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Immaterial to Innovation: The Story of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*

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IMMATERIAL TO INNOVATION: THE STORY OF *ARIAD PHARMACEUTICALS, INC. V. ELI LILLY & CO.*

INTRODUCTION

One of the crucial goals of the patent system is to promote technological advancements.[1] This is especially true in the biomedical sciences field as new insights lead to advancements in diagnosis and treatments.[2] This goal of innovation is affected by the "scope" of patents, and many theories have been put forth on the optimal scope.[3]

The written description requirement in federal patent law[4] serves as one possible check on patent scope. A hotly debated topic both in the Federal Circuit[5] and academia,[6] this requirement faced its greatest challenge in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, a case involving a biotechnology patent.[7] After initially holding that the plaintiffs' broad claims were invalid because the written description inadequately supported them,[8] the Federal Circuit vacated the opinion and granted their petition for rehearing en banc.[9] Among the issues that the court wanted to address was "[w]hether 35 U.S.C. § 112, paragraph 1, contains a written description

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1. Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 808 (1988).

2. *See* Chester J. Shiu, *Of Mice and Men: Why an Anticommons Has Not Emerged in the Biotechnology Realm*, 17 TEX. INTELL. PROP. L.J. 413, 442 (2009).

3. *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 987 (2005).

4. 35 U.S.C. § 112 (2006) ("The specification shall contain a written description of the invention . . . ."). *See also* discussion *infra* Part II.B.

5. *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009) (Linn, J., concurring).

6. *See* Shengfeng Chen, Note, *Pathways to Patents: Applying the Written Description Requirement Doctrine to Patents on Biological Pathways*, 30 HASTINGS COMM. & ENT. L.J. 559, 562 (2008) (arguing that the written description doctrine can serve as an effective check against broad patents on research tools); Wenrong Huang, Note, Enzo's *Written Description Requirement: Can It Be An Effective Check Against Overly Broad Biotechnology Claims?*, 16 ALB. L.J. SCI. & TECH. 1, 4 (2006) (arguing that the loosened written description standard after *Enzo* does not provide enough protection for broad patent claims and that the standard should be returned to the way it was articulated in *Eli Lilly*); William C. Mull, Note, *Using the Written Description Requirement to Limit Broad Patent Scope, Allow Competition, and Encourage Innovation in Biotechnology*, 14 HEALTH MATRIX 393, 396 (2004) (arguing that the written description requirement is being correctly applied by the Federal Circuit); Guang Ming Whitley, Note, *A Patent Doctrine without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617, 619 (2004) (asserting that the written restriction requirement gives too much discretionary power to the judges); David A. Gay & Astrid R. Spain, Rochester *Decision Exacerbates the Written Description Threat to Biotechnology Inventors*, I.P. LITIGATOR, May/June 2005, at 6 (criticizing the written description requirement and its negative effect on certainty involving the validity of patents).

7. *Ariad*, 560 F.3d at 1369–71.

8. *Id.* at 1380.

9. Ariad Pharms., Inc. v. Eli Lilly & Co., 595 F.3d 1329, 1330 (Fed. Cir. 2009).

requirement separate from an enablement requirement?"[10] While the rehearing could have eliminated the written description requirement, some commentators' fears over its possible demise[11] have been assuaged because the Federal Circuit decided to uphold it in its recent opinion.[12] However, other commentators' might not be excited about this development,[13] especially since it has been argued that the Court failed to provide much guidance in its opinion.[14]

This note argues that, while some check on patent scope is necessary, biotechnology companies and universities have effective resources and measures in place to promote and enhance innovation, and to adapt to change. Therefore, while *Ariad* might not have adequately clarified how the written description requirement should be applied, the opinion will have little effect on innovation. In the past, companies have developed strategies in the face of exclusive patent rights that have allowed them to continue their research.[15] These strategies will continue to be successful in the future if the companies accept that there is a separate written description requirement and follow the United States Patent and Trademark Office's examining procedure regarding it. Additionally, the enablement requirement on its own is an effective measure to limit the broadest patents like Ariad's, so upholding the written description requirement was not necessary to promote innovation.

Part I of the note gives a brief overview of various theories on patent scope and the effects of claim drafting on innovation. Part II provides a background on the written description requirement, and compares it to the enablement requirement. Part III uses this background to explore *Ariad* and to demonstrate that the enablement requirement is an effective check on the broadest patents. Lastly, Part IV analyzes the strategies utilized by companies and universities that allow them to continue with their research in the face of patents. These inspired maneuvers will prevent innovation from being stymied even in light of the Federal Circuit's continued reliance on the written description requirement.

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10. *Id.*

11. *See* Huang, *supra* note 6; Chen, *supra* note 6.

12. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

13. *See* Gay & Spain, *supra* note 6; Whitley, *supra* note 6.

14. Howard Skaist, *Guest Post: Ariad v. Lily: Choosing to Not Disrupt the Settled Expectations of the Patent Community*, PATENTLY-O (Mar. 28, 2010, 10:46 PM), http://www.patentlyo.com/patent/2010/03/guest-post-ariad-v-lily-choosing-to-not-disrupt-the-settled-expectations-of-the-patent-community.html.

15. John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 322, 324 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (arguing that companies and universities have the ability to license, "invent around" patents, or ignore patents).

I. SCOPE OF PATENTS AND POSSIBLE EFFECTS ON INNOVATION—VARIOUS PERSPECTIVES ON LEGAL POLICY

A primary concern with the written description requirement is its possible effects on innovation.[16] Since one of the purposes of the patent system is "[t]o promote the Progress of Science and useful Arts,"[17] and patent scope in general has been connected with innovation,[18] it is crucial to analyze the effectiveness of this requirement while paying close attention to its possible influence on how technology develops.[19] The claims set out in a patent application determine the scope of the invention and "distinguish the inventor's intellectual property from the surrounding terrain."[20] Legal commentators have postulated many theories on the ideal scope for patents[21]—particularly biotechnology patents, which have been in the limelight of this debate because of the particular importance of biomedical research to society.[22] These theories are explored in detail below.

