MOBA V. DIAMOND AUTOMATION, INC.: QUESTIONING THE SEPARATE WRITTEN DESCRIPTION REQUIREMENT

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A basic principle of the patent system is that an inventor must contribute something of value to society in exchange for a limited monopoly on an invention.[1] An inventor fulfills this obligation in part through the disclosure requirements of § 112 of the Patent Act.[2] The most confusing and controversial of these disclosure requirements is arguably the separate written description requirement.

In *Moba v. Diamond Automation, Inc.*, the Court of Appeals for the Federal Circuit limited the scope of the written description requirement.[3] The court recognized that the requirement evolved over the past few decades into two separate applications: one that polices priority issues of later-filed claims and one that provides a free-standing disclosure requirement applicable to all claims.[4] Although the court did not explicitly overturn any prior case law, it limited previous cases to their individual facts and restricted both applications of the written description requirement.[5] Judge Rader, although concurring in the opinion, argued separately that the court should eliminate the second role of the written description requirement: the free-standing disclosure requirement.[6]

Moba signifies the Federal Circuit's discontent with the written description requirement as it exists today. Even though the court's careful approach avoided overturning its precedents, it implied that the existence of the requirement does more harm than good. Arguments in favor of eliminating the requirement are abundant, ranging from the redundancies of the requirement with other areas of patent law, to the harm the written description requirement inflicts on innovation. In contrast, arguments sup-

1. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 259-61 (3d ed. 2002).

2. 35 U.S.C. § 112 (2000).

3. 325 F.3d 1306 (Fed. Cir. 2003) (per curiam), *cert. denied*, 124 S. Ct. 464 (2003).

4. *Id.* at 1319-20.

5. *See id.* at 1321.

6. *Id.* at 1322-27 (Rader, J., concurring) (arguing that "[b]y making written description a free-standing disclosure doctrine, [the Federal Circuit] produces numerous unintended and deleterious consequences").

porting the written description requirement are few, and are greatly outweighed by the benefits of disposing of the doctrine.

Part I of this Note provides a brief background of the written description requirement, including its statutory basis, its origin, and its evolution. Part II provides a summary of the *Moba* case. Part III argues that the patent system is best served by eliminating the separate written description requirement entirely.

I. BACKGROUND

A. Statutory Basis for the Written Description Requirement

In 1790, Congress used its constitutional power[7] to enact the first U.S. patent statute.[8] The original statute underwent a number of reenactments until Congress passed the 1952 Patent Act, which is still in effect today.[9] Under this Act, five separate requirements exist to patent an invention: 1) patentable subject matter; 2) novelty; 3) utility; 4) non-obviousness; and 5) disclosure (including written description, enablement, and best mode).[10]

The statutory basis for the current written description requirement stems from 35 U.S.C. § 112. Paragraph one 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.[11]

Although the statute specifically refers to a "written description," it is unclear whether it is independent from the enablement requirement.[12] The statute's reference to written description appears to only illustrate how to fulfill the enablement requirement. In fact, every Patent Act since 1790

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7. The Constitution of the United States gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

8. 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.02[1] (2003).

9. *See id.* § 7.02[4].

10. MERGES & DUFFY, *supra* note 1, at 65, 211, 259, 361, 643.

11. 35 U.S.C. § 112, ¶ 1 (2000).

12. *See* Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1323 (Fed. Cir. 2003) (Rader, J., concurring) (stating that a patent contains an adequate description if it enables a person skilled in the art to make and use the invention).

referred to a requirement for a description in the specification,[13] but only since 1967 has this been interpreted to require a written description requirement separate from an enablement requirement.[14]

B. Origin of the Written Description Requirement

In 1967, the United States Court of Customs and Patent Appeals (CCPA), the predecessor to the Federal Circuit, created a written description requirement separate from the enablement requirement.[15] In *In re Ruschig*, the CCPA affirmed the Patent Office Board of Appeals' rejection of a later-added claim for chlorpropamide on the ground that it was not sufficiently described.[16] The court explained that the general disclosure of the patent application contained about half a million possible compounds and lacked the necessary guides to lead one skilled in the art to the claimed compound.[17]

The CCPA rejected the appellant's argument based on the enablement requirement, emphasizing that "the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented."[18] In particular, the court noted that if the patent was rejected based on § 112, "it is on the requirement thereof that '[t]he specification shall contain a written description of the invention.'"[19] The CCPA concluded that the test for this requirement is whether the specification conveys to someone skilled in the art that the patentee invented the item in question.[20]

