion of the specification that evidences the invention made by the applicant is the description of the invention.⁴⁵ It is no surprise, therefore, that the requirement that written description show “possession” of the invention originated, at least in part, from cases dealing with priority of invention between two inventors arguing about who was the first to conceive of an invention.

The notion that written description should be used to determine whether the applicant conceived of the invention is not merely a fanciful creation of the courts—it is endemic to the entire patent system. It is the only way to ensure, to the extent we care about such things, that the patentee has actually invented the subject matter—not just a constructive reduction to practice by telling others what experiments might be possible, but also the inventor’s subjective conception of the end result.

C. Consistent Meaning

Despite opponents’ arguments that only one test should be used, it is difficult to deny that identification of the invention is a separate statutory

44. See, for example, *Fiers v. Revel*, which makes clear that the description is critical to determining whether an invention was disclosed in an application. 984 F.2d 1164 (Fed. Cir. 1993).

45. Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1196 (2008) (arguing that cases requiring that novel aspects of a claim be enabled by the specification rather than by background knowledge “can only be explained by a doctrine that limits the inventor’s rights to subject matter he actually invented, or the subject matter described in the disclosure”); see also Brief of Amicus Curiae Oskar Liivak in Support of Defendant-Appellant at 16, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, No. 2008-1248 (Fed. Cir. Nov. 18, 2009), available at <http://patentdocs.typepad.com/files/amicus-brief--oskar-liivak.pdf> (“Written description asks whether the specification can corroborate that the claimed subject matter was part of the inventor’s complete and permanent idea of the invention.”).

requirement from instructions on how to make and use it.⁴⁶ This Essay's use of written description to determine conception is consistent with two separate requirements even if there is only one test. Fulfilling the minimal enablement requirement by describing how to make and use the invention does not release the applicant from the obligation to *also* provide a description of the invention sufficient to practice the invention.

Ariad even acknowledges that “[i]dentifying the invention is necessary for enablement, since a specification that does not teach one of ordinary skill *what* to make and use does not enable the skilled artisan to make and use the unidentified subject matter.”⁴⁷ The primary disagreement appears to be whether written description exists only to provide instructions to the public or whether it is also intended to ensure that the applicant actually conceived of the subject matter. If the purpose were limited to public notice, then description of “what to make” is fulfilled by a description of the manufacturing process even if conception is incomplete. If the purpose extends to policing conception, then the requirement is fulfilled only when the applicant's description shows a completed conception.

This Essay argues that written description requires both public instruction and private conception. To be sure, description will often merge with instructions about making and using the invention, but—as discussed in *Rochester* and *Lilly*⁴⁸—this is not always true. Interpreting the statute to require a complete description even if the “make and use” prong is fulfilled provides evidence that the inventor has actually formed a complete conception.⁴⁹

Requiring a description to show conception is consistent with other areas where the specification is judged. For example, tying written description to a completed conception is consistent with the “new matter” policing function of written description that many people agree upon (though there are people who disagree with this as well).⁵⁰ Where the patent specification does not identify

46. Brief for Plaintiffs-Appellees, *supra* note 26, at 43 (“Properly interpreted, the written description requirement of § 112, ¶ 1 requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention.”).

47. *Id.* at 44.

48. See *supra* notes 21-24 and accompanying text.

49. Eli Lilly's counsel alluded to this point, referring to Professor Liivak's amicus curiae argument that description provides a “corroboration of conception.” Audiotape of Oral Argument in *Ariad Pharm., Inc. v. Eli Lilly & Co.*, No. 2008-1248 (Dec. 7, 2009), available at <http://oralarguments.cafc.uscourts.gov/mp3/2008-1248-2.mp3>.

50. For one example of disagreement regarding the new matter policing function of written description, see Brief of Amici Curiae Mark D. Janis and Timothy R. Holbrook in Support of Neither Party at 15-16, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, No. 2008-1248 (Fed. Cir. Oct. 14, 2009), available at http://www.patentlyo.com/janis_holbrook_ariad_amicus_brief.pdf.

the invention sufficiently to support a finding that the inventor conceived of an amended claim at the time of initial filing, it is new matter under § 132.⁵¹ Furthermore, tying §132 new matter to § 112 written description is important, because patents cannot be invalidated under § 132 in litigation unless the patent fails to satisfy § 112.⁵²

Mandatory description is also consistent with how § 112 is used for determining priority between two inventors. Where the specification does not identify the invention sufficiently to support a finding that the inventor conceived of the complete invention, it is not given priority.⁵³

D. Insufficiency of Enablement

Limiting the identification requirement to an “enablement” meaning focused only on public instruction would turn other areas where the specification is used on their heads. Inventors could look around the market and broaden their claims to cover inventions they never thought of and argue that such claims are not “new matter” because a PHOSITA could have figured out how to extend the disclosed conception.⁵⁴ Further, first inventor status would now go to the first person to file a patent application pointing in the right direction, rather than the first to complete the invention.