A. PROSPECT THEORY

Generally, "[p]rospect theory argues for broad patents because, by granting control of a technology, they ensure efficient coordination of innovation."[23] Edmund Kitch, who put forth this theory, relied on important features of the patent system in the development of his argument.[24] First, patent claims are typically broader than what is described in the specification.[25] Second, inventors are typically able to apply for patents "early in the development process."[26] This potentially allows inventions to be patented before they are commercially viable.[27] Since the inventor need only disclose a device that works—and there are statutory bars in place that reward promptness—she is incentivized to file as quickly as possible.[28] While this process may seem counterintuitive, it arguably fulfills one of the

16. Mull, *supra* note 6, at 396 (stressing that the written description requirement enhances innovation).

17. U.S. CONST. art. I, §8, cl. 8; Merges, *supra* note 1, at 808.

18. *See* Adelman, *supra* note 3, at 987.

19. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843 (1990).

20. *Id.* at 844–45.

21. *See* Adelman, *supra* note 3, at 996.

22. David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1680 (2007).

23. Adelman, *supra* note 3, at 996.

24. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267 (1977).

25. *Id.* at 268.

26. *Id.* at 269.

27. *Id.* at 270.

28. *Id.* at 267, 269–70 ("[T]here are rules, such as the priority, time-bar, and patentability rules, which force an early patent application whether or not something of value (and hence a reward) has been found.").

vital roles of the patent system: to disclose what has been invented or discovered "so others have the benefit of the inventor's discovery."[29] Kitch argued that these features allow the patent system to "increase the output from resources used for technological innovation."[30] Believing that a lack of competition was not a problem, and that "unification of control" was important,[31] Kitch appeared to prefer "single-firm domination of a technological prospect."[32]

B. MERGES AND NELSON'S APPROACH

Professors Robert Merges and Richard Nelson believed that competition should play an important role in the patent system and questioned the actual practical effects of unification of control.[33] They emphasized that giving one firm complete control of a given technology would limit rivalry and result in diminished action in that technology's further development.[34] Additionally, they argued that "overly broad rights will preempt too many competitive development efforts."[35] However, they also realized that keeping patent claims "too narrow will not provide enough incentive to develop the asset."[36] Basing their argument on "faster is better," Merges and Nelson theorized that there is probably some connection "between the *speed* with which innovations are introduced and the overall *number* of innovations."[37] The process by which innovations are created varies across industries, and licensing in some of these industries could mitigate the negative effects of broad patents.[38] For example, the Cohen-Boyer patent, which covered a technique to insert a "gene into a host cell," was licensed broadly,[39] preventing any inaction in that technology's development that might have resulted from only one firm having control over the technology.[40] Notwithstanding the mitigation potentials, Merges and Nelson concluded that competition tends "to generate rapid progress and seems a much better social bet than a regime where only one or a few organizations control the development of any given technology."[41]

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29. Merges, *supra* note 1, at 808.
30. Kitch, *supra* note 24, at 265.
31. *Id.* at 285.
32. Merges & Nelson, *supra* note 19, at 871–72.
33. *Id.* at 872.
34. *Id.*
35. *Id.* at 875.
36. *Id.*
37. *Id.* at 878.
38. *Id.* at 880, 883.
39. *Id.* at 906–07. A holder of a broad patent has the ability to prevent too many competitors from entering the field. *Id.* at 875. Therefore, a patentee willing to allow others to develop and improve the invention through licensing has the ability to substantially decrease the possible negative effects the broad patent may have on innovation. *Id.* at 907.
40. *Id.* at 872.
41. *Id.* at 908.

C. ANTICOMMONS AND BIOMEDICAL RESEARCH

A criticism of the above competition model is that it ignores the possibility of the formation of an "anticommons."[42] Michael Heller and Rebecca Eisenberg worried that the patenting of biomedical research might have the unwanted effects of underutilizing scarce resources and limiting innovation.[43] The concern is that if a plethora of patents was owned by too many universities or companies, they would serve as obstacles to future research instead of incentives to engage in risky but potentially rewarding research.[44] Heller and Eisenberg claimed there "has been a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research."[45] The development of specific products might require access to various patents, which, if held by too many competitors could increase transaction costs and unduly delay innovation.[46] A possible unfortunate result of this patent labyrinth is that firms might decide to divert their resources to "less promising projects," or those less beneficial to society.[47]

However, a recent study looking at the biomedical research field determined that an anticommons has not emerged.[48] Since public entities involved in promulgating discoveries largely control the "upstream" research, and certain categories of patents have limited "usefulness," the "fenced in" research domain is much smaller than expected.[49] The author argued that the National Institutes of Health (NIH) leads this public sector and engages in certain activities that prevent the formation of an anticommons.[50] This agency "mandat[es] liberal licensing of any funded discoveries; foster[s] a critical mass of upstream innovators that private for-profit firms dare not sue; and launch[es] initiatives that pre-empt potential anticommons-based business models, often by releasing discoveries and information into the public domain."[51] An example of NIH trying to foster innovation and prevent an anticommons from forming involves a method that creates knockout mice.[52] DuPont developed a method of creating these

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42. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) ("[A] resource is prone to underuse in a 'tragedy of the anticommons' when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.").

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.* at 699.

47. *Id*.

48. Shiu, *supra* note 2, at 416.

49. *Id.* at 415–16.

50. *Id.* at 415.

51. *Id.*

52. *Id.* at 430. Knockout mice have had one or more of their genes modified to stop their expression. *Id.*

mice and licensed it for use in downstream research.[53] However, these licensing agreements contained "reach-through" provisions that appeared to give DuPont ownership of downstream discoveries that depended on the knockout mice.[54] NIH "persuaded DuPont to remove the reach-through provisions from its licensing agreement with *all* universities."[55]

D. BURK AND LEMLEY'S TECHNOLOGY-SPECIFIC APPROACH

Realizing that patent law is applied differently across industries, Dan Burk and Mark Lemley pointed out that the various theories on patent scope might individually apply to one industry better than another.[56] In biotechnology, for example, there are "thousands of patents on DNA sequences that cover specific genes or in some cases fragments of genes" and research in gene therapy that requires the use of multiple patents, which could lead to the formation of an anticommons.[57] Additionally, the "reach-through" licenses previously described have the potential to magnify the problem by further fragmenting rights and preventing downstream researchers from having complete control over their projects.[58] However, in the pharmaceutical industry, the scopes of patents are pretty much "coextensive" with the drugs sold, creating a scenario aligned with prospect theory.[59] The combined voluminous costs of research and development into each new drug and the regulatory oversight by the Food and Drug Administration create a need for strong patent protection that allows for broad patent claims.[60]

The patent system also has "policy levers" in place "permit[ing] patent law to take account of the technology-specific nature of the patent system."[61] The written description requirement is an example of a policy lever that has been applied differently for software patents and biotechnology patents.[62] These policy levers enable courts to influence patent scope.