The written description requirement was born through these few short sentences.[21] Since *Ruschig*, most courts have interpreted § 112 to require three separate disclosure elements: written description, enablement, and best mode.[22] However, the boundary of the written description requirement was not clearly defined, resulting in criticism from both courts and scholars.[23]

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13. *See* 3 CHISUM, *supra* note 8, § 7.02.
14. *Moba*, 325 F.3d at 1323-24 (Rader, J., concurring).
15. *In re* Ruschig, 379 F.2d 990, 996 (C.C.P.A. 1967).
16. *Id.*
17. *Id.* at 993-95.
18. *Id.* at 995.
19. *Id.*
20. *Id.* at 996.
21. *See id.* at 993-95.
22. *See* 3 CHISUM, *supra* note 8, § 7.01.
23. For a discussion of these issues and criticisms, see discussion and footnotes *infra* Part III.

C. Evolution of the Written Description Requirement

1. A Priority Policing Device

After *Ruschig*, the CCPA and then the Federal Circuit applied the written description requirement in numerous situations with often inconsistent results. This new doctrine created much confusion about its application, as illustrated by one district court's comment that "[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is [concerning the written description requirement]."[24] This confusion prompted the Federal Circuit in *Vas-Cath Inc. v. Mahurkar* to summarize the case law development of the requirement and to provide guidelines for its correct application.[25]

In *Vas-Cath*, the Federal Circuit reversed and remanded a district court's ruling that two patents involving dual-lumen hemodialysis catheters were invalid.[26] The issue in the case was whether the appellant's previously abandoned design application provided adequate disclosure to fulfill the § 112 written description requirement.[27] The respondent conceded that the design application enabled one of skill in the art to practice the invention.[28]

The Federal Circuit explained that the written description requirement most often applies when an applicant later files claims not present in the original application.[29] Conceptually, the court stated that the test is whether "the applicant [conveys] 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*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*"[30] In essence, the Federal Circuit's analysis of the written description requirement in *Vas-Cath* narrowed the CCPA's broad analysis in *Ruschig*, and limited the written description requirement to cases of priority.[31]

The Federal Circuit again endorsed the use of the written description requirement to police priority issues in *Gentry Gallery, Inc. v. Berkline Corp.*, when the court introduced an "essential element" concept.[32] In

24. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991) (quoting Vas-Cath Inc. v. Mahurkar, 745 F. Supp. 517, 522 (N.D. Ill. 1990)).
25. *Id.* at 1560-64.
26. *Id.* at 1559, 1567.
27. *Id.* at 1559-60.
28. *Id.* at 1559.
29. *Id.* at 1560.
30. *Id.* at 1563-64.
31. *See id.* at 1560-64.
32. 134 F.3d 1473, 1479 (Fed. Cir. 1998).

1998, plaintiff Gentry Gallery appealed a district court judgment that defendant Berkline did not infringe one of its patents for reclining seats in a sectional sofa, while Berkline cross-appealed the district court's holding that the patent claims were not invalid.[33] Berkline argued that since the disclosure only described "a console positioned between [the reclining seats] that accommodates the controls for both of the reclining seats," claims relating to recliner controls not located on the console were invalid for lack of disclosure.[34]

The Federal Circuit ruled that the patent's original disclosure did not allow for later-amended claims with recliner controls not on the console.[35] The court stated that the "[patent's] original disclosure serves to limit the permissible breadth of [the patent's] later-drafted claims."[36] The court considered the location of the controls on the console to be an "essential element" of the invention.[37] It held that the amended claims violated the written description requirement because one of skill in the art would understand it as essential for the invention to have the controls specifically on the console.[38]

2. A Free-Standing Disclosure Requirement

The written description requirement would probably not be subject to such an intensive level of debate had the Federal Circuit confined the requirement strictly to priority issues. However, in the 1997 case, *Regents of the University of California v. Eli Lilly & Co.*, the Federal Circuit expanded the written description requirement to contain a free-standing disclosure requirement applicable to all claims, blurring the boundary between the enablement and written description requirements.[39]

In *Eli Lilly*, the Regents of the University of California appealed a district court's ruling that claims in a patent for recombinant DNA technology were invalid.[40] Although the patent claimed human, vertebrate, and mammalian insulin DNA, the specification only listed the nucleotide sequence of rat insulin DNA, along with a general method for obtaining the human insulin DNA.[41] The Federal Circuit ruled that whether or not the patent provided an enabling disclosure, its claims were invalid based on

33. *Id.* at 1474.
34. *Id.* at 1478.
35. *Id.* at 1479.
36. *Id.*
37. *Id.* at 1479-80.
38. *Id.* at 1480.
39. 119 F.3d 1559 (Fed. Cir. 1997).
40. *Id.* at 1562.
41. *Id.* at 1562-63.

the written description requirement because the patent specification did not specifically disclose a DNA sequence for human insulin.[42] The court stated that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[43] The Federal Circuit essentially created a new heightened standard for written description concerning biotechnological inventions.[44] The court transformed the earlier standard, which focused only on the priority of the invention, into a new free-standing disclosure requirement applicable to all claims.

