

# ***Ariad* Decision Affirms a Separate Written Description Requirement – Detailed Case Summary**

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## **Overview**

On March 22, 2010, the Court of Appeals for the Federal Circuit (CAFC)<sup>1</sup> issued its long-anticipated *en banc*<sup>2</sup> decision in the *Ariad* case<sup>3</sup>. In its decision, the CAFC affirmed that a written description requirement that is separate from the enablement requirement exists under the first paragraph of 35 U.S.C § 112. Accordingly, the first paragraph of 35 U.S.C. § 112 continues to have three requirements (written description, enablement and best mode), rather than just enablement and best mode.

The key points of the decision are as follows:

- (1) By agreement of the parties, the dispute centers on the standard to be applied to the written description requirement and whether it applies to original claim language;
- (2) The CAFC ruled that the first paragraph of 35 U.S.C. § 112 contains both a written description and an enablement requirement;
- (3) The CAFC argued that the Supreme Court recognizes separate written description and enablement requirements;
- (4) *Stare decisis* supports the written description requirement;

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<sup>1</sup> The CAFC has jurisdiction in patent cases for all appeals from federal district courts where patent cases are originally heard. The CAFC also has jurisdiction over cases decided by the Board of Patent Appeals and Interferences (BPAI) during patent prosecution. The only court that litigants can appeal a CAFC decision to is the United States Supreme Court, which tends to rarely choose to hear patent cases, although the number of patent cases that the Supreme Court has chosen to hear in recent times has increased from historical averages.

<sup>2</sup> The CAFC typically hears cases in a panel of three judges. However, an *en banc* hearing involves an enlarged panel of the CAFC judges. In *Ariad*, a poll was circulated to all twelve judges of the CAFC and at least seven of the judges decided to rehear the case *en banc*.

<sup>3</sup> *Ariad Pharmaceuticals et al. v. Eli Lilly and Company*, Slip Op. 2008-1248 (CAFC 2010).

- (5) Whether the written description requirement is separate from enablement is a distinction without a difference insofar as both approaches require a written description in the specification;
- (6) While original claims are part of the original specification, original claim language alone does not necessarily disclose the subject matter it claims;
- (7) “Possession” means “possession as shown in the disclosure”;
- (8) The written description requirement is not “super-enablement”; and
- (9) Basic research without a practical use cannot be patented.

## Background

To understand the full scope and intricacies of the issue, a background discussion should prove helpful. The requirements for the specification of a patent application are provided for by the first paragraph of 35 U.S.C. § 112, which states:

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.<sup>4</sup>

The section has been interpreted to have three requirements: (1) enablement; (2) written description; and (3) best mode. The enablement requirement has been interpreted to require the specification to enable one of ordinary skill in the art of the claimed invention to make or use the claimed invention without undue experimentation.<sup>5</sup> The best mode requirement is a safeguard against the desire on the part of some to obtain patent protection without making a full disclosure as

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<sup>4</sup> Emphasis added.

<sup>5</sup> See Manual of Patent Examining Procedure (MPEP) § 2164.01; see also *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

required by the statute. The best mode requirement prevents inventors from disclosing only what they know to be an inferior embodiment, while retaining the best embodiment for themselves.<sup>6</sup>

With respect to the written description requirement, the requirement mandates that a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.<sup>7</sup> The written description requirement is said to serve both to satisfy an inventor's obligation to disclose the technological knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the claimed invention.<sup>8</sup> The enablement requirement is also said to serve a teaching function in its role as a *quid pro quo*, or exchange, in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.<sup>9</sup> Thus, the underpinnings of the written description requirement appear to be primarily equitable in nature, seeking to give the public disclosure of specific embodiments of an invention in exchange for the grant of a limited monopoly on the claimed technology.

However, in litigation, courts may decide that a patent fails to meet the written description requirement without ever reaching important enablement

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<sup>6</sup> See MPEP § 2165; see also *In re Nelson*, 280 F.2d 172 (CCPA 1960).

<sup>7</sup> See MPEP § 2163(I); see also *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003).

<sup>8</sup> See *Ariad*, 560 F.3d at 1373 and 1374; see also *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

<sup>9</sup> See *Ariad*, 560 F.3d at 1374; see also *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002).

issues.<sup>10</sup> The written description requirement has been said by Judge Rader of the CAFC to be a form of “super-enablement” that courts will turn to first since the written description requirement is generally more stringent than the enablement requirement.<sup>11</sup> As such, courts allegedly often choose to bypass considering enablement issues in favor of analyzing the written description requirement. Further, it is considerably easier for an Examiner to make a proper rejection for alleged lack of compliance with the written description requirement than it is for an Examiner to reject claims as allegedly not being enabled since a proper enablement rejection requires, among other things, addressing the *Wands* factors.<sup>12</sup>

This failure to address enablement in favor of only addressing the written description requirement is precisely what happened in *Ariad*. In that case, the CAFC held that Ariad’s patent<sup>13</sup> was invalid for failing to meet the written description requirement. Because the CAFC determined that the written description requirement was not met, the issue of enablement was never considered.<sup>14</sup> Failure to address the enablement requirement in favor of

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<sup>10</sup> *Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and The President and Fellows of Harvard College v. Eli Lilly and Co.*, 560 F.3d 1366, 1374 (Fed. Cir. 2009); see also *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002).