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53. *Id.* (citation omitted). "Reach-through" provisions appear to give ownership rights of discoveries made as a result of the licenses to the licensor. *Id.*

54. *Id.*

55. *Id.* at 431.

56. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1595 (2003).

57. *Id.* at 1625–26.

58. *Id.* at 1626.

59. *Id.* at 1617.

60. *Id.* at 1616.

61. *Id.* at 1630.

62. *Id.* at 1653–54.

E. ADELMAN'S APPROACH

David Adelman argued that biotechnology patenting has not threatened biomedical innovation as much as other theorists have predicted.[63] Legal commentators have failed to analyze "the interplay between the underlying science and patent policy," and ignored the fact that biotechnology "research opportunities far exceed the capacities of the scientific community," creating "an effectively unbounded, uncongested common resource."[64] Additionally, the underlying biomedical sciences are more complex than the media portrays, creating barriers to innovation.[65] One of these barriers results from an attenuated connection between disease susceptibility and genes.[66] This creates the need for "trial-and-error research" as "identifying useful drug targets and understanding the biology of diseases [is] challenging."[67] As a result, there are many approaches to treating diseases; the complexity of human biology diminishes the chance that a patent anticommons would form.[68]

F. CONCLUSION

The various economic theories on patent scope and its effect on innovation provide a much-needed background to a discussion on written description and enablement. While the scholars who put forth these theories might have reached different conclusions, they all stressed the importance of innovation as a goal of the patent system. This goal can be achieved by using the enablement requirement as a means to invalidate the broadest patents, and allowing corporations and universities to utilize their varying strategies to promote research and innovation.[69]

II. BACKGROUND OF ENABLEMENT AND WRITTEN DESCRIPTION REQUIREMENTS—TWO CHECKS THAT AFFECT PATENT SCOPE

The exhaustive literature regarding the effect of patent scope on innovation shows that some checks against broad claims are necessary. The disclosure requirement checks provided for in 35 U.S.C. § 112 limit "the exclusionary power conferred by a patent."[70] The statute requires that the

> specification . . . 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

63. Adelman, *supra* note 3, at 986.
64. *Id.* at 986–87.
65. *Id.* at 1006, 1008.
66. *Id.* at 1008.
67. *Id.* at 1013.
68. *Id.* at 1014, 1018.
69. Walsh et al., *supra* note 15, at 322.
70. Gay & Spain, *supra* note 6, at 2.

> pertains, or with which it is most nearly connected, to make and use the same . . . .[71]

Courts have gleaned, in part, two requirements from this statutory language: "enablement" and "written description."[72] Together they "set forth what an inventor must give back to the public" in exchange for the exclusive rights of the patent.[73] For enablement, the patentee must include a specification that "teach[es] those in the art to make and use the invention without undue experimentation."[74] For written description, "a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'"[75] This section analyses the enablement and written description requirements with an eye towards critical cases involving biotechnology patents.

A. ENABLEMENT

The enablement requirement was initially applied in cases involving biotechnology patents to "police broad claims."[76] Even though the patent has to include enough information "to enable one of ordinary skill in the art to make and use the invention . . . without undue experimentation," the fact "[t]hat some experimentation is necessary does not constitute a lack of enablement."[77] Additionally, a patent need not necessarily disclose all "embodiments" of the invention.[78] In the case *In re Wands*, the Federal Circuit considered eight factors in analyzing whether undue experimentation was necessary to make and use the invention.[79] These factors are:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[80]

Later cases clarified that courts do not need to analyze "all the *Wands* factors to find a disclosure enabling."[81]

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71. 35 U.S.C. §112 (2006).
72. *See, e.g.*, Whitley, *supra* note 6, at 617.
73. Huang, *supra* note 6, at 5.
74. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (citations omitted).
75. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) (citing Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)).
76. Huang, *supra* note 6, at 6.
77. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1212 (Fed. Cir. 1991).
78. Huang, *supra* note 6, at 6.
79. *In re Wands*, 858 F.2d at 737.
80. *Id.* (citation omitted).
81. *Amgen,* 927 F.2d at 1213.

In *Wands*, the Federal Circuit held that a patent claiming immunoassay methods "for the detection of hepatitis B surface antigen [HBsAg] by using high-affinity monoclonal antibodies of the IgM isotype" was not invalid for lack of an enabling description.[82] This patent disclosed a procedure for producing sufficient amounts of antibodies by creating hybridomas from mice lymphocytes.[83] These hybridomas secrete both IgG and IgM antibodies that bind to HBsAg, even though the method only calls for the IgM isotype.[84] However, after analyzing the various hybridoma cell lines created, the patentees deposited a specific hybridoma cell line that was found to secrete the IgM antibodies.[85] The court decided that undue experimentation was not needed to acquire the antibodies even though, out of the 143 high-binding hybridoma cell lines that were created, only four secreted IgM antibodies that had sufficiently high binding affinity to HBsAg.[86] The patentees analyzed only nine of the hybridomas "beyond the initial screening for HBsAg binding," and it is reasonable to conclude that some of the cell lines not tested produce IgM.[87] Additionally, "[t]here was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known."[88] People of ordinary skill in the art know that they need to analyze multiple cell lines before finding ones that secrete the desired antibody.[89]

Unlike in *Wands,* the Federal Circuit in *Amgen, Inc. v. Chugai Pharmaceuticals Co.* found a patent invalid for lack of enablement.[90] One of the patents at issue claimed "all possible DNA sequences that will encode any polypeptide having an amino acid sequence 'sufficiently duplicative' of EPO to possess the property of increasing production of red blood cells."[91] The court looked to whether the scope of the specification was coextensive with the scope of the claim and found that it was not.[92] Even though the specification need not disclose all embodiments of the invention, the patent at issue only disclosed the process of making EPO and

82. *In re Wands*, 858 F.2d at 733, 740.