Critics of this viewpoint will say that enablement is enough and that as long as someone with a bright idea can rely on others with skill to complete an invention, the goals of the patent system will be fulfilled.⁵⁵ The veracity of this conclusion is not so clear. Skill levels and technology are as high as they have ever been, and enablement is easier to show as skill in the art increases. For example, the Federal Circuit considers skill levels in computer software so high

51. 35 U.S.C. § 132 (2006); *see also* *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1247 (Fed. Cir. 2002) (“While it is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others, there must be support for such amendments or additions in the originally filed application.”).

52. *See* 35 U.S.C. § 282; *Aristocrat Techs. Austl. PTY Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 662 (Fed. Cir. 2008) (construing § 282 narrowly, such that improper revival of abandoned patent under § 133 is not a defense in litigation).

53. *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993) (“The issue here, however, is conception of the DNA of the count, not enablement. . . . Since Fiers seeks to establish priority under section 102(g), the controlling issue here is whether he conceived a DNA coding for -IF, not whether his method was enabling.”).

54. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998).

55. *See, e.g., Robin C. Feldman, The Inventor’s Contribution*, 2005 UCLA J.L. & TECH. 6 (arguing that the enablement requirement can sufficiently determine the scope of the invention).

that completely opaque patent specifications are considered enabling.⁵⁶ This phenomenon is not limited to computer science. For example, *In re Kubin*⁵⁷ endorses the “obvious to try” test for skilled therapeutics researchers.⁵⁸

Thus, if a highly skilled PHOSITA could find the answer by trying some reasonable experiments, then enablement will be satisfied for a disclosure even if the applicant has not done such experiments. Ariad’s argument is already tending in this direction, arguing that it is unfair to force universities to spend the money necessary to conduct the “obvious” experiments that would have provided the information required by a strong description requirement.⁵⁹

Taken to the limit⁶⁰—as some enterprising patentees will surely do—enablement without written description will allow people to obtain broad patents too early in the invention process, long before they have actually invented something. Ford or Chrysler, rather than Robert Kearns,⁶¹ could have patented the intermittent windshield wiper because they had the idea first and a PHOSITA was later able to reduce it to practice. The only requirement would be that the patentee move the process far enough along that others might finish the work.

E. Written Description and Broad Claims

There is still room for broad, genus type claims that grant inventors the full scope of their inventions.⁶² However, applicants must identify the principles

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- 56. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1164-65 (2002) (“Still, it is remarkable that the Federal Circuit is willing to find the enablement requirement satisfied by a patent specification that provides *no* guidance whatsoever on how the software should be written. . . . Programming is a highly technical and difficult art. Unfortunately, the Federal Circuit’s peculiar direction in the software enablement cases has effectively nullified the disclosure requirement for software patents.”).
 - 57. 561 F.3d 1351 (Fed. Cir. 2009).
 - 58. *Id.* at 1358-61.
 - 59. Brief for Plaintiffs-Appellees, *supra* note 26, at 38-40; *see also* Lefstin, *supra* note 45, at 1213 (“[I]f accumulating the information needed to describe the genus is difficult and time-consuming, though ‘enabled,’ then perhaps enablement is doing a poor job of implementing the quid pro quo of the patent system.”).
 - 60. *See, e.g.*, Lefstin, *supra* note 45, at 1186 (“All material objects which are enabled by the combination of my disclosure and the prior art, excluding those which are known or obvious in light of the prior art.”).
 - 61. *See, e.g.*, Kearns v. Wood Motors, Inc., 773 F. Supp. 979, 980 (E.D. Mich. 1990) (discussing the development of intermittent windshield wipers in the early 1960s).
 - 62. F. Scott Kieff, *Blame Within the Patentee’s Domain? Failing the Patentability Requirements of Written Description and On-Sale Bar*, reprinted in DONALD S. CHISUM ET AL., PRINCIPLES OF

that link a particular described embodiment to the broad claim.⁶³ For example, in the *Incandescent Lamp Patent*⁶⁴ case the Court noted: “If the patentees had discovered . . . a quality common to [all fibrous substances] . . . and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad.”⁶⁵

There is also still room for the prophetic inventor, who can visualize but not build an invention, so long as the visualization is complete and the specification describes the visualized conception (and how to practice it) rather than asking others to discover it through experimentation.

