ENCOURAGING FURTHER INNOVATION: *ARIAD* V. *ELI LILLY* AND THE WRITTEN DESCRIPTION REQUIREMENT

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I. INTRODUCTION

In 1790, Congress passed the first American patent statute, which contained a written description requirement for all patents.[1] The Patent Act was subsequently amended,[2] yet the written

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[1] Patent Act of 1790, ch. 7, §§ 1–7, 1 Stat. 109. *see infra* note 15; Janice C. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 618 (1998); *see also* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1343 (Fed. Cir. 2010) (en banc). The Act stated:

> The grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, [if necessary,] of the thing or things, by him or them invented or discovered, and described as aforesaid, in said patents; which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, *but also* to enable a workman or other person skilled in the art . . . to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term.

Patent Act of 1790, ch. 7, § 2, 1 Stat. at 110–11 (emphasis added). The second part of the statute following "but also" articulates a separate "enablement requirement." *Id.*

[2] Patent Act of 1793, ch. 11, § 3, 1 Stat. 318, 321–22 ("Every inventor, before he can receive a patent shall . . . deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same."); Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 ("[H]e shall deliver a written description of his invention or discover, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound,

description requirement is still included in the most up-to-date patent law statute.[3] Existing in nearly the same form for over 200 years, the written description requirement is an essential element to patent law. Recently, however, the purpose and scope of this foundational patent requirement has become a subject of heated debate within the patent law community.[4] Highlighted by the Court of Appeals for the Federal Circuit's (CAFC) controversial decision in the 2010 case *Ariad Pharmaceuticals v. Eli Lilly & Co.*,[5] much of the debate focuses on the CAFC's recent application of the written description requirement to emerging biotechnology inventions,[6] and, as a result, on the potential impact on biotechnology innovation and on innovation within the patent system as a whole.[7]

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and use the same."); Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201; Patent Act of 1952, ch. 950, 66 Stat. 752.

[3] 35 U.S.C. § 112 (2006) ("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 . . . .").

[4] *See, e.g.*, *Ariad*, 598 F.3d at 1361–67 (Radar, J., dissenting); Anascape, Ltd., v. Nintendo of America, Inc., 601 F.3d 1333, 1341–42 (Fed. Cir. 2010) (Gajarsa, J., concurring); Brief for Amgen, Inc. as Amicus Curiae Supporting Respondent at 5–7, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280); Brief for Microsoft Co. as Amicus Curiae Supporting Respondent at 2–4, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280); Brief for Regents of the University of California et al. as Amici Curiae Supporting Petitioner at 8–10, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280) [hereinafter *Regents Amicus Brief*]; Brief for the United States as Amicus Curiae Supporting Respondent at 1–2, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280); Chris Holman, Ariad v. Eli Lilly*: Pragmatism Prevails over Coherent Patent Doctrine*, HOLMAN'S BIOTECH IP BLOG (Mar. 23, 2010, 11:17 A.M.), http://holmansbiotechipblog.blogspot.com/2010/03/ariad-v-eli-lilly-pragmatism-prevails.html.

[5] *Ariad*, 598 F.3d 1336 (majority opinion).

[6] *See, e.g.*, Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J. L. & TECH. 267 (2000).

[7] *See Ariad*, 598 F.3d at 1359 (Newman, J., concurring); *Regents Amicus Brief*, *supra* note 4, at 9–10; Warren Woessner, Ariad v. Lilly *Comes Down (On Us)—Judge Lourie Rules!*, PATENTS4LIFE BLOG (March 23, 2010), http://www.patents4life.com/2010/03/ariad-v-lilly-comes-down-on-us-%E2%80%93-judge-lourie-rules/. *See generally* Cantor, *supra* note 6 (discussing how the trend of using the written description and enablement requirements to limit biotechnology patents in particular); David Kelly, *The Federal Circuit Transforms the Written Description into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents*, 13 ALB. L.J. SCI. & TECH. 249 (2002) (discussing how the current application of the written description requirement could create special standards for the biotechnology industry and how this could negatively impact biotechnology innovation); Shraddha A. Upadhyaya, *The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims*, 4 MINN.

The *Ariad* case was brought by, among others, Ariad Pharmaceuticals, Inc. and the Massachusetts Institute of Technology (collectively, "Ariad"), who alleged infringement of their patent by Eli Lilly & Company ("Lilly").[8] Ariad's invention was a method that stopped a specific protein from binding to human cells in harmful amounts.[9] The court invalidated a number of Ariad's claims under the written description requirement because Ariad, while describing a useful method, failed to describe a specific agent that could accomplish the claimed method.[10] Essentially, Ariad did not possess every invention it claimed on the day it filed for a patent.[11] Contesting the court's use of the written description requirement, Ariad argued that the requirement is satisfied as long as an inventor merely identifies his invention and through this identification "enable[s] one of skill in the art to make and use the claimed invention."[12]

Analyzing the current written description statute, 35 U.S.C. § 112,[13] the court affirmed the long-held notion that the first paragraph of § 112 included two separate patent requirements: the written

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INTELL. PROP. REV. 65 (2002) (discussing how the current application of the written description requirement departs from precedent, and how this uncertainty might pose problems for the future of biotechnology innovation).

[8] *Ariad*, 598 F.3d at 1340. Other parties include the Whitehead Institute for Biomedical Research and Harvard University. *Id.* at 1336.

[9] *Id.* at 1341.

[10] *Id.* at 1352–53. In fact, through the collaborative work of the plaintiffs, the NF-[K]B protein was discovered in the mid-1980s. Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106, 112 (D. Mass. 2007). During the prosecution of their initial claims, the plaintiffs were consistently rejected by the Patent Office because they failed to describe all necessary "agents" that would have the desired result of inhibiting NF-[K]B. *Id.* at 112–13. The primary reason for rejection was the plaintiff's failure to satisfy the enablement requirement of § 112. *Id.* The broad claims that the Patent Office eventually approved removed the description of any "agent." *Id.* at 113. After the *Ariad* decision, it seems that it would have been equally appropriate to invalidate the original claims under the written description requirement for failure to adequately show possession of the plaintiffs' claimed genus. *See infra* notes 234–48 and accompanying text.

[11] *Ariad*, 598 F.3d at 1352.

[12] *Id.* at 1342, 1344.

[13] The written description statute 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.

35 U.S.C. § 112 (2006).

description requirement and the enablement requirement.[14] To satisfy the enablement requirement, a patent applicant must, through the patent specification, "teach those [of ordinary skill] in the art to make and use the invention without undue experimentation."[15] To satisfy the written description requirement, a patent applicant must, through the patent specification, allow a person of ordinary skill in the art to see that the inventor has "possession" of the claimed invention.[16] These two requirements have always been intertwined in the same paragraph of the patent statute.[17] They both encourage full disclosure of a patentee's invention in exchange for the exclusive rights granted by a patent.[18] The enablement requirement, however, might be satisfied if an inventor, aware of a general result, structures his claims to include a broad range of inventions that he may or may not have possessed at the time he filed for a patent.[19] Rapid advances and shifting norms in a particular field allow an inventor to anticipate changes and make claims based on mere speculation, which makes any inquiry into what the inventor intended to teach confusing and unclear. The written description requirement avoids this pitfall by simply establishing—based on specific examples in the specification—whether or not the inventor actually possessed the full scope of his claimed invention at the time of filing.