83. *Id.* at 734. Hybridomas are created by fusing cancerous myeloma cells with lymphocytes. *Id.* The resulting hybrid cell can "divide and grow indefinitely in cell culture." *Id.*

84. *Id.*

85. *Id.* This cell line "was deposited at the American Type Cultural Collection." *Id.* Written disclosures are sometimes insufficient to enable the public to make and use the invention. *Id.* at 735. When this is the case, one can comply "with the enablement requirement [by depositing] the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues." *Id.* (citation omitted).

86. *Id.* at 738, 740.

87. *Id.* at 739. It is possible to extrapolate that some of the stored cells produce IgM because 4 of the 9 hybridomas tested produce IgM. *Id.*

88. *Id.* at 740.

89. *Id.*

90. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1219 (Fed. Cir. 1991).

91. *Id.* at 1203, 1212 ("Erythropoietin (EPO) is a protein . . . which stimulates the production of red blood cells.").

92. *Id.* at 1214.

a few "analogs."[93] The number of potential EPO analogs greatly dwarfed the ones disclosed.[94] Manipulating the nucleotide sequence that codes for EPO to change just one amino acid in the EPO protein can make "over 3,600 different EPO analogs."[95] Additionally, "over a million different analogs can be made by substituting three amino acids."[96] Therefore, the patent did not disclose "enough sequences to justify grant of the claims sought."[97]

Wands and *Amgen* both provide a framework for how the Federal Circuit has used the enablement requirement to police broad patent claims. The *Wands* patent was upheld because it sufficiently disclosed enough information to allow a person of ordinary skill in the art to make and use the invention.[98] On the other hand, the broad patent claims in *Amgen* were struck down because the possible analogs that fit within the claims overshadow the few disclosed in the specification.[99] Therefore, enablement serves as a possible check on patent scope.

B. THE WRITTEN DESCRIPTION REQUIREMENT

The written description requirement was first used by courts to prevent patentees from amending their applications to include claims not supported by the written description in their original application, thereby preventing them from unfairly benefitting from the earlier filing date.[100] However, the Federal Circuit later decided to use the requirement to limit broad claims in the original application as well.[101]

In *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* the court held that a patent's specification did not sufficiently describe the cDNA claimed.[102] The broadest claim in the patent claimed "'[a] recombinant *plasmid* [that contained] . . . within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a *vertebrate*, which mRNA encodes insulin.'"[103] The patent also had separate claims for "recombinant prokaryotic *microorganisms*" that contained vertebrate, mammalian, and human insulin-encoding cDNA.[104] Even though the patentee tried to claim insulin-encoding cDNA contained in recombinant

93. *Id.* at 1213–14.
94. *Id.* at 1213.
95. *Id.*
96. *Id.*
97. *Id.*
98. *In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988).
99. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).
100. Huang, *supra* note 6, at 7.
101. *See id.* at 10 (citing Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1562 (Fed. Cir. 1997)).
102. *Eli Lilly & Co.*, 119 F.3d at 1566.
103. *Id.* at 1563.
104. *Id.*

organisms in all species within the vertebrate and mammalian genera, the specification only disclosed a description of rat-insulin cDNA, and a method for obtaining the human insulin-encoding cDNA, "along with the amino acid sequences of human insulin."[105] Holding that "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,'" the court found the claims at issue were not adequately described.[106] Though an adequate description of a genus does not require a description of every species in that genus, the nucleotide sequence of rat–insulin cDNA is not by itself a representative sample "of species within the genus." [107] Additionally, "a method of preparing a cDNA or even describing the protein that the cDNA encodes . . . does not necessarily describe the cDNA itself."[108]

The next important case that ultimately narrowed the holding of *Eli Lilly* was *Enzo Biochem, Inc. v. Gen-Probe, Inc.*[109] In *Enzo*, the patent at issue claimed "nucleic acid probes that selectively hybridized" to DNA of *N. gonorrhoeae* over DNA of *N. meningitidis* at a ratio greater than five-to-one.[110] Enzo deposited three nucleic acid probes that "had a selective hybridization ratio of greater than fifty," and the patent specifically referenced these deposited probes.[111] In addition, the specification described "the binding affinity of the claimed nucleotide sequence."[112] However, the Federal Circuit initially held that a functional description alone is inadequate to fulfill the written description requirement because "it does not describe the [nucleic acid] probe itself."[113] Moreover, even though the deposited sequences might have conveyed possession, "possession alone is [not] always sufficient to meet that requirement."[114] Burdening the public by requiring them "to go to a public depository and perform experiments to

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105. *Id.* at 1567.
106. *Id.* at 1566–67.
107. *Id.* at 1568–69.

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id.
108. *Id.* at 1567.
109. *See* Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo II*), 323 F.3d 956 (Fed. Cir. 2002); Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo I*), 285 F.3d 1013 (Fed. Cir. 2002).
110. *Enzo I*, 285 F.3d at 1015–16. *N. gonorrhoeae* is the bacteria that causes gonorrhea. *Id.* at 1015. The detection of this bacterium has been difficult because nucleic acid probes that bind to it also generally bind to *N. meningitidis*, another bacteria. *Id.*
111. *Id.* at 1016.
112. *Id.* at 1017.
113. *Id.* at 1018.
114. *Id.* at 1020.

identify an invention is not consistent with the statutory requirement to describe one's invention in the specification."[115]

After Enzo petitioned the Federal Circuit for rehearing, the court decided to "vacate the prior decision, and reverse the district court's grant of summary judgment that Enzo's claims are invalid for failure to meet the written description requirement."[116] In reaching this conclusion, the court held "that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1."[117] However, since the claims in the patent not only claimed the deposited nucleic acid probes, but also "subsequences and mutated variations" of them, the court reversed and remanded to allow a determination of "whether a person of skill in the art" would understand that the patentee "possessed" this material based on the description and "information obtainable from the deposits."[118] Furthermore, the Federal Circuit concluded that some functional descriptions are adequate for the written description requirement, and ruled that the lower court should determine "whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public."[119]