3. Recent Developments

Both *Gentry Gallery*'s "essential element" concept[45] and *Eli Lilly*'s free-standing disclosure requirement[46] received an avalanche of criticisms.[47] Thereafter, the Federal Circuit tried to limit the expansive application of the written description requirement. First, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the court held that the written description requirement for genetic material does not always require a DNA sequence, but may be satisfied by reference to a deposited nucleotide sequence.[48] Second, in *Amgen Inc. v. Hoeschst Marion Roussel, Inc.*, the Federal Circuit further distanced itself from its holdings in *Gentry Gallery* and *Eli Lilly*, allowing satisfaction of the written description requirement based on correlation to a known substance.[49]

In *Enzo*, the assignee of a patent for selectively hybridizing nucleic acid probes for the genetic material of the bacteria that cause gonorrhea appealed a district court's invalidity holding based on the written description requirement.[50] The Federal Circuit originally affirmed the decision, but in 2002, after a petition for rehearing, the court vacated the prior decision, and reversed the district court's holding.[51] The court held that refer-

42. *Id.* at 1575.
43. *Id.* at 1566-67.
44. *See id.*
45. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998).
46. *Eli Lilly*, 119 F.3d at 1566-69.
47. For a discussion of some of these criticisms, see discussion and footnotes *infra* Part III.A.
48. 323 F.3d 956, 960 (Fed. Cir. 2002).
49. 314 F.3d 1313, 1332 (Fed. Cir. 2003).
50. *Enzo*, 323 F.3d at 960-62.
51. *Id.* at 960.

ence in the specification to a biological deposit in a public depository fulfills the written description requirement.[52]

The Federal Circuit acknowledged the similarities between the enablement and written description requirements, and held that the practice of depositing biological material now fulfills both requirements.[53] Later, the court declined to rehear the *Enzo* appeal en banc.[54] Judge Rader, joined by Judge Gajarsa and Judge Linn, strongly dissented from this decision and argued that both *Enzo* and *Eli Lilly* misapplied the written description requirement.[55]

Amgen, decided in early 2003, involved patents for the production of erythropoietin, a hormone that controls the production of red blood cells in bone marrow.[56] The Federal Circuit stated that the purpose of the written description requirement is "to prevent an applicant from later asserting that he invented that which he did not."[57] In doing so, the court focused on the priority policing role of the written description requirement to the exclusion of the independent disclosure function of *Eli Lilly*.[58] In fact, the Federal Circuit stated that the defendant's arguments based on a free-standing disclosure requirement were unpersuasive.[59]

The Federal Circuit distinguished *Eli Lilly*, holding that the written description requirement "may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure."[60] The court concluded that the substances in this case were "not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend."[61] Additionally, the *Amgen* court clarified *Gentry Gallery*, explaining that they did not create an "essential element" test which would only allow claims that incorporated what the inventor considered to be essential to the invention.[62] The court distinguished *Gentry Gallery* and described it as an application of the established rule that a broadly drafted claim must be supported by the disclosure.[63]

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52. *Id.* at 965.
53. *Id.*
54. *Id.* at 970.
55. *Id.* at 976-83 (Rader, J., dissenting).
56. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1319 (Fed. Cir. 2003).
57. *Id.* at 1330.
58. *See id.* at 1330-31.
59. *See id.* at 1331.
60. *Id.* at 1332.
61. *Id.*
62. *Id.* at 1333.
63. *Id.*

Overall, the Federal Circuit retreated from the heightened written description requirement that it created in *Gentry Gallery* and *Eli Lilly*, and limited both cases to their facts.[64] In light of this background, the Federal Circuit decided *Moba*.[65]

II. CASE SUMMARY

A. Facts and Procedural History

Diamond Automation, Inc. ("Diamond") produces and sells high-speed egg processing machines.[66] Diamond obtained a variety of patents on egg processing technology, including United States Patents 4,519,494 ("the '494 patent")[67] and 4,519,505 ("the '505 patent").[68] Moba, B.V. and Staalkat, B.V. compete with Diamond and sell their machines in the United States through FPS Food Processing (collectively "FPS").[69]

FPS sued Diamond in 1995 in the United States District Court for the Eastern District of Pennsylvania, seeking a declaratory judgment that the '494, '505, and two other patents were invalid and not infringed by their machines. Diamond counterclaimed that the patents were valid and infringed. After claim construction, the parties tried the case before a jury. Before jury deliberation, Diamond moved for entry of Judgment as a Matter of Law (JMOL) that FPS infringed and induced infringement of the four patents. The jury found that the patents were valid and not infringed. The judge denied the JMOL motion, and affirmed the jury's verdict. Diamond again moved for JMOL, and the judge again denied the motion.[70]

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64. *See id.* at 1332-34.