Ariad's application of the written description requirement not only fits into the patent system as a whole, but also conforms to Congress's overall policy goals over the last thirty years with regard to biotechnology innovation.[20] The current patent system is a result of

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[14] *Ariad*, 598 F.3d at 1344 ("We . . . hold that § 112, first paragraph, contains two separate description requirements: a "written description [i] of the invention *and* [ii] of the manner and process of making and using [the invention]." (internal quotation marks omitted)).

[15] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1998); *see also* 35 U.S.C. § 112 (2006); Cantor, *supra* note 6, at 283. The enablement requirement is also found in the 1790 patent statute alongside the written description requirement. *See* sources cited *supra* note 2. A patent is enabled as long as a person of ordinary skill in the art can make and use the invention. *See* Mueller, *supra* note 1, at 622.

[16] *Ariad*, 598 F.3d at 1351.

[17] *See* 35 U.S.C. § 112 (2006); *supra* notes 1–3 and accompanying text.

[18] *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991); Cantor, *supra* note 6, at 268.

[19] *See infra* Part II.D.

[20] Recent publications provide additional insight into the written description requirement's place in the overall goals of the patent system, and how *Ariad* maintains the "quid pro quo" of the patent system to reward exclusive rights for adequate and appropriate disclosure of an invention. *See, e.g.*, Jacob Adam Schroeder, *Written Description: Protecting the Quid Pro Quo Since 1973*, 21 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 63 (2010). In his article, Professor Schroeder details

the constitutional mandate for Congress to "promote the Progress of Science and useful Arts."[21] The system provides a monetary incentive to inventors by granting them exclusive rights to their inventions.[22] To earn these rights, an inventor must satisfy a number of requirements, including written description.[23] To that end, the patent system ensures that an inventor has a legitimate right to his claimed invention (i.e., that he actually invented it) and provides members of the public with notice of the invention so that they may use the inventor's knowledge for further innovation.[24] Using these general goals as a backdrop, Congress has targeted the biotechnology industry by providing further incentives designed to fuel biotechnology innovation. The Bayh-Dole and Hatch-Waxman Acts signify two major efforts by Congress to stimulate U.S. biotechnology innovation: the former by providing patent protection to entities that perform the majority of the country's biotechnology research,[25] and the latter by, among other things, providing an experimental use exception against infringement suits for those performing certain targeted biotechnology research.[26]

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the primary stances of the current Federal Circuit judges with regard to the scope and purpose of the written description requirement. *Id.* at 84–89. The article also includes a look at how the requirement has been applied at different times over the last 200 years. *Id.* at 72–84. *But see* Krista Stone, *Written Description After* Ariad v. Eli Lilly*: 35 U.S.C. § 112's Third Wheel*, 11 J. HIGH TECH. L. 191 (2011) (arguing that the CAFC in *Ariad* problematically upset the settled expectations of inventors, particularly those in the biotechnology, and, by focusing on the written description requirement, missed an opportunity to strengthen enablement case law).

[21] U.S. CONST., art. I, § 8, cl. 8.

[22] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576–80, 1676 (2003); Cantor, *supra* note 6, at 285–87.

[23] 35 U.S.C. §§ 100–376 (2006). Specifically, among other requirements, a patent applicant's claimed invention must be patentable subject matter, be novel, not be obvious in light of a prior invention, *id.* §§ 101–103, include the best mode for carrying out the invention, and must include claims that "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." *Id.* § 112. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218 (2010) (discussing patentable subject matter); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (discussing nonobviousness); Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043 (Fed. Cir. 1995) (discussing requirements for distinctly pointing out the claimed subject matter); *see also* 35 U.S.C. §§ 101–03, 112 (2006).

[24] *See* Burk & Lemley, *supra* note 22, at 1576.

[25] *See* 32 U.S.C. §§ 200–12 (2006); *see also infra* notes 151–83 and accompanying text.

[26] 35 U.S.C. § 271(e) (2006); *see also* Sara Boettiger & Alan B. Bennet, *Bayh-Dole: If We Knew then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320–23 (2006); Elizabeth Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 59 ME. L. REV. 283, 295–98 (2007).

Ariad's application of the written description requirement is particularly appropriate in the complex and unpredictable field of biotechnology where the true scope of a claimed invention may be unclear.[27] Such was the case in *Ariad* where the inventors attempted to claim a broad invention that they did not actually possess. If courts erroneously grant broad exclusive rights to those who do not actually possess the claimed invention, further innovation can be stifled as other researchers may not be able to further the inventive process.[28] For a complex and ever-changing field like biotechnology, the written description requirement provides a useful and straightforward tool for courts in determining what invention an inventor actually possessed at the time he filed his claim, avoiding the alternative of an in-depth inquiry into the overall nature of technology over the years.

Some argue, however, that the written description requirement as applied in *Ariad* and its predecessors[29] unfairly targets biotechnology patents by demanding too much specificity from inventors who work on groundbreaking basic research.[30] The fear is that the pioneers of a technology, specifically those at the university level, will lose their ability to gain patents over their discoveries as other entities pick up on basic discoveries and turn those into finalized products.[31] Further, some scholars argue that *Ariad* represents a deviation from prior written description jurisprudence, leading some to believe that the CAFC's interpretation of the requirement is inaccurate and improper.[32] These scholars fear that *Ariad*'s interpretation of the written description requirement will negate the incentives for those performing the basic research that fuels biotechnology innovation, thus impacting negatively the future of U.S. biotechnology research as a whole.[33]

Despite these fears, the written description requirement, as applied in *Ariad*, is unlikely to put an end to the current successes of the biotechnology industry. In fact, it is likely that the CAFC's use of the requirement in *Ariad* will have a positive impact on overall

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[27] *See* Burk & Lemley, *supra* note 22, at 1676; Cantor, *supra* note 6, at 287.

[28] *See* Burk & Lemley, *supra* note 22, at 1676–78.

[29] *See, e.g.*, Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303 (Fed. Cir. 2004).

[30] *See* Kelly, *supra* note 7, at 266 (noting that the written description rewards those who can sequence DNA the fastest and not those who made a breakthrough discovery in the first place); Upadhyaya, *supra* note 6, at 110.

[31] *See, e.g.*, Kelly, *supra* note 7, at 267–68.

[32] *See* Kelly, *supra* note 7, at 270; Upadhyaya, *supra* note 8, at 110.