The Federal Circuit again analyzed the written description requirement in *University of Rochester v. G.D. Searle & Co.,* a case involving a patent for methods of administering "a non-steroidal compound that selectively inhibits activity of the [COX-2] gene product to a human host in need of such treatment."[120] The patent did not disclose any compounds that might have this effect or even hypothesize how they might be produced or obtained.[121] Furthermore, there was a lack of evidence showing that the inventors themselves knew of specific compounds that fit the description in the patent.[122] Indeed, the district court even found that the claims at issue

115. *Id.* at 1021.
116. Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo II*), 323 F.3d 956, 960 (Fed. Cir. 2002).
117. *Id.* at 965.
118. *Id.* at 966.
119. *Id.* at 968.
120. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 917–18 (Fed. Cir. 2004). COX-1 and COX-2 are cyclooxygenases that are involved in various biological pathways in the human body. *Id.* at 917. COX-1 plays a role in protecting the stomach lining while "COX-2 is expressed in response to inflammatory stimuli." *Id.* Scientists believe that aspirin, ibuprofen, and other "[t]raditional non-steroidal anti-inflammatory drugs" act by inhibiting these cyclooxygenases. *Id.* However, since these drugs inhibit both COX-1 and COX-2, they have the unfortunate side effect of causing stomach problems. *Id.* at 918. Therefore, University of Rochester scientists tried to develop a method of only inhibiting COX-2, instead of both enzymes. *Id.*
121. *Id.* at 919.
122. *Id.*

were not enabling.[123] While the Federal Circuit did not consider the enablement issue on appeal, it did affirm the district court's finding that the patent lacked an adequate written description.[124] The patent did

> not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art at the relevant time.[125]

In essence, the disclosure only laid out a potential research plan for finding the necessary compounds and a potential function of the compounds in the event they were found.[126] However, in reaching this conclusion, the court argued that the written description requirement has been recognized for a long time, in part because past cases invalidated claims that were broader than the disclosure.[127] While this may be true, the Federal Circuit also invalidated broad claims that were not coextensive with the disclosures on enablement grounds.[128]

C. CONFUSION SETS IN

The written description requirement has been confusingly applied over the years.[129] At first, *Eli Lilly* required a specific accounting of the invention's scientific characteristics in order to satisfy the written description requirement.[130] However, *Enzo* appeared to loosen this requirement, and held that some functional descriptions might satisfy written description.[131] Additionally, references to a deposit in the specification are now sufficient.[132] *Rochester*, on the other hand, "took a no-drug, no patent approach."[133] Indeed, "[t]he court's invention of a separate written description requirement has 'create[d] confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude.'"[134] As a result, there had been uncertainty in how patent-related business should be conducted.[135]

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123. *Id.*
124. *Id.* at 929–30.
125. *Id.* at 929 (citation omitted).
126. *Id.* at 926–27.
127. *See id.* at 923 (citing *In re* Moore, 155 F.2d 379, 382 (C.C.P.A. 1946)).
128. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).
129. Chen, *supra* note 6, at 572.
130. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).
131. Enzo Biochem, Inc. v. Gen-Probe Inc. (*Enzo II*), 323 F.3d 956, 968 (Fed. Cir. 2002).
132. *Id.* at 965.
133. Chen, *supra* note 6, at 572.
134. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1381 (Fed. Cir. 2009) (Linn, J., concurring) (citing Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1326 (Fed. Cir. 2004) (Linn, J., dissenting from denial of rehearing en banc)).
135. *Id.*

III. AN ANALYSIS OF THE FEDERAL CIRCUIT'S RECENT DECISION—*ARIAD PHARMACEUTICALS, INC. V. ELI LILLY & COMPANY*

Confusion over the written description requirement led the Federal Circuit to grant en banc review of whether written description is a separate requirement from enablement.[136] This portion of the note will provide an in-depth look at *Ariad* and why the patent at issue is not enabling. The analysis will demonstrate that enablement—on its own without an independent written description requirement—is a sufficiently effective check against the broadest patents. However, since the Federal Circuit held that the written description is a separate requirement, this note will also analyze the rehearing opinion and whether it clarifies how to apply the requirement.

A. FACTUAL AND PROCEDURAL HISTORY

The patent at issue in *Ariad* involves a method for regulating the activity of the transcription factor NF-κB.[137] While NF-κB is an essential molecule that plays a crucial role in activating genes that help combat deleterious extracellular influences, it also "can be harmful in excess."[138] Realizing that reducing NF-κB activity might mitigate detrimental disease symptoms, the inventors filed a patent that claimed a method for "reducing NF-κB activity."[139] The specification of the patent only disclosed "three classes of molecules potentially capable of reducing NF-κB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules."[140] After the patent was issued on June 25, 2002, the plaintiffs sued Eli Lilly for infringement, and the jury found the patent enabling with an adequate written description.[141] Eli Lilly appealed.[142]

B. THE MAJORITY OPINION AND THE CONCURRING OPINION

The majority found that the claims at issue were invalid because the specification's written description was inadequate.[143] Central to this holding was the fact that Ariad did not disclose any molecule "capable of reducing NF-κB activity."[144] Even though Ariad only claimed the method of NF-κB reduction, the written description requirement is only satisfied with "adequate description of the molecules that Ariad admits are necessary to

136. Ariad Pharms., Inc. v. Eli Lilly & Co., 595 F.3d 1329, 1330 (Fed. Cir. 2009).
137. *Ariad*, 560 F.3d at 1369–70. Transcription factors are molecules that regulate the expression of genes. *Id.* at 1369.
138. *Id.* at 1369.
139. *Id.* at 1370.
140. *Id.* at 1373.
141. *Id.* at 1369–70.
142. *Id.* at 1371.
143. *Id.* at 1380.
144. *Id.* at 1373.

perform the methods."[145] While Ariad did disclose three hypothetical classes of molecules that might have this desired effect, the overall specification was insufficient.[146] Most of the information concerning the sole "specific inhibitor" example given was gleaned from a figure not disclosed until after the effective filing date of the application.[147] Therefore, it could not "offer substantial evidence for the jury determination."[148] Additionally, the rest of the evidence constituted "a vague functional description and an invitation for further research [which did] not constitute written disclosure of a specific inhibitor."[149] Moreover, the specification provided no examples of dominantly interfering molecules.[150] Even though the third class of molecules—"decoy molecules"—was also posed hypothetically, the specification included examples of their structures via specific DNA sequences.[151] While the court held that this disclosure was an adequate description of the decoy molecules, it also held that the specification did not "adequately describ[e the use of] those molecules to reduce NF-κB activity."[152] It concluded that the disclosure, which merely stated that NF-κB "would bind the decoy" and lead to "negative regulation," did not provide a "descriptive link between the table of decoy molecules and reducing NF-κB activity."[153] Therefore, in light of the fact that "[t]he state of the art at the time of filing was primitive and uncertain," the claims at issue were held invalid, "leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure."[154]