65. Very recently, the Federal Circuit addressed its first significant written description case since *Moba*. Univ. of Rochester v. G.D. Searle & Co., Inc., No. 03-1304, 2004 WL 260813 (Fed. Cir. Feb. 13, 2004). The court affirmed a district court's grant of summary judgment of invalidity of a patent for a method of treating inflammation. *Id.* at *2. The Federal Circuit based its decision on the patent's failure to fulfill the written description requirement. *Id.* This case further magnifies the confusion within the Federal Circuit concerning the written description requirement. After narrowing the application of the doctrine for a number of years, the court applied the written description requirement more broadly than ever before by applying a heightened free-standing disclosure requirement to a non-genetic material. *Id.* at *9. This case illustrates many of the problems associated with a separate written description requirement. *See infra* Part III.

66. Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1309 (Fed. Cir. 2003).

67. U.S. Patent No. 4,519,494 (issued May 28, 1985).

68. U.S. Patent No. 4,519,505 (issued May 28, 1985).

69. *Moba*, 325 F.3d at 1312.

70. *Id.*

Diamond appealed to the Federal Circuit, arguing that the FPS machines infringed claim 28 of the '494 patent and claim 24 of the '505 patent. FPS cross-appealed the validity judgment of the two claims.[71] The Federal Circuit ruled that the jury correctly determined that FPS did not infringe claim 28 of the '494 patent, and affirmed the district court's denial of Diamond's JMOL.[72] Additionally, the Federal Circuit affirmed the validity of claim 24 of the '505 patent, but ruled that Moba literally and directly infringed the claim, therefore reversing the district court's denial of JMOL on the issue. The court also remanded the case for further determination as to whether FPS Food Processing induced its customers to infringe claim 24.[73]

B. Per Curiam Opinion

Since FPS argued that the claims at issue were invalid for failing to meet the written description requirement, the Federal Circuit took the opportunity to reevaluate the requirement. The court acknowledged that case law contains two applications of the written description requirement: priority policing and free-standing disclosure.[74]

The first application of the written description requirement is the traditional use of the requirement to ensure that an inventor possessed, as of the original filing date, the subject matter of any later claims. This guarantees that an applicant does not claim more than what is found in the original invention.[75] The court noted that although § 132 of the patent statute prohibits the addition of new matter to the specification or claims,[76] both the CCPA and the Federal Circuit decided to regulate the addition of new matter to claims using § 112.[77] CCPA case law even indicates that a rejection under § 132 is the same as a rejection under the first paragraph of § 112.[78]

The Federal Circuit then ruled that the first application of the written description requirement did not apply to the facts of this case because FPS never claimed that the specification of the '505 patent did not show possession of a later-added claim.[79]

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71. *Id.*
72. *Id.* at 1322.
73. *Id.*
74. *Id.* at 1319-20.
75. *Id.* at 1319.
76. 35 U.S.C. § 132(a) (2000) ("No amendment shall introduce new matter into the disclosure of the invention.").
77. *Moba*, 325 F.3d at 1319.
78. *Id.*
79. *Id.* at 1320.

The second application of the written description requirement concerns situations without priority issues, and requires a heightened level of disclosure of the relevant invention, as in *Eli Lilly*.[80] Building on its limitation of the free-standing disclosure requirement in *Enzo* and *Amgen*,[81] the Federal Circuit stated in *Moba* that the "disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing."[82] Rather than focus on specific rules, the court declared that the specification must be analyzed from the viewpoint of one of skill in the art.[83] The court came just short of overturning *Eli Lilly* and the second application of the written description requirement.[84] It stated that in previous cases, when the record convinced one of skill in the art to make and use the invention, it also convinced one of skill in the art that the inventor possessed the invention.[85]

Based on its new iteration of the written description requirement, the Federal Circuit held that the specification described every element of the claim in question in such a manner that one of ordinary skill in the art would recognize that the inventor was in possession of the invention at the time of filing the application.[86] Therefore, the court ruled that the specification satisfied the written description requirement.[87]

C. Concurring Opinions

1. Judge Rader

Although Judge Rader concurred in the opinion, he challenged the rationale of a separate written description requirement.[88] He stated that this court and previous courts applied the judge-made doctrine beyond the purpose for which it was originally created: priority protection.[89] Judge Rader reasoned that anytime a patentee claims anything beyond the preferred embodiment of the invention as outlined in the specification, a de-

80. *See id.* at 1320-21.

81. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332 (Fed. Cir. 2003); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).

82. *Moba*, 325 F.3d at 1321.

83. *Id.* at 1320.

84. *See id.* at 1321.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* at 1322-24 (Rader, J., concurring).

89. *Id.* at 1322 (Rader, J., concurring).

fendant can argue that the patent is invalid for failure to describe the entire invention.[90]

To illustrate the confusion created by the written description requirement, Judge Rader pointed out that "[u]nder Federal Circuit case law, [the plaintiff] asked this jury to decide that the patent's disclosure can enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention. Puzzling."[91] Judge Rader declared that there is no statutory basis for the current written description requirement and that any disclosure that enables is sufficient to show that the inventor was in possession of the invention.[92] He concluded that "to enable is to show possession, and to show possession is to enable."[93]

Although Judge Rader recognized that the addition of new matter is already prohibited by § 132, he reasoned that using § 112 to police new claims does no harm because the CCPA ruled that a rejection of an amended claim under § 132 is equivalent to a rejection under § 112.[94] Additionally, Judge Rader believed that the new matter doctrine does not need to extend beyond priority issues because the enablement requirement encompasses all other issues.[95]

Judge Rader was especially critical of the written description requirement as it appears in *Eli Lilly*, equating it to a "super-enablement" rule.[96] He stressed the negative impact that this non-statutory rule has not only on future inventions, but also on all biotechnology patents since the late 1970s.[97] It is also a problem to impose a different disclosure standard on biotechnology than on other areas of technology, especially with the technology-neutral language of the Patent Act.[98]

Judge Rader concluded by noting that the Federal Circuit has an obligation to swiftly correct these kinds of errors through an en banc hearing.[99] He also agreed with Judge Bryson's concurrence in that the problem may lie with the entire line of cases beginning with *Ruschig*.[100]

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90. *Id.* (Rader, J., concurring).
91. *Id.* at 1323 (Rader, J., concurring).
92. *Id.* (Rader, J., concurring).
93. *Id.* at 1326 (Rader, J., concurring).
94. *Id.* at 1324 (Rader, J., concurring).
95. *Id.* (Rader, J., concurring).
96. *Id.* at 1325 (Rader, J., concurring).
97. *Id.* (Rader, J., concurring).
98. *Id.* at 1325-26 (Rader, J., concurring).
99. *Id.* at 1327 (Rader, J., concurring).
100. *Id.* (Rader, J., concurring).

2. Judge Bryson

As one of the judges on the *Eli Lilly* panel, Judge Bryson stated that he did not believe that *Eli Lilly* departed from existing case law.[101] He stipulated that perhaps the problem is not with the *Eli Lilly* case, but rather with the whole line of cases going back to *Ruschig*.[102] Judge Bryson suggested that the Federal Circuit address this broader issue en banc.[103]

III. DISCUSSION

Moba continues the Federal Circuit's restriction of the written description requirement that it began in *Enzo* and *Amgen*.[104] One possible next step for the Federal Circuit is to follow Judge Rader's admonishment in *Moba* and correct the errors of the *Eli Lilly* doctrine through an en banc hearing.[105] Although this would solve many of the problems with the written description requirement, an even better solution would be to follow Judge Bryson's suggestion to reconsider the entire line of cases since *Ruschig*.[106] The Federal Circuit should overturn that entire line of cases, which would not only eliminate the free-standing disclosure role of the written description requirement, but also its priority policing role. This approach would remedy all of the problems associated with the separate written description requirement.

A. Returning the Written Description Requirement to Its Pre-*Eli Lilly* Position Would Partially Solve the Problem

Returning the written description requirement to its pre-*Eli Lilly* status means removing the free-standing disclosure requirement created by *Eli Lilly* and returning the written description requirement to its former role of only policing priority issues. This would solve many of the problems created by the requirement.