[33] Kelly, *supra* note 7, at 270 (discussing *Lilly*, a predecessor to *Ariad*).

biotechnology growth and innovation.[34] By applying a simpler and more straightforward analysis, courts can more easily identify overbroad claims that the Patent Office should not have granted. Further, a strong written description requirement encourages patent applicants to provide the public with a more detailed description of their invention, helps police overbroad claims, and ensures that inventors complete their inventions before they are awarded a patent.[35] Through the written description requirement, the system can appropriately reward those who have legitimate rights to their inventions by providing additional confidence to those willing to commit to the long-term investment that is required to develop many biotechnology products.

This Comment argues that *Ariad*, through the enforcement of the written description requirement, illustrates how the CAFC is promoting biotechnology innovation. *Ariad* demonstrates that the written description requirement is an important tool that furthers the congressional policies of the Bayh-Dole Act, Hatch-Waxman Act, and the U.S. patent system in general. Part II outlines the general U.S. patent requirements, focusing specifically on the history of the written description requirement, which dates back to the first Patent Act of 1790. Part II shows, through historical and modern case law, how courts have applied the requirement and why the *Ariad* decision upholds the traditional purpose of the requirement. Part III discusses the general nature of the biotechnology industry, with particular focus on the Bayh-Dole and Hatch-Waxman Acts and the overall policies that the U.S. patent system seeks to promote in the industry. Part IV discusses the *Ariad* decision in detail, looking at both the CAFC's analysis supporting its interpretation of the written description requirement and its ultimate holding with regard to this requirement. Finally, Part V explains how the *Ariad* decision and the CAFC's interpretation of the written description requirement are positive steps towards fixing the current innovation problems in the biotechnology industry and how the decision furthers the overall goals of the patent system. Specifically, Part V argues that the decision balances the competing interests in the biotechnology industry and encourages innovation through industry-university

[34] *See* discussion *infra* Part V.

[35] *See* discussion *infra* Part V; s*ee also* Patrick Brian Giles, *How to Claim a Gene: Application of the Patent Disclosure Requirements to Genetic Sequences*, 27 GA. ST. U. L. REV. 695 (2011) (discussing the separate enablement and written description requirements, how they impact the scope of genetic sequence patents, and a potential method for adequately disclosing genetic sequence genus claims).

cooperation, thereby promoting the congressional intent of the Bayh-Dole and Hatch-Waxman Acts. Part VI concludes.

II. OVERVIEW OF PATENT REQUIREMENTS ESTABLISHED BY U.S.C. TITLE 35

A. *General Patent Characteristics*

The patent system as a whole is designed to promote progress and innovation by granting inventors exclusive rights to their inventions.[36] The monetary incentive of exclusive rights to an invention encourages inventors to constantly innovate.[37] The system then benefits the general public, as inventors are pushed to create beneficial technologies that, without any encouragement, they might not have otherwise invented.[38] Before rewarding an inventor, however, the system must ensure that the invention actually contributes to the arts. To that end, Congress enacted a series of requirements that must be satisfied in order to determine if an invention is patentable: utility,[39] novelty,[40] and nonobviousness.[41] To warrant the issuance of a patent, an invention must provide some benefit to society and must not be a merely generalized idea, a technology that is already in existence, or an obvious improvement on existing technology.[42]

While an invention's value to society lies in its ability to contribute to the useful arts, to an inventor, a patent is only as valuable as its overall scope and duration.[43] If the scope of an inventor's patent is narrow, other inventors can simply design around the original invention once it is disclosed to the public.[44] Further, under the current system, a patent generally lasts for only twenty years from the inventor's filing date.[45] Given the delays that could occur between a patent's filing date and the date on which the

[36] U.S. CONST. art. I, § 8, cl. 8; *see also* Burk & Lemley, *supra* note 22, at 1580.

[37] *See* Burk & Lemley, *supra* note 22, at 1580.

[38] *Id.*

[39] 35 U.S.C. § 101 (2006).

[40] *Id.* § 102.

[41] *Id.* § 103 (2006); *see also* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) ("The claimed subject matter must be useful, novel, and not obvious."); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990).

[42] *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS §§ 1.01, 3.01, 4.01, 5.01 (2010).

[43] *See* Cantor, *supra* note 6, at 270; Merges & Nelson, *supra* note 41, at 840.

[44] Cantor, *supra* note 6, at 270.

[45] 35 U.S.C. § 154(2) (2006).

product is released on the market, an inventor's exclusivity period may end up being significantly shorter than that to which he is entitled under the patent system.[46] In order to provide a sufficient incentive for inventors to continue to innovate, the value of a patent must be greater than the overall cost of investment in discovering that invention.[47]

Just as patents that are too narrow provide too little compensation for inventors, patents that are too broad may provide too much.[48] It is important that a patent only include an inventor's actual contribution to the useful arts so that future inventors can be rewarded for their own contributions. In addition, progress is only attainable if an inventor discloses the full scope of his invention so that others can gain the full benefit of the inventor's discovery; this disclosure also allows others to avoid infringing on the inventor's exclusive rights.[49] It is in this regard that the written description fits into the patent system. Every patent applicant must provide a full and detailed description of his invention to prove that he not only possesses the claimed invention but also that he can teach others how to make and use the invention.[50] Simply put, the patent system assumes that if an inventor actually invented what he claims, he should have little difficulty describing it in detail to others of equal skill and teaching them how to accomplish the same task; if he cannot, it is unlikely that he actually invented what he is claiming.

Finally, because an inventor is awarded exclusivity from the date he files for a patent, the inventor must satisfy the descriptive requirements as of that date.[51] Generally, an inventor cannot subsequently expand his claimed invention once he has applied to

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[46] Biotechnology products in particular have long delays between the date on which patent applications are filed and the date on which the products hit the market. Burk & Lemley, *supra* note 22, at 1683. These delays are the result of high levels of regulatory scrutiny. *Id.* Specifically, it is estimated that new drugs released in the mid-90s averaged a mere twelve years of exclusivity by the time they were introduced to the market. Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 852–53 (2002).

[47] *See* Merges & Nelson, *supra* note 41, at 868–69.

[48] *See* Burk & Lemley, *supra* note 22, at 1584.

[49] *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002).

[50] *See id.* at 736 ("[The] patent application must describe, enable, and set forth the best mode of carrying out the invention." (citing 35 U.S.C. § 112 (2006))).

[51] *See, e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991); *In re* Glass, 492 F.2d 1228, 1231–32 (C.C.P.A. 1974).

obtain his exclusive rights.[52] Once an invention has been disclosed to the Patent Office or the public, that invention becomes a part of the useful arts.[53] Accordingly, an inventor attempting to expand upon his earlier disclosure may no longer be awarded exclusive rights to his invention if his subsequent claim is merely a knock-off of his earlier one.[54]

Overall, each separate requirement for a patent must further the goal of promoting progress in the useful arts. This was the goal of the first Patent Act and continues to be the goal today.[55] As the *Ariad* case demonstrates, the written description requirement is essential to promoting that goal.[56] As the court explained, courts have used the requirement since its creation to ensure that an inventor actually invented what he originally claimed, while also encouraging inventors to fully describe their invention so that others could use that knowledge to innovate.[57] The requirement maintains the "*quid pro quo* in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time."[58] This is as true today in *Ariad* as it was when the original Patent Act was passed in 1790.