In the concurring opinion, Judge Linn argued that there is no separate written description requirement.[155] This additional requirement, Judge Linn continued, has had the unfortunate effect of creating confusion and uncertainty in the law.[156] Moreover, the concurrence observed that deciding the case on written description grounds prevented the court from reviewing an important enablement issue.[157] Ariad broadly claimed "any method for reducing NF-κB activity in cells, including both known and unknown methods."[158] Judge Linn mentioned that the court has not "addressed [the enablement] requirement in relation to the type of claims at issue here—that

145. *Id.* at 1374.
146. *Id.* at 1374–76.
147. *Id.* at 1374.
148. *Id.*
149. *Id.*
150. *Id.* at 1375.
151. *Id.*
152. *Id.*
153. *Id.*
154. *Id.* at 1376.
155. *Id.* at 1381 (Linn, J., concurring).
156. *Id.*
157. *Id.*
158. *Id.*

is, claims written broadly enough to cover any method for achieving a particular result."[159] Judge Linn concluded that these broad claims might be per se invalid because "the specification cannot enable unknown methods."[160]

C. THE COURT SHOULD HAVE DECIDED THE CASE ON ENABLEMENT GROUNDS

Judge Linn made a valid point when arguing that Ariad's broad method claims might be invalid for lack of enablement. Past Federal Circuit precedent clearly shows that the court has held similarly broad claims invalid for failing to enable. Because narrower claims have been struck down on enablement grounds and broad method claims are problematic,[161] the facts of *Ariad* suggest that the enablement requirement can serve as an effective check against the broadest patents. Moreover, if the written description requirement still serves a purpose, it is to limit claims that might happen to survive an enablement analysis. The Federal Circuit has made a habit of deciding cases on written description grounds without reaching an enablement analysis.[162] Therefore, the Federal Circuit should not even reach an analysis of a patent's written description until it decides whether a patent is enabling. However, even in the recent rehearing decision, the Federal Circuit failed to conduct an enablement analysis of the Ariad patent.[163]

The *Ariad* patent does not include enough information "to enable one of ordinary skill in the art to make and use the invention . . . without undue experimentation."[164] While the patent in *Amgen* was struck down even though it sufficiently disclosed some embodiments of the invention,[165] the patent in *Ariad* did not sufficiently disclose any embodiments of the claimed invention.[166] Undue experimentation would be needed to find a way to make and use the invention because, of the three hypothetical classes of molecules posed, no molecules were disclosed as of the effective date of filing for two of the classes, and the method to use molecules of the third class was vague at best.[167] Unlike the material in *Wands*,[168] no

159. *Id.*
160. *Id.*
161. *Id.*
162. *See id.*; Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929–30 (Fed. Cir. 2004) ("In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further."); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997) ("Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin . . . .").
163. *See* discussion *infra* Part III.D.
164. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1212 (Fed. Cir. 1991).
165. *Id.* at 1213–14.
166. *Ariad*, 560 F.3d at 1376.
167. *Id.* at 1374–76.
168. *See In re* Wands, 858 F.2d 731, 734–35 (Fed. Cir. 1988).

molecules were deposited in *Ariad*. Lastly, the Federal Circuit in *Ariad* held that the "art at the time of filing" was nascent and untested,[169] unlike the state of the art in *Wands*. In the latter case, the court held that the skill in the art as of the filing date was high enough so that the techniques required to utilize the invention were recognized in the field.[170] Therefore, the Federal Circuit would also likely hold the claims at issue in *Ariad* invalid for lack of enablement. As a result, the enablement requirement as it stands now serves as an effective control measure for these broadest patents.

D. THE REHEARING DECISION

Even though the Federal Circuit decided to rehear *Ariad*, and even though enablement serves as an effective check against broad patents, the Federal Circuit ultimately decided that the written description is indeed a separate requirement.[171] Relying, in part, on statutory interpretation, the court argued that "[i]f Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently."[172] After it agreed that written description is a separate requirement, the court looked to how it should be applied. The court affirmed that the description in the specification "must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'"[173] To satisfy this test, courts should determine "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."[174]

However, the court admitted that "[t]he term 'possession' . . . has never been very enlightening."[175] In an attempt to clarify how "possession" should be interpreted, the court specified that the purpose of the written description requirement is disclosure.[176] Therefore, the standard "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art."[177] This inquiry into possession is a question of fact, and so may vary depending on the facts of each case.[178] As a result, the court declined "to predict and adjudicate all the factual scenarios to which the written description requirement could be applied."[179]

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169. *Ariad*, 560 F.3d at 1376.
170. *In re Wands*, 858 F.2d at 740.
171. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d. 1336, 1354 (Fed. Cir. 2010).
172. *Id.* at 1344.
173. *Id.* at 1351 (quoting Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).
174. *Id.*
175. *Id.*
176. *Id.*
177. *Id.*
178. *Id.*
179. *Id.*

It also refused to provide any bright line rules.[180] Instead, it set out certain principles that have been applied in the past; for instance, the court reiterated that "a [mere] constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement."[181] Moreover, actual "possession" alone is insufficient because possession must be demonstrated by the specification.[182] And, while the court admitted that "written description and enablement often rise and fall together," it also argued that the written description requirement is needed for instances when claims cannot be described because they cannot be invented, but "do not require undue experimentation to make and use."[183] Lastly, the court recited its precedent when describing how to apply the written description requirement.[184]

With this decision, it has been argued that the Federal Circuit did not provide much direction in how the written description requirement should be applied.[185] Indeed, for the most part, it simply rehashed prior precedent without clarification. The decision, therefore, is likely to have less of an impact[186] on the patent landscape than many had hoped or thought, especially as the court explicitly acknowledged that the written description and enablement requirements are generally either both met or not met together. Therefore universities and companies will, for the most part, draft successful patents even if they only follow enablement alone. However, their licensing and litigation strategies should help them adapt to the now concrete written description requirement as well.