1. The Written Description Requirement as Applied in Eli Lilly *Is Redundant with the Enablement Requirement*

One of the strongest arguments against the written description requirement's *Eli Lilly* application is that it is unnecessary, because anything

101. *Id.* (Bryson, J., concurring).
102. *Id.* (Bryson, J., concurring).
103. *Id.* (Bryson, J., concurring).
104. *See, e.g.*, Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332 (Fed. Cir. 2003); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).
105. *Moba*, 325 F.3d at 1327 (Rader, J., concurring).
106. *Id.* at 1328 (Bryson, J., concurring).

that would be rejected by the free-standing disclosure role of the written description requirement could also be rejected by the § 112 enablement requirement.[107]

Statutory support of a written description requirement separate from the enablement requirement is quite weak.[108] The wording of the statute indicates that if an invention enables one skilled in the art, then it must, by definition, have an adequate written description.[109] Additionally, the legislative history of § 112 does not contain any indication that written description is a separate requirement from enablement.[110] This poses additional concerns because, as a judicially created doctrine, the written description requirement does not have the benefit of hearings or additional study and debate that usually accompany new statutes or revisions.[111]

In *Moba*, the Federal Circuit implied that a written description that fulfills the enablement requirement usually fulfills the written description requirement.[112] Without overturning *Eli Lilly*, the court distinguished it and stated that "[i]n *Enzo* and *Amgen*, the record showed that the specification that taught one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention."[113] Since making and using an invention is enablement, and convincing an artisan that the inventor possessed the invention is written description, the Federal Circuit indicated that enablement is often the same as written description. In fact, except for *Eli Lilly*, in every recent case before the Federal Circuit,

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107. 35 U.S.C. § 112, ¶ 1 (2000).

108. In *In re Barker*, Chief Judge Markey heartily dissented, arguing that one cannot enable an invention without also adequately describing it. 559 F.2d 588, 594-95 (C.C.P.A. 1977) (Markey, C.J., dissenting). He stated that "[t]he attempt to create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response . . . is mistaken." *Id.* at 594; *see* 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, 61 (2000) (describing the distinction between the written description and enablement requirements as artificial).

109. *See Moba*, 325 F.3d at 1323 (Rader, J., concurring); Limin Zheng, Note, Purdue Pharma L.P. v. Faulding Inc., 17 BERKELEY TECH. L.J. 95, 96 (2002) (stating that "[o]n its face, the statutory purpose of the written description is to allow any person skilled in the art 'to make and use the same'").

110. *See* 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, 470 (1998) (analyzing the legislative history for § 112 and concluding that it does not distinguish between written description and enablement).

111. *See id.*

112. *See Moba*, 325 F.3d at 1321.

113. *Id.*

the court held that each patent that satisfied the enablement requirement also satisfied the free-standing disclosure requirement of written description.[114]

2. *The Written Description Requirement Was Unnecessary in the Cases that Used It*

The biggest problem with *Eli Lilly* is that it created an additional doctrine when an additional doctrine was not necessary. All of the cases between *Eli Lilly* and *Moba* that analyzed the free-standing disclosure requirement either distinguished *Eli Lilly*[115] or made an exception in order to not apply the doctrine.[116]

In *Enzo*, the Federal Circuit held that a nucleotide-by-nucleotide sequence was unnecessary and that publicly depositing biological material is sufficient to fulfill the written description requirement.[117] Similarly, in *Amgen*, the Federal Circuit held that a patentee satisfies the written description requirement if in the knowledge of the art the function is sufficiently correlated to a known structure.[118] It appears as though the Federal Circuit is trying to find any difference that can distinguish the later cases from *Eli Lilly*, thereby limiting the application of the free-standing disclosure requirement.

More importantly, the Federal Circuit could have come to the same conclusion in *Eli Lilly* under the enablement requirement.[119] A patent must enable those skilled in the art to make and use the invention without undue experimentation.[120] The court could have easily ruled that the patent at issue was invalid because it would require undue experimentation to obtain the human insulin DNA. Some of the undue experimentation factors that possibly support this argument are "the quantity of experimentation necessary," "the amount of direction or guidance presented," and "the predictability or unpredictability of the art."[121] Additionally, since the enablement

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114. *See, e.g.*, Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332 (Fed. Cir. 2003); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).

115. *Moba*, 325 F.3d at 1320; *Amgen*, 314 F.3d at 1332.

116. *See Enzo*, 323 F.3d at 966; *see also* Chandra Garry, Note, Enzo Biochem, Inc. v. Gen-Probe, Inc., 18 BERKELEY TECH. L.J. 195 (2003) (providing an overview of *Enzo* and its effect on the written description requirement).

117. *Enzo*, 323 F.3d at 966. If *Enzo* is limited to its facts, then the *Eli Lilly* line of cases is further limited. *See* Garry, *supra* note 116, at 207.

118. *Amgen*, 314 F.3d at 1332.

119. *See Moba*, 325 F.3d at 1324 (Rader, J., concurring).