B. *History of Written Description*

The written description requirement for patents issued in the United States is found under 35 U.S.C. § 112, which states, "The specification shall contain a written description of the invention . . . ."[59] Since the original Patent Act of 1790, the written description requirement has been used to provide the public with notice of the scope of an inventor's "exclusive rights" (i.e., the patent that an inventor is claiming).[60] Through a written description, an inventor both shows that his invention is in fact an invention—

[52] *Vas-Cath*, 935 F.2d 1555. A patent may, at times, be expanded upon a reissue. *See* 35 U.S.C. §§ 251–255 (2006).

[53] *See, e.g.*, 35 U.S.C. §§ 102, 112 (2006); Merges & Nelson, *supra* note 41, at 844–45.

[54] *Vas-Cath*, 935 F.2d 1555.

[55] Patent Act of 1790, ch. 7, §§ 1–7, 1 Stat. 109 ("An Act to promote the progress of Useful Arts.").

[56] *See* discussion *infra* Part V.

[57] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350–52 (Fed. Cir. 2010).

[58] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 (Fed. Cir. 2004) (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002)) (internal quotation marks omitted); *see* Schroeder, *supra* note 20, at 104.

[59] 35 U.S.C. § 112 (2006); *Ariad*, 598 F.3d at 1344.

[60] *See* Mueller, *supra* note 1, at 619–20.

describing how the invention is different from anything already known—and puts the public '"in possession' of the boundaries of a patentee's asserted monopoly" so that it can avoid infringing on the patent.[61]

The Supreme Court provided an interpretation of the written description requirement in 1822 in *Evans v. Eaton*.[62] The primary issue in *Evans* was whether the defendant infringed on the plaintiff's patent for an improved "hopperboy."[63] The plaintiff claimed as his invention "the peculiar properties or principles which this machine possesses, in the spreading, turning, and gathering the meal at one operation, and the rising and lowering of its arms by its motion, to accommodate itself to any quantity of meal it has to operate upon."[64] In his claim, the plaintiff did not disclose "any distinct improvement."[65] Even if the plaintiff had in fact created a patentable invention, the Court invalidated the patent for failure to satisfy the written description requirement.[66] The Court explained the purpose of the written description requirement:

> [To] put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.[67]

The Court also noted that the written description was necessary to prevent patentees from claiming patents "broader than [their] invention."[68] The *Evans* case continues to be an important guideline for modern application the written description requirement.[69]

The *Evans* interpretation is still relevant because the language of the written description requirement has remained essentially the same since the first Patent Act in 1790 even though the current language more closely resembles the language in the Patent Act of

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[61] *Id.* at 619 (quoting Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822)).

[62] *Evans*, 20 U.S. (7 Wheat.) 356.

[63] *Id.* at 424. The "hopperboy" was a "mechanical device used to stir and cool flour prior to its packing." Mueller, *supra* note 1, at 618–19 (internal quotation marks omitted).

[64] *Evans*, 20 U.S. (7 Wheat.) at 428.

[65] *Id.* at 433.

[66] *Id.* at 435.

[67] *Id.* at 434.

[68] *Id.* at 430.

[69] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345 (Fed. Cir. 2010) (citing *Evans*, 20 U.S. (7 Wheat.) at 433–34).

1836.[70] Although the initial purpose of the written description requirement seems relatively straightforward, the Patent Act of 1870 seemed to diminish the role of the written description.[71] The 1870 Act added the statutory requirement for the modern "claims."[72] While the written description language still remains, its purpose of specifically describing the scope of the invention can appear redundant in light of the newly enacted requirement to "particularly point out and distinctly claim" the invention.[73] Despite this apparent redundancy, the written description requirement still serves its purpose of rejecting inadequate original claims and also invalidating amended claims that subsequently add "new matter" to the originally claimed invention.[74]

The written description requirement applies to an inventor's claimed invention on the date that the inventor files the application for a patent.[75] The inventor's initial patent application must allow a person having ordinary skill in the art to know that the inventor has "possession" of his claimed invention on the day he files his patent application.[76] This original written description becomes the basis for subsequent amendments or alterations to the original patent application.[77] An inventor may amend his originally claimed patent

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[70] *See* Upadhyaya, *supra* note 7, at 69 n.34 (quoting *In re* Barker, 559 F.2d 588, 593 (C.C.P.A. 1977); *see also* Patent Act of 1836, ch. 357, 5 Stat. 117, 119 (stating that an inventor "shall deliver a written description of his invention or discover, and of the manner and process of making, constructing, using, and compounding the same").

[71] *See* Mueller, *supra* note 1, at 620.

[72] *See id.*; *see also* Patent Act of 1870, ch. 230, §26, 16 Stat. 198, 201 (noting that before an inventor may receive a patent he must "particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery; and *said specification and claim* shall be signed by the inventor") (emphasis added); Markman v. Westview Instruments, 517 U.S. 370, 379 (1996) ("Claim practice did not achieve statutory recognition until the passage of the Act of 1836 . . . and . . . did not become a statutory requirement until 1870."). The statute notes both a specification *and* a claim in the margin. Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201. The previous Act of 1836 noted: "[A]nd in the case of any machine [the inventor] shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119. The statute only notes specification in the margin. *Id.*

[73] Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201; *see also* Mueller, *supra* note 1, at 620.

[74] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1565 (Fed Cir. 1991); *see also* Cantor, *supra* note 6, at 296–97; Upadhyaya, *supra* note 7, at 71.

[75] *See Vas-Cath*, 935 F.2d at 1563–64; Cantor, *supra* note 6, at 296.

[76] 35 U.S.C. § 112 (2006); Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822).

[77] *See, e.g.*, *Vas-Cath*, 935 F.2d 1555; Anascape, Ltd. v. Nintendo of Am., Inc., 601 F.3d 1333 (Fed. Cir. 2010); *see also* 35 U.S.C. §§ 120, 251 (2006); Burk & Lemley, *supra* note 22, at 1652–53.

in a couple of different ways. For one, after a patentee files an application for a patent, he may subsequently amend his patent through a continuation application.[78] The continuation, however, may not include new matter that was not found in the original written description.[79] Additionally, an inventor can surrender and amend a "defective" patent if the inventor inadvertently, through the specification, claimed more or less than he had a right to patent or made an error in his specification.[80] The amendment, or "reissue," may broaden the scope of a patent as long as it is within two years of the issuance of the initial patent.[81] The reissue, however, may not introduce new matter to the application for reissue.[82] Accordingly, the scope of the original patent application—the written description—is essential to inventors seeking to clarify their original claims.