IV. UNIVERSITY AND CORPORATE STRATEGIES THAT LIMIT PATENT EFFECTS ON INNOVATION

The fact that broad patents like the one in *Ariad* could be kept in check with the enablement requirement—and that universities and companies have developed strategies that effectively permit their continued research[187]—highlights the point that a heightened written description requirement is not a necessary control mechanism for innovation. However, even with this requirement, the strategies will prevent innovation from

180. *Id.*
181. *Id.* at 1352 (citing Falko-Gunter Falkner v. Inglis, 448 F.3d 1357. 1366–67 (Fed. Cir. 2006)).
182. *Id.*
183. *Id.*
184. *Id.* at 1353.
185. Skaist, *supra* note 14.
186. Kevin E. Collins, *An Initial Comment on* Ariad*: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PATENT L.J. 60, 61, *available at* http://www.patentlyo.com/files/collins.ariad.pdf.
187. Walsh et al., *supra* note 15, at 322.

being stymied.[188] This section of the note analyzes some of these strategies and shows that many of the concerns over patents' effect on innovation have not come to pass.[189] Additionally, it will present examples of how these approaches attempt to resolve potential problems created by both broad and narrow patents. Lastly, the section will conclude with a suggestion for the best method of maintaining innovation in biomedical research.

A recent study analyzed corporate and university strategies that have been used to limit the impediment of biomedical innovation by conducting "interviews with personnel at biotechnology and pharmaceutical firms and universities in considering the effects of research tool patents on industrial or academic biomedical research."[190] Research tools in this context "include any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing disease."[191] The patent at issue in *Ariad* is an example of a research tool patent because it is for potential molecules "capable of reducing NF-κB activity."[192] The goal of reducing this transcription factor was to mitigate symptoms of diseases.[193] Therefore, the patent at issue in *Ariad* and others are relevant to this discussion.

Two situations may occur in the biomedical field that could impede innovation. First, an anticommons may form in the biomedical field.[194] As described earlier,[195] an anticommons forms when there are "multiple patents covering different components of some product, its method of manufacture, or inputs into the process through which it is discovered."[196] However, biomedical research efforts may also be prevented and innovation impeded when there are instead relatively few patents on "key tool[s] or discover[ies]."[197] When these broad patents are not shared, they "may limit the use of these discoveries in subsequent discovery and consequently limit the pace of innovation."[198] The *Ariad* patent is such a broad patent because it potentially includes all molecules that are capable of lowering NF-κB activity.[199] However, even though *Ariad* is an example of a potentially

188. *Id.* at 322–23 (asserting that many companies liberally and broadly license their patents in the belief that "by giving several firms a nonexclusive license they increase the chances that one will discover a useful drug").

189. *Id.* at 324.

190. *Id.* at 287. The authors of this study conducted seventy interviews with various employees at firms and universities to determine the effect of patents on innovation. *Id.*

191. *Id.*

192. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1373 (Fed. Cir. 2009).

193. *Id.* at 1370.

194. Walsh et al., *supra* note 15, at 293–96.

195. *See supra* notes 42–47 and accompanying text.

196. Walsh et al., *supra* note 15, at 293.

197. *Id.* at 305.

198. *Id.* at 288.

199. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1373 (Fed. Cir. 2009).

problematic patent, there is evidence that innovation has not been stymied by the formation of an anticommons.

There has been little to no evidence that an anticommons has formed.[200] While the amount of biotechnology patents increased rapidly from 1985 to 2000, and with it the number of licenses needed for individual projects—creating an ever-increasing complexity in the patent landscape—many researchers believe that the costs are manageable and worth the potential for "downstream discoveries."[201] First, there has been almost no "breakdown in negotiations over rights that lead to an R&D project's cessation."[202] The majority of the time researchers were able to obtain the necessary patent rights for their projects through licensing.[203] Second, even though hundreds of patents are typically considered for a biomedical project initially, relatively few—if any—of those will end up needing to be licensed.[204] While the resulting licensing fees might still be high, they usually result in a loss for research projects, and the potential for high royalty fees rarely stops such projects from continuing.[205] The costs are considered to "be within reason largely because the productivity gains conferred by the licensed research tools were thought to be worth the price."[206] Additionally, these costs are often discounted for government and university researchers.[207] Therefore, while several narrow patents that cover a field may lead to higher licensing costs, innovation does not appear unreasonably impeded.

Moreover, there does not seem to be an unchecked problem with exclusive licensing and broad patents.[208] The concern, discussed earlier, "is that restrictive assertion or licensing of patents on research tools—especially foundational upstream discoveries upon which subsequent research must build . . . may undermine the advance of biomedical research."[209] These research tools were originally placed in the public

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200. Walsh et al., *supra* note 15, at 297–305.

201. *Id.* at 293, 301. 2,000 biotechnology patents were issued in 1985, while over 13,000 have been issued in 2000. *Id.* at 293.

202. *Id.* at 298.

203. *Id.* ("Of the 55 respondents who addressed this issue . . . , 54 could not point to a specific project stopped because of difficulties in getting agreement from multiple IP owners.").

204. *Id.* at 294.

> [Respondents] said that there may be a large number of patents to consider initially—sometimes in the hundreds, and that this number is surely larger than in the past. However, respondents then went on to say that in practice there may be, in a complicated case, about 6-12 that they have to seriously address, but that more typically the number was zero.

Id.

205. *Id.* at 299–300.

206. *Id.* at 301.

207. *Id.* at 302 ("Celera, for example, licenses their databases to firms for about $5 million to $15 million per year and to university labs for about $7,500 to $15,000.").

208. *Id.* at 322–23.