<sup>11</sup> See *Enzo*, 323 F.3d at 982.

<sup>12</sup> See Manual of Patent Examining Procedure (MPEP) § 2164.01; see also *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

<sup>13</sup> See Baltimore et al. (U.S. Patent No. 6,410,516). The patent is a complex biotechnology patent titled “Nuclear Factors Associated with Transcriptional Regulation” that pertains to artificially reducing the activity of a transcription factor called “NF-KB”.

<sup>14</sup> See *Ariad*, 560 F.3d at 1402.

dismissing a patent as invalid for an inadequate written description has also occurred in other CAFC cases.<sup>15</sup>

After failing to win its argument that the patent at issue satisfies the written description requirement, Ariad filed a petition for an *en banc* rehearing on June 2, 2009. In the petition, Ariad boldly argued that the written description analysis is not consistent with the plain text of the statute and that the written description requirement conflicts with precedent set both by the United States Supreme Court<sup>16</sup> and the CAFC. Ariad's arguments relied heavily on dissenting opinions by CAFC judges from various cases. Previous petitions for *en banc* rehearing to determine whether a separate written description requirement exists had been denied.<sup>17</sup> However, the CAFC decided to grant Ariad's petition and asked the parties of *Ariad* to file briefs addressing the following issues:

- (a) Whether the first paragraph of 35 U.S.C. § 112 contains a written description requirement separate from the enablement requirement; and
- (b) If a separate written description requirement is set forth in the statute, what the scope and purpose of the requirement is.

These questions have been briefed by the parties and addressed by the CAFC's decision, which is discussed in detail below.

### **The Core Dispute – the Standard to be Applied to Written Description**

The CAFC first argued that the positions of Ariad and Lilly converge more than they would first appear to.<sup>18</sup> Ariad argued that the specification should

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<sup>15</sup> See *e.g.*, *Enzo*; see also *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

<sup>16</sup> The petition alleged that the written description requirement is counter to both *The Telephone Cases*, 126 U.S. 1 (1888) and *Tilghman v. Proctor*, 102 U.S. 707 (1881).

<sup>17</sup> See *e.g.*, *University of Rochester v. G.D. Searle & Co.*, *denial of rehearing en banc*, 375 F.3d 303 (Fed. Cir. 2004).

<sup>18</sup> See *Ariad* Slip Op. at 6.

describe (i) what an invention is; and (ii) how to make and use it.<sup>19</sup> However, “Ariad argues that this first step of ‘identifying’ the invention applies only in the context of priority (i.e., claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims ‘constitute their own description.’”<sup>20</sup> Lilly, on the other hand, asserted that a “separate written description requirement applies to all claims—both original and amended—to ensure that inventors have actually invented the subject matter claimed.”<sup>21</sup> The CAFC noted that both parties “agree that the specification must contain a written description of the invention to establish what the invention is.”<sup>22</sup> Accordingly, the CAFC identified that “[t]he dispute, therefore, centers on the standard to be applied and whether it applies to original claim language.”<sup>23</sup>

### **Interpretation of the Statute**

With respect to interpretation of the first paragraph of 35 U.S.C. § 112, Ariad argued that a written description is required (i) of the invention; and (ii) of the manner and process of making and using it.<sup>24</sup> Ariad argued that because the original Patent Act was “(i) to distinguish the invention from the prior art, and (ii) to enable a person skilled in the art to make and use the invention”, when Congress assigned the function of defining the invention to the claims in 1836, the written description requirement was amended to only serve a single purpose: enablement.<sup>25</sup> On the other hand, Lilly argued, in essence, that the statute holds

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<sup>19</sup> See *Id.*

<sup>20</sup> *Id.* at 6-7.

<sup>21</sup> *Id.* at 7.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> See *Id.* at 8.

<sup>25</sup> See *Id.* at 8-9.

that (i) the specification shall contain a written description of the invention; (ii) and the specification shall contain a written description of the manner and process of making and using the invention enabling one skilled in the art to make or use it.<sup>26</sup>

The CAFC agreed with Lilly, stating that the first paragraph of 35 U.S.C. § 112 contains two separate description requirements: a written description (i) of the invention; and (ii) of the manner and process of making and using the invention.<sup>27</sup> Ariad argued that “the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement.”<sup>28</sup> However, the CAFC disagreed that there was a basis for this argument.