In recent years, the CAFC has used the written description requirement to police abuse of the amendment process and to determine whether to award priority to an earlier invention date over subsequent amendments.[83] The seminal case in which the CAFC applied the written description requirement to subsequent patent applications is *Vas-Cath v. Mahurkar*.[84] In *Vas-Cath*, the inventor initially filed a "design application" disclosing a drawing of his invention, which was included in a subsequent filing that provided a more detailed description of the initial drawing.[85] The court held that the written description requirement is satisfied if the original application "convey[s] with reasonable clarity to those skilled in the art" that the inventor "was in possession *of the invention*," the invention being "*whatever is now claimed*."[86] While this description does not have to be exact, it should not be so broad as to cover

[78] *See* 35 U.S.C. §§ 119, 120 (2006); 37 C.F.R. § 1.114 (2011). An inventor who is successfully granted a continuation may claim the original filing date of his invention as his invention date. 35 U.S.C. § 120 (2006).

[79] 35 U.S.C. § 132 (2006); *see also* Gentry Gallery Inc., v. Berkline Corp., 134 F.3d 1473, 1479–80 (Fed. Cir. 1998); Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of* Eli Lilly *and its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 6 (2007).

[80] *Id.* § 251. The error cannot be purposeful or deceptive. *Id.*; *see also* Cantor, *supra* note 6, at 296.

[81] § 251.

[82] *Id.*

[83] *See, e.g.*, *Vas-Cath,* 935 F.2d at 1563–64.

[84] *Id.*

[85] *Id.* at 1558–59.

[86] *Id.* at 1563–64.

inventions the inventor did not in fact invent.[87] While *Vas-Cath* focused on subsequent amendments to a claim, the Supreme Court has noted that a claim can still be invalid if the inventor cannot show he possessed the claimed invention at the time of filing.[88]

The Supreme Court highlighted the limits of a broad patent claim in the pre-1870 case *O'Reilly v. Morse*.[89] Morse, the pioneer of the telegraph, the invention at issue in the case, attempted to extend his claim to include every possible improvement that used electric or galvanic current in a similar fashion to his telegraph system.[90] Specifically, in his eighth claim, Morse boldly stated:

> I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discovered.[91]

The Court made it clear that while Morse discovered an incredibly useful and novel invention, he had not discovered that the electric or galvanic current would always have the exact same effect no matter what machinery was used.[92] Specific and complex machinery were required to produce the effect that Morse was claiming.[93] Morse had thus not invented or "discovered" additional uses of electric or galvanic current beyond the method and machinery described in his claim.[94] The Court made it clear that allowing such a broad patent would stifle further discoveries that were certainly not part of Morse's original claim.[95] The Court further explained that if it allowed the eighth claim, no specification would be needed beyond a statement that by using X (electro-magnetism), one can accomplish Y (print intelligible characters at a distance).[96]

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[87] *Id.* at 1563.

[88] *See supra* text accompanying notes 62–69 & *infra* text accompanying notes 89–96.

[89] 56 U.S. (15 How.) 62 (1853).

[90] *Id.* at 112.

[91] *Id.*

[92] *Id.* at 117.

[93] *Id.*

[94] *Id.*

[95] *Morse*, 56 U.S. (15 How.) at 113.

[96] *Id.* at 119.

In 1967, the Court of Customs and Patent Appeals (CCPA), the predecessor to the CAFC, reaffirmed the use of the written description requirement to invalidate original claims.[97] The case, *In re Ruschig*, dealt with the sole issue of whether the patent applicant's claim was "supported by the disclosure of [applicant's] application."[98] In his claims, the patent applicant disclosed a number of different chemical reagents.[99] The applicant then attempted to claim that he had disclosed a particular chemical compound, chlorpropamide.[100] The applicant believed that he was entitled to claim chlorpropamide because the compound could be created through a combination of three of the reagents listed in the claim and because he had disclosed a number of specific compounds that the reagents could create.[101] The judge, however, noted that the listed reagents could "encompass something like half a million possible compounds."[102] The compounds that the applicant listed provided no particular guidance or description of the creation of chlorpropamide.[103] Analyzing the claim as a question of fact, the court held that the claim did not disclose chlorpropamide.[104] Nothing in the claim, other than a list of different compounds, indicated that the applicant had actually invented chlorpropamide.[105] Applying the written description requirement, the court essentially found that the applicant was not entitled to the broad patent he claimed merely because he disclosed the elements necessary to achieve a particular result—the creation of chlorpropamide.[106] The patentee must show that he has possession of the specific invention—the species—that he is claiming, or for a broad patent, he must show that he has possession of the genus.[107] The CCPA's holding in *In re Ruschig* reaffirmed the use of the written description requirement as a method to invalidate original claims.

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[97] *See In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); Upadhyaya, *supra* note 7, at 72.

[98] *In re Ruschig*, 379 F.2d at 991.

[99] *Id.* at 993.

[100] *Id.*

[101] *Id.*

[102] *Id.*

[103] *Id.* at 994–96.

[104] *In re Ruschig*, 379 F.2d at 995–96.

[105] *Id.* at 995.

[106] *Id.* at 995–96.

[107] Alison Aubrey Richards, Ariad v. Eli Lilly—*The Federal Circuit Confirms the Written Description Requirement*, SOFTEC (Oct. 6, 2010, 10:30 AM), http://www.softec.org/blogs/business_and_technology_law/archive/2010/10/06/ariad-v-eli-lilly-the-federal-circuit-confirms-the-written-description-requirement.aspx.

C. *Modern Use of Written Description in the CAFC*

In more recent years, the CAFC has continuously used the written description requirement to invalidate original claims. *Regents of the University of California v. Eli Lilly & Co.* ("*Lilly*"),[108] heard before a panel of the CAFC, is one of the more significant cases applying the written description to modern patents.[109] The plaintiffs in *Lilly* discovered the gene sequence that allowed the production of rat insulin.[110] Insulin is commonly used to treat people afflicted with diabetes.[111] The claims at issue claimed broad categories including the genetic code to "vertebrates" and "mammalian and human insulin."[112] The CAFC held the broad claims invalid for failure to satisfy the written description.[113] In its reasoning, the court cited plaintiff's failure to precisely describe the broad class of "vertebrate or mammalian insulin cDNA" that the plaintiff was claiming.[114] But because the rat DNA sequence was merely one species of a broader genus of claims that include all vertebrate DNA, the discovery and recitation of the rat insulin code did not sufficiently describe the other sequences that plaintiff attempted to claim.[115]

Distinguishing the written description from other patentability doctrines, the court noted that with the rat DNA sequence, a person of ordinary skill in the art could eventually discover the human sequence.[116] Thus, even if the description rendered the broad claims obvious,[117] the written description was not necessarily satisfied.[118] The court held, "[b]ecause the . . . specification provides only a *general method* of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA."[119] The panel decision in *Lilly* regarding the use of the written

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[108] 119 F.3d 1559 (Fed. Cir. 1997).