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

121. *Id.* at 737.

requirement is a question of law, which can be reviewed de novo, as opposed to the written description requirement, which is a question of fact and must be reviewed for clear error, the Federal Circuit has much more control over the direction of the enablement requirement. This is important as the Federal Circuit attempts to create stability and uniformity in patent law.

Furthermore, even though the Federal Circuit removed much of the harm caused by *Eli Lilly* by limiting the case to its facts, it is still important to overturn the holding in *Eli Lilly* to prevent the problems discussed below.

3. *The Free-Standing Disclosure Requirement of the Written Description Requirement Creates Many Additional Problems*

One important problem with the written description requirement is that it makes the litigation process more difficult and confusing than it needs to be.[122] Any time that a patent claims more than the preferred embodiment as described in the specification, the defendant can argue that the patent is invalid for failure to describe the complete invention.[123] Judge Rader argued that this result makes the jury face "the cumbersome task of separating two doctrines for sufficiency of disclosure in a patent."[124] These additional arguments increase the time and expense of both the trial process and the patent prosecution process.[125] Given these increased costs, the written description requirement threatens the balance within the patent system by reducing the incentive to invest in and patent new technologies.

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122. *See Moba*, 325 F.3d at 1322-23 (Rader, J., concurring); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 634 (1998) (maintaining that *Eli Lilly* "results in an unacceptable blurring between the written description and enablement requirements"); Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After* Regents of the University of California v. Eli Lilly & Co., 32 IND. L. REV. 537, 551-52 (1999) (discussing the controversy and uncertainty created by *Eli Lilly*); Zheng, *supra* note 109, at 95 (stating that the Federal Circuit failed to create a workable standard for the written description requirement).

123. *See Moba*, 325 F.3d at 1322-23 (Rader, J., concurring).

124. *Id.* at 1323.

125. *See id.* at 1325 (arguing that the new law may tax a biotechnological patent drafter beyond reasonable limits); Mueller, *supra* note 122, at 651-52 (stating that after *Eli Lilly*, inventors will delay the filing of gene inventions until after they precisely determine the corresponding DNA sequences); Michael Delmas Plimier, Note, Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co., 13 BERKELEY TECH. L.J. 149, 150 (1998) (discussing a reduction in the incentive to invent because of the requirement for a large disclosure, but only narrow protection); Zheng, *supra* note 109, at 95 (arguing that the inconsistent and often over-stringent written description requirement discourages inventors to disclose and seek patent protection).

The *Eli Lilly* rule created additional problems by requiring a different level of disclosure in the biotechnology field than in other fields, even though the Patent Act does not specifically allow this difference.[126] This allows earlier cases to control the perception of different industries and removes any later flexibility.[127] Additionally, the *Eli Lilly* holding and its heightened disclosure rule present potentially severe consequences for existing biotechnology inventions.[128] Judge Rader reasoned that since the new rule appeared in 1997, it jeopardizes the validity of any biotechnology invention back to the late 1970s.[129] Although this may be somewhat of an overstatement, the uncertainty about past inventions along with the uncertainty of the disclosure required in future inventions could dramatically hinder innovation in biotechnology, arguably one of the most important and beneficial technologies to mankind.

One possible argument against eliminating the free-standing disclosure role of the written description requirement is that overturning precedent would destabilize established law. However, this argument is very weak. First, although litigants use the *Eli Lilly* argument for a heightened written description requirement more frequently, the Federal Circuit applied the requirement in only two specific cases before *Moba*, *Eli Lilly* and *Enzo*, and it eventually rejected the application in *Enzo* by creating an exception to the rule.[130] Second, the *Eli Lilly* case itself was a deviation from thirty years of precedent.[131] The case drastically altered the written description requirement as created in *Ruschig*, and therefore, overturning the case would be a return to precedent.

Although eliminating the free-standing disclosure role of the written description requirement would solve many problems, a better solution, which would remove all of the problems created by the requirement, is to eliminate the written description requirement altogether.

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126. *See Moba*, 325 F.3d at 1325-26 (Rader, J., concurring) (stating that the written description requirement creates a technology-specific requirement in a technology-neutral statute); Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002) (noting that the Federal Circuit "has imposed stringent enablement and written description requirements on biotechnology patents that do not show up in other disciplines").

127. *See* Burk & Lemley, *supra* note 126, at 1157.

128. *See Moba*, 325 F.3d at 1325 (Rader, J., concurring); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222 (1998) (arguing that "[t]he decision in Lilly is an unmitigated disaster that if followed, has the potential for causing untold havoc in the biotechnology field").