Both of these principles are illustrated in the *Telephone Cases*,⁶⁶ a case whose meaning is hotly disputed. Ariad argues that the case supports a simple enablement standard.⁶⁷ Lilly argues that it requires both description and enablement.⁶⁸

Lilly has the better of this argument; the Court delineated the two requirements of describing the invention and telling others how to practice it:

[I]t is enough if [the inventor] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, *and* if he points out some practicable way of putting it into operation. [Bell] *described* . . . his process of

PATENT LAW 313-16 (4th ed. 2008) (arguing that a written description need not be as stringent as its opponents argue).

63. *Singh v. Brake*, 317 F.3d 1334, 1343-44 (Fed. Cir. 2003) (holding that a broad claim is described where the inventor identified the relevant permutations and described the “meaningful” species); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (“[T]he written description requirement would be met . . . if the functional characteristic . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.”); F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 112 (2003) (stating that disclosure must “provide[] a clear indication of how to determine membership in the genus”); Lefstin, *supra* note 45, at 1211.
64. 159 U.S. 465 (1895). Sawyer and Man conceived of one embodiment for the light bulb, but claimed all light bulbs without describing how the conception of one bulb would encompass all light bulbs.
65. *Id.* at 472.
66. 126 U.S. 1 (1888).
67. See, e.g., Brief for Plaintiffs-Appellees, *supra* note 26, at 19.
68. Brief for Defendant-Appellant Eli Lilly & Co. on Rehearing En Banc at 17, Ariad Pharm., Inc. v. Eli Lilly & Co., No. 2008-1248 (Fed. Cir. Nov. 9, 2009) [hereinafter Brief for Defendant-Appellant], available at <http://patentdocs.typepad.com/files/lillys-principal-brief.pdf>.

transmitting speech . . . [and] then *pointed out two ways* in which this might be done⁶⁹

Lilly's argument, however, may go too far by arguing that "[t]he specification must enable the 'full scope' of the claims and not merely one embodiment," and that Ariad failed to describe any "completed" molecules.⁷⁰

Bell would likely fail Lilly's interpretation of written description because he was a prophetic inventor who only described one embodiment of his broad claims and failed to ever complete his invention prior to filing. It was undisputed that Bell had not completed a fully working device prior to his patent application. Further, the device he described reflected only one of the two ways Bell described to transmit speech.⁷¹ Nonetheless, the Court allowed a claim to the broad process of sending voice using either the vibration or the variable resistance method. The Court's reasoning about the principles of the invention indicates that the invention was described even if an embodiment was not, the essence of prophetic patenting. Further, the patent description shows Bell's conception of the broader invention. First, the Court notes that "[b]oth forms of apparatus operate on a closed circuit by gradual changes of intensity, and not by alternately making and breaking the circuit"⁷² Second, the general principle of gradual electrical changes, and not any particular embodiment, was key to the broad claim:

It was left for Bell to discover that the failure was due, not to workmanship, but to the principle which was adopted as the basis of what had to be done. He found that [the prior art would never work], but that the true way was to operate on an unbroken current by increasing and diminishing its intensity.⁷³

The Telephone Cases highlight the importance of describing the conceived invention, and also demonstrates that the description requirement need not be a barrier to patenting broad and prophetic inventions. Even though Bell only

69. *The Telephone Cases*, 126 U.S. at 536 (emphasis added).

70. Brief for Defendant-Appellant, *supra* note 68, at 53.

71. Compare *The Telephone Cases*, 126 U.S. at 535 ("It is quite true that when Bell applied for his patent he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line"), with *id.* at 538 ("[A device] acting on the variable resistance mode is not described, further than to say that the vibration of the conducting wire in mercury, or other liquid, included in the circuit, occasions undulations in the current, and no other special directions are given as to the manner in which it must be constructed.").

72. *Id.* at 538.

73. *Id.* at 544.

described how to make one embodiment of the broader principle, he was entitled to the general and broad method that he discovered because he was able to describe “the exact electrical condition that must be created to accomplish his purpose.”⁷⁴

F. Written Description and Ariad

Bell’s patent shows that the role of written description in policing conception is not nearly as onerous as its detractors fear. The patent specification need only show that the applicant conceived of the invention and allow others to practice it. So long as the description shows conception of the broad principle, then a broad claim is appropriate.

Under this standard, perhaps surprisingly, the *Ariad* inventors may very well satisfy the written description requirement.⁷⁵ The patent claims a method for providing therapeutic benefits by decreasing NF- B activity.⁷⁶ The patent describes three classes of molecules that might decrease such activity. For example, it describes the basic principles of one such class; it teaches the use of “decoy molecules” to reduce NF- B activity, as well as the chemical mechanism that makes such molecules decoys.⁷⁷ The patent then lists ten different gene sequences that could be used as decoys. It also describes a test that would determine which molecules in each of the three classes would be effective at reducing activity.⁷⁸

This description seems to show that the inventors conceived of a broad principle that they then described.