[109] *See* Kelly, *supra* note 7; Upadhyaya, *supra* note 7. *But see* Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Examination*, 104 NW. U. L. REV. COLLOQUY 382, 393–94 (2010); Holman, *supra* note 79, at 4–5.

[110] *Lilly*, 119 F.3d at 1562–63.

[111] *Id.* at 1562.

[112] *Id.* at 1563.

[113] *Id.* at 1568.

[114] *Id.*

[115] *Id.* at 1568.

[116] *Lilly*, 119 F.3d at 1567.

[117] *See* 35 U.S.C. § 103 (2006).

[118] *Lilly*, 119 F.3d at 1567.

[119] *Id.* (emphasis added).

description requirement to invalidate original claims sparked significant controversy and dissent among legal commentators and the CAFC itself, setting the stage for a rehearing on the issue before the entire CAFC.[120]

D. *Enablement*

As noted, the first paragraph of § 112 contains another major requirement separate from the written description: enablement. The relevant statutory text states:

> The specification shall contain . . . [a written description] of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .[121]

Unlike the written description requirement, which is a question of fact,[122] the enablement requirement is a question of law.[123] The enablement requirement, like the written description requirement, is used to limit the scope of a patent.[124] Enablement asks if a person of ordinary skill in the art could, at the time of filing, make and use the patentee's claimed invention without "undue experimentation."[125] Further, enablement does not specifically ask what the invention is or what the inventor invented; it merely asks if one of ordinary skill in the art could make the invention having read the specification.[126] Simply put, enablement focuses on what others can accomplish given

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[120] *See, e.g.*, Holman, *supra* note 109 at 17–18.

[121] 35 U.S.C. § 112 (2006) (emphasis added).

[122] *See, e.g.*, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[123] *See* Cantor, *supra* note 6, at 283. Essentially, the written description requirement requires a factual determination of whether the specification itself demonstrates to a person of ordinary skill in the art that the inventor possessed the actual invention. *Ariad*, 598 F.3d at 1352. Enablement, on the other hand, looks to whether certain information, which is necessary to the make and use of the invention, existed on the date that applicant filed for a patent. *See, e.g.*, *In re* Glass, 492 F.2d 1228, 1231–32 (C.C.P.A. 1974); *In re* Wands, 858 F.2d 731, 736 (Fed. Cir. 1988).

[124] *See* Cantor, *supra* note 7, at 283–84.

[125] *Id.* When considering "undue experimentation," courts look to a number of factors. *Id.* As articulated in *In re Wands*, these factors include: "(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." *Wands*, 858 F.2d at 736; *see also infra* Part III (discussing unpredictability in biotechnology).

[126] 35 U.S.C. § 112 (2006); Burk & Lemley, *supra* note 22, at 1649.

a description of the invention (i.e., "can you make X"), while the written description requirement focuses on what the inventor actually disclosed (i.e., "what is X"). The scope of what another can make given an inventor's disclosure may not necessarily coincide with what an inventor actually invented.

As two coexisting elements in paragraph one of § 112, enablement and written description are so often intertwined by the simple fact that in order to make an invention, one would almost certainly need to know what the invention is.[127] Accordingly, the two requirements "often rise and fall together."[128] Cases like *In re Ruschig*, however, show that a disclosed invention might at times enable a person skilled in the art to make an invention even though the invention is not described.[129] Additionally, enablement encourages expansive claims that include after-arising technology.[130] While this encouragement may provide a positive incentive for patent applicants creating pioneering technologies, it also encourages inventors to provide generalized claims that may include inventions to which the inventors are not entitled. The written description requirement articulated in *Ariad* provides a method for the courts to stop patent applicants who attempt to misuse the patent system by over-extending their claims to cover inventions that they have not yet invented.[131] Accordingly, investment and progress are encouraged as inventors can be confident that the system will adequately award exclusive rights.

[127] § 112.

[128] *Ariad*, 598 F.3d at 1352.

[129] Another example highlighted in the *Ariad* case is if an inventor claims a methyl compound, but fails to disclose a propyl or butyl compound. *Ariad*, 598 F.3d at 1352 (citing *In re* DiLeone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971)). While the process to make the methyl compound enables others to create the propyl and butyl compounds, the two compounds have not been described and are thus not entitled to a patent. *Id.* Accordingly, a claim should not be valid if it merely describes a broad method, while indicating that the inventor did not possess the full scope of the invention.

[130] *See, e.g.*, *In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977). A patent will not fail enablement merely because the state of the art or technology changes, thus enabling "after arising" technologies that are covered by the patent but were not intended by the initial disclosure. *Id.*

[131] *Ariad*, 598 F.3d at 1353–54.

III. BIOTECHNOLOGY AND PATENT POLICY

The patent law system is designed to "promote innovation by granting exclusive rights to encourage invention."[132] In order to accomplish this goal, the system must provide inventors with exclusive rights to their inventions as a reward for the time and money that they invested in the difficult work of invention, and at the same time, avoid stifling innovation by granting overbroad patents.[133] The biotechnology industry in particular requires careful analysis when granting patents due to both the nature of the science—the focus of this Comment—and also the ethical issues that arise with biotechnology.[134]

A. *The Biotechnology Industry and Patents*

Biotechnology has been described as "any technique that uses living organisms or substances from these organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses."[135] The broad array of modern biotechnology patents has largely been encouraged since the 1980 Supreme Court case *Diamond v. Chakrabarty*.[136] In *Chakrabarty*, the Supreme Court examined a patent concerning genetically modified bacteria.[137] The Court held that the bacteria were patentable, noting that patentable subject matter included "anything under the sun that is made by man" and that "Congress plainly contemplated that the patent laws would be given wide scope."[138] The biotechnology products that are of primary concern to critics of *Ariad* generally include manipulations of genetic material, proteins, hormones,

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[132] *See* U.S. CONST. art. I, § 8, cl. 8; *Ariad*, 598 F.3d at 1353–54; Burk & Lemley, *supra* note 22, at 1580.

[133] *See Ariad*, 598 F.3d at 1353–54; Burk & Lemley, *supra* note 22, at 1580–81; Cantor *supra* note 6, at 268.

[134] Cantor, *supra* note 6, at 268.

[135] Sandra Schmieder, *Scope of Biotechnology Inventions in the United States and in Europe—Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 163, 171 (2005) (internal quotation marks omitted); *see also* Linda R. Judge, *Biotechnology: Highlights of the Science and Law Shaping the Industry*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 79, 79 (2004) (noting that biotechnology includes "the use of living organisms or their products to modify human health and/or the human environment typically by using the techniques of gene splicing and recombinant DNA technology").

[136] 447 U.S. 309 (1980); *see also* Schmieder, *supra* note 135, at 84.

[137] *Chakrabarty*, 447 U.S. at 309.