The CAFC then turned to the argument made by some amici, and supported by Judges Rader and Linn, that the only description requirement is enablement. The CAFC dismissed this argument, reasoning

If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently. Specifically, Congress could have written the statute to read, “The specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same,” or “The specification shall contain a written description of the manner and process of making and using the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.”<sup>29</sup>

The CAFC, citing *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883), stated that the amici’s reading violates the rule of statutory construction that Congress does

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<sup>26</sup> See *Id.* at 9.

<sup>27</sup> See *Id.* at 10.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 11.

not use unnecessary words, noting that it was their [the CAFC's] duty to give effect, if possible, to every word and phrase of a statute.<sup>30</sup>

The CAFC further cited policy considerations, noting that every patent must describe an invention as part of the *quid pro quo* for obtaining a patent, and that enablement is a different task.<sup>31</sup> Requiring applicants to provide a description of the claimed invention allows:

- (1) the United States Patent and Trademark Office to examine applications effectively;
- (2) courts to understand the invention, determine compliance with the statute, and to construe claims; and
- (3) the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.<sup>32</sup>

### **The Supreme Court Recognizes Separate Requirements**

The CAFC found that Supreme Court precedent recognizes “a written description requirement separate from an enablement requirement even after the introduction of claims.”<sup>33</sup> The Supreme Court stated in *Schreiber-Schroth Co. v. Cleveland Trust Co.* that the first paragraph of enablement serves:

- [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.<sup>34</sup>

The CAFC held that only the first element involved enablement and that “[a]lthough the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the

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<sup>30</sup> See *Id.*

<sup>31</sup> See *Id.* at 12.

<sup>32</sup> *Id.*

<sup>33</sup> See *Id.* at 13

<sup>34</sup> See *Id.* See also *Schreiber-Schroth v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938).

Court did.”<sup>35</sup> The CAFC further stated that *Gill v. Wells*, and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* indicate that the statute serves a purpose other than enablement both before and after *Schriber-Schroth*.<sup>36</sup>

### ***Stare Decisis Supports the Written Description Requirement***

The CAFC also held that in addition to Supreme Court precedent, *stare decisis* impels upholding the written description requirement.<sup>37</sup> The written description requirement has been the law for over 40 years, per *Ariad*, and “to change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions.”<sup>38</sup> Accordingly, settled expectations counsel against changing the requirement.

### **Whether the Written Description Requirement is Separate from Enablement is a Distinction without a Difference**

*Ariad* argued that “a written description of the invention is required but is not separate from enablement because it identifies the invention that must be enabled, and this, in *Ariad*’s view, differs from first requiring the invention to be described and then separately requiring it to be enabled.”<sup>39</sup> As indicated by the title of this section, the CAFC viewed this argument as a distinction without a difference “insofar as both approaches require a written description of the invention in the specification.”<sup>40</sup> If the claimed invention does not appear in the

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<sup>35</sup> See *Ariad* Slip Op. at 13-14.

<sup>36</sup> See *Gill v. Wells*, 89 U.S. (22 Wall.) 1 (1874); see also *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

<sup>37</sup> See *Ariad* Slip Op. at 15-16.

<sup>38</sup> See *Id.* at 16.

<sup>39</sup> *Id.* at 17.

<sup>40</sup> See *Id.*

specification, the claim fails regardless of whether the invention is enabled.<sup>41</sup> The claims at issue in *Ariad* were genus claims, covering the use of **all** substances achieving the desired result of reducing the binding NF-KB to NF-KB binding sites.<sup>42</sup> Thus, in *Ariad*'s case, while a genus encompassing around half a million possible compounds was described, the specific chemical chlorpropamide was not mentioned.<sup>43</sup>

### **Original Claim Language does not Necessarily Disclose the Subject Matter it Claims**

*Ariad* argued that "as long as the claim language appears in ipso verbis in the specification as filed, the applicant has satisfied the requirement to provide a written description of the invention."<sup>44</sup> Lilly, on the other hand, argued that the written description requirement applies to all claims and the specification must objectively demonstrate that the applicant invented (was in possession of) the claimed subject matter.<sup>45</sup> The CAFC again agreed with Lilly and batted down any notion that the written description requirement is restricted to establishing priority.<sup>46</sup> Further, the CAFC noted that there is no difference between original and amended claims for the purposes of the written description requirement.<sup>47</sup>

*Ariad* also argued that the original claims identify whatever they state, leaving only the question of enablement.<sup>48</sup> The CAFC disagreed, noting that while original claims are part of the original specification and many original claims

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<sup>41</sup> See *Id.*

<sup>42</sup> See *Id.* at 4.