209. *Id.* at 296.

domain, but they recently have been patented more and more.[210] However, while there are examples of cases where broadly interpreted patents on targets "prevent[ed] others from engaging in the subsequent development needed to bring the patented technology to market," it appears to make economic sense to broadly license these patents.[211] If these broad patents on targets are "exploited on an exclusive basis," a social cost results that may be detrimental to firms.[212] For example, various pharmaceutical firms have "libraries" of drugs that might affect the patented targets.[213] These libraries are highly differentiated across the firms, so the odds of finding an ideal drug for the target increase with the availability of the license.[214] However, the capabilities of the firms obviously depend on their size, and the strategies vary.[215] Additionally, firms still complain about the patentees' exclusive use of research tools—especially of "'targets,' which refers to any cell receptor, enzyme, or other protein implicated in a disease, thus representing a promising locus for drug intervention."[216] Notwithstanding the concerns regarding broad patents on research tools, "the problem was generally considered to be manageable" because "of private strategies and institutional responses that limited the adverse effects of the changing IP landscape."[217]

Two reasons innovation has not been unreasonably impeded in the biomedical field are the strategies developed by firms and universities and their ability to adapt. For one thing, it is relatively easy to contract and license out patents.[218] Many companies have also decided to license targets liberally and broadly because it enhances the probability of discovering useful drugs.[219] However, when licensing is not the optimal strategy, universities and firms can also "invent around" patents, ignore patents, create public databases, or challenge patents in court.[220] Therefore, even with the written description requirement now firmly in place, universities and firms already have a portfolio of strategies to adapt and the ability to develop more.

Firms and universities usually have the ability to "invent around" patents.[221] This is even true in the face of broad patents on targets because, even in those cases, it is unlikely that they would "confer exclusive rights to

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210. *Id.*
211. *Id.* at 307–11.
212. *Id.* at 310–11.
213. *Id.* at 311.
214. *See id.*
215. *Id.* ("[M]uch of the university licensing of biomedical innovations to small firms is on an exclusive basis.").
216. *Id.* at 310.
217. *Id.* at 322.
218. *Id.*
219. *Id.* at 323.
220. *Id.* at 323–24.
221. *Id.* at 323.

working on a disease."[222] Many diseases—including cancer, AIDS, and heart disease—are very complex and multiple proteins, multiple receptors, and multiple drugs might work and need to be tested.[223] The *Ariad* patent, while overly broad, was only for molecules that inhibit NF-κB. There are likely other transcription factors that are involved in the expression of disease symptoms. Therefore, even the *Ariad* patent would have been unlikely to confer exclusive rights. Moreover, the enablement requirement is perfectly capable of limiting similarly broad patents without the written description requirement.

If inventing around patents is not successful, another option is to ignore patents on upstream inventions and soldier on with the research without them.[224] It is particularly hard to ascertain whether research tool patents are being infringed, so many firms and universities try their hand at remaining under the radar.[225] Researchers, especially those at universities, "have a reputation for routinely ignoring IP rights in the course of their research."[226] However, they are usually shielded from lawsuits because many firms do not want to enforce their patents against them.[227] Damages are likely to be comparatively low and the probability of resultant bad publicity high.[228] Additionally, many firms want to develop and maintain friendly relationships with universities to promote the sharing of information.[229] To encourage this trusting environment, firms sometimes give out research tools to universities for free.[230] These universities, as a rule, also "do not assert their rights against one another."[231] The fact that firms do not typically enforce their rights against universities and sometimes "feel that it is not worth their while to assert their patents on all other firms that might be infringing,"[232] shows that they might be taking strategic risks. "[In most instances] the cost of pursuing these cases greatly outweighs their value."[233] Therefore, firms will now more likely tend to avoid lawsuits to prevent their patents from being held invalid for failure to have adequate written descriptions.

The complex strategies utilized by universities and corporations, as shown, are more than enough to overcome the potentially additional burden of the written description requirement, especially since they already had to

222. *Id.* at 324.
223. *See id.*
224. *Id.*
225. *Id.*
226. *Id.*
227. *Id.* at 325.
228. *Id.*
229. *Id.*
230. *Id.* at 326.
231. *Id.* at 327.
232. *Id.* at 328.
233. *Id.*

adapt to this requirement in the past. Now that the written description requirement has been more firmly embedded into patent law, it will serve as merely one factor in an analysis of whether to use licensing or litigation as protective measures. Indeed, "[m]aximising the value of patents requires careful planning and continual diligence."[234] In order for universities and firms to effectively manage their patents, they need to carefully assess "the costs, risks and rewards of licensing and litigation options."[235] Some patents may not be worth litigation expenses, while others may not be right for licensing purposes.[236]

Licensing might be the best strategy for patent owners because it is "generally less expensive then pursuing litigation" and "can also lead to significant market expansion and generate new sources of revenue for the patent owner through the business relationship."[237] Licensing is more predictable, and since it is cooperative in nature, it might enhance a business' reputation more so than litigation.[238] However, as licensing is, in a sense, a compromise, "the patent holder must cede some value of the patented technology to the licensee."[239] This is why litigation might occasionally prove a better strategy to enforce one's patent rights. With litigation, a patent holder "seeks to maintain exclusive control, avoiding the risks of lost commercial exploitation or tarnishment of the property."[240] On the other hand, the significant costs and uncertainty make litigation a weaker strategy in many situations.[241] Indeed, litigation could cost up to ten million dollars.[242] Corporations and universities should rely on the *Ariad* rehearing when deciding on what strategy to utilize.

CONCLUSION

This note has discussed why innovation will be unaffected by the Federal Circuit's decision to uphold the written description requirement. Corporations and universities already have several strategies in place to prevent innovation from being impeded, and these strategies help limit the fallout from anticommons formations, broad patents, and exclusive licensing.[243] Furthermore, the enablement requirement already serves as an effective check on the broadest and most unfair patents, like the one in

234. Bruce C. Haas & Christopher V. Beckman, *United States Patent Enforcement: Licensing and Litigation Considerations*, BUILDING AND ENFORCING INTELLECTUAL PROPERTY VALUE 68, 68 (2008), *available at* http://www.buildingipvalue.com/08_USA/68-71fitzpatrick.pdf.
235. *Id.*
236. *Id.*
237. *Id.* at 69.
238. *Id.*
239. *Id.*
240. *Id.* at 70.
241. *Id.* at 70–71.
242. Walsh et al., *supra* note 15, at 315.
243. *Id.* at 322, 331.

Ariad. Therefore, the written description requirement will not have a significant impact on how universities and firms do business. If anything, it will only serve as one factor in an analysis of what strategies to utilize.

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