[138] *Id.* at 308–09.

genetic sequences, and chemical processes that eventually result in therapeutic treatments—more specifically, biopharmaceutical products.[139] Resulting products and claims involve different drugs or gene sequences that are used medicinally, as diagnostic tests, or as a basis for further research.[140] These products inherently have a high public demand due to the obvious social benefits (i.e., saving human lives and treating thousands of health conditions) they provide.[141]

As a whole, biotechnology involves complex physiological systems that create a "high degree of uncertainty and risk."[142] Long-term development costs are necessary to create new products or to improve upon old ones.[143] Additionally, biotechnology can often lead

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[139] *See* Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1, 21–25 (2005); Schmieder, *supra* note 135, at 171–73.

[140] *See* Burk & Lemley, *supra* note 22, at 1676–78. Over the years, courts have attempted to pinpoint the scope of patentable biotechnology products. For example, prior to *Chakrabarty*, in *In re Fischer*, the CCPA examined a claim for a complex solution containing adrenocorticotrophic hormones (ACTH). 427 F.2d 833, 834 (C.C.P.A. 1970). The solution was useful because it could be injected safely into humans as a treatment for arthritis. *Id.* The court held that a description of amino acids—sequences of DNA form corresponding amino acids—was sufficient structural information to identify the claimed invention; however, the claim was incomplete because it only included twenty-four of the thirty-nine amino acids required to complete the sequence. *Id.* at 836. Further, the patentee attempted to claim any ACTH solution having a potency range greater than 111%. *Id.* at 834. The court held that the scope far exceeded the inventor's actual claim because his solution was limited to 230%. *Id.* at 839.

Subsequent cases dealing with biotechnology products demanded even more specific disclosures. *See, e.g.*, Ariad Pharm., Inc. v. Eli Lilly & Co., 589 F.3d 1336, 1350 (Fed. Cir. 2010) (holding that in order to claim a broad genus, an inventor must disclose "a representative number of species falling within the scope of the genus . . . so that one of skill in the art can 'visualize or recognize' the members of the genus"); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 925 (Fed. Cir. 2004) (holding that method claims involving chemicals other than DNA and RNA must also describe actual compounds and sufficient materials that obtain the desired result, thus outlining the scope of the claimed invention); Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566–67 (Fed. Cir. 1997) (holding that a method for preparing a sequence of DNA or the corresponding amino acid sequence does not sufficiently describe the scope of a claim under § 112 and noting that such claims "require a precise definition, such as by structure, formula, chemical name, or physical properties"); Fiers v. Revel, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993) (holding that an adequate written description of DNA requires a disclosure of the DNA sequence and not merely the corresponding mRNA reference from which the DNA sequence could be obtained); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213–14 (Fed. Cir. 1991) (holding that the inventor could not claim all genetic sequences that produced EPO-like (a hormone) activity merely by disclosing "the gene and a handful of analogs whose activity has not been clearly ascertained").

[141] *See* Schmieder, *supra* note 135, at 178.

[142] Burk & Lemley, *supra* note 22, at 1676.

[143] *Id.*

to unforeseeable functions and research results with any product, even if that product has been available and improved upon for many years.[144] Further, because much of the technology involves testing on human patients and high-risk consequences to consumers, the industry is heavily regulated.[145] Accordingly, the costs and risks associated with creating biotechnology products are enormous.

For example, in its amicus brief in *Ariad* on behalf of Eli Lilly, Amgen Inc., a pioneer in the biotechnology industry, discussed the difficulties of producing biotechnology products.[146] Amgen explained that costs for research and development "for each successful therapeutic product" average between "$800 million to $1.2 billion" and that such products typically take over ten years to develop.[147] Further, "only five out of 250 products ever make it to human testing, and for every product that does make it to market, approximately nine products fail in clinical testing."[148] Even still, "of those products that make it to market, only about 20% ever recoup the average investment cost."[149] Additionally, the relative ease of creating a generic follow-on product that avoids the risk, uncertainty, and many other complications associated with creating biotechnology drugs leaves innovators of these products in a position in which they require strong patent protection in order to make their investment worthwhile.[150]

B. Bayh-Dole and Hatch-Waxman Acts

The most important influence on the growth of the biotechnology industry was the Bayh-Dole Act of 1980.[151] In fact, some believe the Act to be "possibly the most inspired piece of

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[144] *Id.*

[145] *Id. See, e.g.*, Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 35 U.S.C. §§ 271(e), 156 (2006) and 21 U.S.C. § 355(j) (2006)).

[146] Brief for Amgen, Inc. as Amicus Curiae Supporting Respondent at 1, 13–15, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280).

[147] *Id.* at 13–14.

[148] *Id.*

[149] *Id.* at 15.

[150] *See* Burk and Lemley, *supra* note 22, at 1677.

[151] 35 U.S.C. §§ 200–212 (2006); *see also* Heather Hamme Ramirez, Comment, *Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons" in Biotechnology Research and Development*, 53 EMORY L.J. 359, 364–65 (2004).

legislation to be enacted in America over the past half-century."[152] The Act's primary purpose was to use the patent system to promote collaboration between federally funded research institutions and private industry, which was designed to further overall biotechnology innovation.[153] Bayh-Dole encouraged innovation by (i) ensuring that "private parties contributing to publicly funded research would retain the right to develop any subsequent inventions," (ii) motivating the "employees of government-owned, government operated laboratories to make and license commercializable inventions," and (iii) "favoring American over foreign industry in conferring ownership rights to publicly funded technology."[154] Essentially, government-subsidized research institutions were allowed to retain patents, unlike the previous framework, in which such patents became the property of the government.[155] The Bayh-Dole Act worked in conjunction with the Stevenson-Wydler Technology Innovation Act of 1980.[156] The Stevenson-Wydler Act explained the potential for scientific progress through cooperative research, noting how discoveries were occurring in university and federal laboratories, but were being implemented for public and commercial use through private industry.[157] Thus, the

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[152] Editorial, *Innovation's Golden Goose*, 365 ECONOMIST 3, 3 (2002), *available at* http://www.economist.com/node/1476653.

[153] According to Congress:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. § 200 (2006); *see also* Dana Katz & Jon F. Merz, *Patents and Licensing, Policy, Patenting of Inventions Developed with Public Funds*, *in* 2 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 854, 861–62 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 120 (2001).

[154] *Id.* § 200.

[155] *Id.*

[156] 15 U.S.C. §§ 3701–3714 (2006).

[157] § 3701.