<sup>43</sup> See *Id.* at 17.

<sup>44</sup> *Id.* at 19.

<sup>45</sup> See *Id.*

<sup>46</sup> See *Id.* at 19-20.

<sup>47</sup> See *Id.* at 23.

<sup>48</sup> See *Id.* at 20.

will satisfy the written description requirement, certain claims will not.<sup>49</sup> From the CAFC's discussion, this was particularly likely to be the case with respect to genus claims. However, determining precisely what disclosure is required to meet the written description requirement is not subject to a rigid formula and must be analyzed on a case-by-case basis. A sufficient description of a genus requires disclosure of a representative number of species falling within the scope of the genus or structural features common to all members thereof such that one skilled in the art can "visualize or recognize" the members of the genus.<sup>50</sup> A variety of species should be disclosed such that the specification amounts to more than a "wish" or a "plan".<sup>51</sup>

**"Possession" Means "Possession as Shown in the Disclosure"**

With respect to the need for an inventor to show "possession" to meet the written description requirement, the CAFC believes that "[t]he term 'possession' has never been very enlightening."<sup>52</sup> Rather, because the hallmark of written description is disclosure, the CAFC held that "possession as shown in the disclosure" is a more complete formulation.<sup>53</sup> However, regardless of the specific formulation, the CAFC held that "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" and "[b]ased on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor

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<sup>49</sup> See *Id.*

<sup>50</sup> See *Id.* at 21.

<sup>51</sup> See *Id.* at 22.

<sup>52</sup> See *Id.* at 23-24

<sup>53</sup> See *Id.* at 24.

actually invented the invention claimed.”<sup>54</sup> While the inquiry is fact-specific depending on the technology at hand, merely rendering the invention obvious in the written description is insufficient.”<sup>55</sup>

### **Written Description Requirement is not “Super-Enablement”**

The CAFC rejected Ariad’s contention that the written description doctrine was a form of “super-enablement” standard for the chemical and biotechnology arts.<sup>56</sup> Per the above, this contention has also been raised by Judge Rader. “[A]lthough written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.”<sup>57</sup> Further, if a genus is defined by its function or result, the written description requirement ensures that the specification recites sufficient materials to accomplish that function.<sup>58</sup>

### **Basic Research without a Practical Use cannot be Patented**

Basic research by universities, to the extent that it remains a mere idea, cannot be patented.<sup>59</sup> “Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the latter patentable inventions of others ... [a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”<sup>60</sup> Rather, the research must be

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<sup>54</sup> *Id.*

<sup>55</sup> See *Id.* at 24-25; see also *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

<sup>56</sup> See *Ariad Slip Op.* at 26.

<sup>57</sup> *Id.*

<sup>58</sup> See *Id.* at 27.

<sup>59</sup> See *Id.* at 28.

<sup>60</sup> *Id.*, quoting *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

reduced to some concrete, disclosed form. While universities may initially view such a ruling as disadvantageous, patents on abstract ideas are impermissible even without the *Ariad* decision. Hopefully, the *Ariad* decision will encourage further cooperation between corporations and universities to more quickly reduce research into practical forms and to eventually commercialize inventions.

### **Original CAFC *Ariad* Decision, and Written Description Requirement, Maintained**

Because the written description requirement was deemed to exist, the reasoning from the three judge decision in 2009 was maintained and incorporated into the *en banc* panel's decision.<sup>61</sup> An adequate description of the molecules was not present in *Ariad*'s patent. The vast scope of the generic claims was unsupported by the scant examples provided in the specification.<sup>62</sup> Judge Newman wrote a concurrence that stresses that "the overriding policy of the patent system requires both written description and enablement" and that "the transition from theory to practice" is required.<sup>63</sup> Judge Gajarsa stated in a concurrence that the interpretation of the first paragraph of 35 U.S.C. § 112 is one over which reasonable people can disagree and that the majority's interpretation is reasonable.<sup>64</sup> As could be predicted by their previous opinions, Judges Rader and Linn dissented, arguing that there is no separate written description requirement and that the "possession" requirement is not found in the statute. Thus, the written description requirement remains as part of the first paragraph of 35 U.S.C. § 112 under the CAFC's interpretation, applicants will

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<sup>61</sup> See *Ariad* Slip Op. at 29-38.

<sup>62</sup> See *Id.* at 37.

<sup>63</sup> See *Id.*, *Newman concurrence* at 2-3.

<sup>64</sup> See *Id.*, *Gajarsa concurrence* at 1-2.

continue to occasionally see written description rejections during prosecution and litigants will continue to sometimes lose their cases for failure to comply with the written description requirement without reaching the issue of enablement.