First, the inventors identified a new protein called NF- B. They described the principle by which it works in the human body and how its reduction would have particular therapeutic benefits. They then described not only the conditions necessary to reduce it, but also suggested specific sequences and classes that might also work and a specific test to determine whether they would work. This appears to evidence a complete conception; the description is certainly as complete as Bell’s in the *Telephone Cases*. Like Bell, the inventors surely could have done more; but if the concern is whether the inventors

74. *Id.* at 535.

75. Lawrence B. Ebert, *Ariad/Lilly Is NOT Like Rochester/Searle!*, IPBiz, Jan. 26, 2007, <http://ipbiz.blogspot.com/2007/01/ariadlilly-is-not-like-rochestersearle.html>.

76. Brief for Plaintiffs-Appellees, *supra* note 26, at 52 (describing a claim for a “method for reducing, in eukaryotic cells, the level of expression of genes . . . the method comprising reducing NF- B activity in the cells”).

77. *Id.* at 54.

78. *Id.* at 55.

actually conceived what they had discovered—the conditions required for a sequence to act as a reducer—then this description implies that they did exactly that.

Even if the inventors listed three classes for investigation but only provided examples in one class, as suggested by the initial Federal Circuit opinion,⁷⁹ the ability to identify these classes may be based on a conception of the principles of reducing NF- κ B with certain types of molecules. This is no different than the description given by Bell, who only described one type of telephone apparatus even though he also described the principles that would work with other types.

Of course, others might need to perform tests to find the most appropriate decoys or other reducing agents, but this is no different than Bell's contemporaries who had to experiment to perfect the telephone using variable resistance. These are enablement issues, and here the jury found that one with skill in the art could (and did) make decoys based on the disclosure.⁸⁰ Thus, the court's finding that a "linkage" was not described⁸¹ is more of an enablement issue than a description issue.⁸² Requiring such linkage turns the written description requirement into impermissible "super-enablement," requiring more than a description of how a PHOSITA could make or use the invention.

Second, this description is certainly more complete than the description in *Rochester*. The primary difference is the completeness of the conception. While the *Rochester* inventors discovered that some NSAIDs solely affected the newly discovered enzyme, they did not describe any underlying principle that differentiated one NSAID from another, specific classes of NSAIDs that would pass the test, or any other underlying principles for the types of NSAIDs to be administered. In the absence of such a description, the identification of at least some starting materials might have indicated a complete conception, but the *Rochester* patent did not disclose such starting materials either. The *Ariad* inventors, on the other hand, appear to have described both the underlying

79. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1373 (Fed. Cir.), *reh'g granted*, 2009 U.S. App. LEXIS 18981 (Fed. Cir. Aug. 21, 2009).

80. Brief for Plaintiffs-Appellees, *supra* note 26, at 56.

81. *Ariad*, 560 F.3d at 1375 ("As Dr. Latchman pointed out, there is no descriptive link between the table of decoy molecules and reducing NF- κ B activity.").

82. *Id.* at 1377 ("The state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure.").

principles of molecules that would decrease NF- κ B activity and several starting materials.⁸³

To the extent that Ariad's competitors consider the patent too broad, they take issue with the patent system generally; the law has never required inventors to discover each and every embodiment of the broad principles they claim. The question should be whether Ariad described the broad principles of its invention sufficiently to show that its conception was complete at the time of filing.

IV. CONCLUSION

Written description helps fulfill dual goals of the patent system: securing claims as broad as the inventor's contribution, but preventing claims that are broader than the inventor's contribution. This does not mean that written description need be "super-enablement."⁸⁴ To be sure, it is difficult to prove that one described an invention when the patent specification does not disclose the conceived invention. Where, however, the inventor has conceived of the invention, providing a description of the invention is much easier.

This is not intended to diminish the contributions of pioneering researchers who face patent invalidation; they routinely discover new, useful, and important subject matter. However, they cannot claim the subject matter that they do not actually discover and leave for others to find. Proponents of each side of the *Ariad* case have failed to recognize this middle ground. Contrary to Ariad's argument, § 112 includes a real written description requirement. Contrary to Lilly's argument, Ariad's patent likely satisfies that requirement.

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83. This analysis is not comprehensive; it may turn out that the claim at issue in *Ariad* is not described. For example, there was much dispute about the timing of disclosures in the patent. *Id.* at 1374.

84. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1652-53 (2003) (describing biotechnology as being held to a higher written description standard than other industries such as software).

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