129. *Moba*, 325 F.3d at 1325 (Rader, J., concurring).

130. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 965 (Fed. Cir. 2002).

131. *See id.* at 980-81; Pitlick, *supra* note 128, at 223.

B. The Separate Written Description Requirement Should Be Eliminated Entirely

Eliminating the written description requirement entirely would discard both the free-standing disclosure and the priority policing roles of the requirement. This would solve all of the problems created by the written description requirement. In support of this solution are the previous arguments against the free-standing disclosure requirement, combined with the following arguments against the priority policing role of the written description requirement.

1. The Written Description Requirement Is Redundant with the New Matter Prohibition

Just as enablement encompasses the free-standing disclosure role of the written description requirement, the new matter prohibition encompasses the priority policing role of the written description requirement. Section 132 of the Patent Act states in part that "[n]o amendment shall introduce new matter into the disclosure of the invention."[132] Anything that would be rejected by the priority policing role of the written description requirement could also be rejected by the § 132 new matter prohibition. If the patentee adds new matter, then they did not possess the invention that includes the new matter at the time of filing.

In fact, both the CCPA and the Federal Circuit specifically stated that when dealing with an amended claim, a rejection under the § 132 new matter prohibition is equivalent to a rejection under the § 112 written description requirement.[133] In *Vas-Cath*, the Federal Circuit acknowledged that the question of adequate support for later-filed claims had also been analyzed under the § 132 new matter doctrine.[134] Precedent makes it clear that the existence of the priority policing role of the written description requirement does not provide any valuable addition to patent law.

2. The Priority Policing Role of the Written Description Requirement Creates Additional Problems

Even though, as Judge Rader suggested, the use of the written description requirement in priority issues by itself probably does no significant harm,[135] it is still important to eliminate the doctrine for other reasons. This is best illustrated by the existence of the *Eli Lilly* free-standing dis-

132. 35 U.S.C. § 132(a) (2000).

133. *Moba*, 325 F.3d at 1319; *In re* Rasmussen, 650 F.2d 1212, 1214 (C.C.P.A. 1981).

134. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

135. *See Moba*, 325 F.3d at 1319.

closure requirement. If a separate written description requirement had not existed in 1997, the district court and then the Federal Circuit would not have been able to spin a second application from it. The confusion and debate concerning *Eli Lilly* would never have started and the problems and concerns discussed in the previous sections would not exist. Even if the Federal Circuit now limits the written description requirement to its priority policing function, courts may find it adaptable for another use in the future, thus creating additional problems.

Another problem with using the written description requirement as a priority policing device is that courts can still misinterpret its application, as illustrated by *Gentry Gallery*.[136] Such a possibility introduces a level of unpredictability for practitioners that would not exist if the Federal Circuit eliminated the doctrine entirely.[137] This situation required the court to repeatedly clarify the holding in *Gentry Gallery*.[138]

The argument that eliminating the written description requirement would harm the precedent created by the *Ruschig* line of cases has some merit. However, the *Ruschig* case itself was a violation of precedent, in that it created a separate written description doctrine on its own. The Federal Circuit thus has a responsibility to correct the mistakes of its precedent court rather than further and expand the mistake.[139] Additionally, since all of the cases dealing with priority could be similarly analyzed under § 132, eliminating the written description requirement would not really be overturning case law. Courts would still perform a similar analysis, only under a different statutory provision.

Since both functions served by the written description requirement are redundant, the existence of the doctrine is unnecessary. Furthermore, since the doctrine creates additional problems, the Federal Circuit should eliminate the written description requirement entirely.[140]

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136. *See* Cynthia M. Lambert, Note, Gentry Gallery *and the Written Description Requirement*, 7 B.U. J. SCI. & TECH. L. 109, 131 (2001) (discussing the alarm among practitioners because of *Gentry Gallery*).

137. *See* Pretty, *supra* note 110, at 480 (discussing the unpredictability created by *Gentry Gallery*).

138. *See, e.g.*, Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1333 (Fed. Cir. 2003).

139. *See Moba*, 325 F.3d at 1327 (Rader, J., concurring).

140. One scholar suggested that the Federal Circuit "resist the narcotic of the written description requirement and redirect their energies towards refining the enablement concept" as a means for fixing the problem. Janis, *supra* note 108, at 107.

IV. CONCLUSION

Moba illustrates the problems associated with the separate written description requirement. The judge-made doctrine does not contribute any additional value to the other patentability requirements. Its effects are redundant with the enablement and new matter requirements of patent law. Additionally, the written description requirement creates confusion and discourages patenting and innovation. The Federal Circuit should dispose of the separate written description requirement entirely.