Act's main purpose was to "[renew, expand, and strengthen]" cooperation between these public and private entities through "technology transfer, personal exchange, joint research projects" and more.[158] Both Acts authorized the creation of technology transfer offices at universities, nonprofit facilities, and federally funded research institutions that provided a mechanism for publicly funded entities to identify and utilize technologies that have potential commercial applications.[159]

Prior to the Bayh-Dole Act, the high risk/reward ratio for investing in biotechnology was such that few companies or institutions looked at developing these products.[160] Before the Act, a mere five percent of discoveries that the National Institutes of Health funded resulted in new improved products related to biotechnology innovation.[161] Within thirty years of passage, the Act has created over 5,000 new companies based around university research.[162] In those same thirty years, these companies developed "153 new drugs, vaccines or in vitro devices" that made it to the market.[163] The Bayh-Dole Act is credited with creating the biotechnology industry in the United States, and has been described as "possibly the most important piece of legislation to be enacted in America over the past half century."[164]

Specifically, the economic growth of universities demonstrates the effects of the Bayh-Dole Act. In 1997, universities accounted for almost $500 million in biotechnology proceeds from their own patents.[165] That number went to almost $1 billion by 2002.[166] Additionally, as of 1981, universities had 436 biotechnology patents,

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[158] § 3701; *see also* § 3702.

[159] *Id.* § 3710; 35 U.S.C. § 202 (2006).

[160] *See Phyllis Gardner Testimony*, BIO (July 10, 2002), http://www3.bio.org/ip/action/tt20030710.asp.

[161] *Id.* The National Institutes of Health, the top medical research agency in the United States, is "the largest source of funding for medical research in the world." NAT'L INSTS. HEALTH, http://www.nih.gov/about/index.html (last visited June 10, 2012).

[162] *Thirty Years After Passage, Bayh-Dole Act Drives the Economy, Protects Public Health*, NEWSWISE (May 3, 2010, 12:00 PM), http://www.newswise.com/articles/thirty-years-after-passage-bayh-dole-act-drives-the-economy-protects-public-health.

[163] *Id.*

[164] *Id.*; Chester G. Moore, Comment, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 152 (quoting *Innovation's Golden Goose*, *supra* note 152, at 3).

[165] *See* Rowe, *supra* note 26, at 295.

[166] *Id.*

while in 2001 they had nearly 3,203.[167] As a whole, biotech patents increased from 18,695 in 1996 to 47,473 in 2002, a 154% increase.[168] Even in recent years, startup investment and new product development through technology transfers remains high. In 2008 and 2009 combined, as a result of university research, 1,306 new commercial products were introduced and 1,196 new companies were formed.[169] Overall investment has also been consistently high, with sponsored research expenditures totaling $111.37 billion over the same two years.[170] In 2009 alone, the total licensing income through technology transfer offices totaled $2.3 billion.[171]

Notwithstanding this tremendous success, the Bayh-Dole Act is not without its critics and its problems. The quick expansion of the biotechnology industry, coupled with the granting of broad patents for biotechnology inventions and research tools, has created concern regarding downstream biotechnology research.[172] Future products often require the use of a combination of many different previously patented products.[173] If a patentee holding a broad or crucial patent refuses to license his invention, or if the cost of licensing is prohibitively expensive, future inventors will be unable to perform even the basic research necessary to create additional improvements in the field.[174] Even when an inventor is able to purchase the necessary licenses, research costs begin to increase significantly with each additional product purchase.[175] With each subsequent innovation, inventors must charge higher prices for their own

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[167] *Id.*

[168] *See* Schmieder, *supra* note 135, at 177.

[169] Press Release, Ass'n of Univ. Tech. Managers, AUTM U.S. Licensing Activity Survey Summary: FY2009 (2009), *available at* http://www.autm.net/AM/Template.cfm?Section=Documents&Template=/CM/ContentDisplay.cfm&ContentID=5237; Press Release, Ass'n of Univ. Tech. Managers, AUTM U.S. Licensing Activity Survey Summary: FY2008 (2008) [hereinafter AUTM 2008], *available at* http://www.autm.net/AM/Template.cfm?Section=Licensing_Surveys_AUTM&CONTENTID=4513&TEMPLATE=/CM/ContentDisplay.cfm [hereinafter AUTM 2009].

[170] AUTM 2008, *supra* note 169; AUTM 2009, *supra* note 169.

[171] AUTM 2009, *supra* note 169.

[172] *See, e.g.*, Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347 (2004). Research tools are devices or products that are necessary to perform basic research. *Id.* at 348.

[173] Moore, *supra* note 164, at 154.

[174] Derzko, *supra* note 172, at 348; *see also infra* notes 323–40 and accompanying text.

[175] Moore, *supra* note 164, at 155.

products in order to recover the costs spent on obtaining licenses.[176] This increased cost is eventually transferred to the average consumer.[177] In addition to rising costs, some argue that allowing federally funded research institutions to gain patent protection essentially translates to a government giveaway.[178] Patents that would normally be owned by the government would now belong to private industries and the research institutions themselves.[179]

Overall, the Bayh-Dole Act as a whole was a fundamental shift in the incentive structure for research and development at federally funded institutions.[180] Providing universities and other federally funded institutions with access to the patent system gave commercial investors a financial incentive to tap into the facilities where a significant amount of research was already being performed.[181] Consequently, the growth of the U.S. biotechnology industry can be directly tied to the passage of the Bayh-Dole Act.[182]

The Act led to a tremendous increase in private investment in universities and, in turn, to great progress in innovation.[183] As universities began to profit from investment and patent protection, however, concerns arose regarding patent infringement by institutions that were no longer protected by the experimental use doctrine.[184] Under this doctrine, researchers could use patented devices in their research without becoming susceptible to an infringement suit as long as the research was merely philosophical curiosity as opposed to motivated by profit.[185] Once universities were able to gain patent protection, research that led to profit became more commonplace.[186] Particularly, in a 1984 case involving biopharmaceutical products, the CAFC severely restricted the experimental use exception, holding that entities developing generic versions of patented products while the patent was still in force no

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[176] *See* Burk & Lemley, *supra* note 22, at 1611–13

[177] *Id.*

[178] Moore, *supra* note 164, at 154.

[179] *Id.*

[180] *See* Sara Boettiger and Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY, 320–23 (2006).

[181] *Id.*; *see also* 32 U.S.C. §§ 200–212 (2006).

[182] *See* Boettiger, *supra* note 179, at 320–23; *see also* §§ 200–212.

[183] Rowe, *supra* note 26, at 295–97.

[184] *See id.* at 290.

[185] *Id.* at 284. There is also an experimental use exception involving "use" under. *Id.* § 102(b). This paper focuses on the experimental use "research" exception as codified under § 271(e). *See infra* notes 189–205 and accompanying text.

[186] *See* Rowe, *supra* note 26, at 290.

longer fit under the exception.[187] Continuing to pursue the overall goal of promoting private-public collaboration in biotech research, Congress' responded swiftly to the CAFC's holding by passing the Hatch-Waxman Act that same year.[188]

The Hatch-Waxman Act provided another huge boost to biotechnology innovation and collaborative research by codifying an experimental use research exception against infringement claims for those developing biopharmaceutical products.[189] As a trade-off, inventors received longer exclusivity periods while generic product developers and researchers were free to use the patented inventions during the course of the patent life.[190] Working in conjunction with the Act's abbreviated new drug application (ANDA) process, researchers could, without infringing, perform the necessary testing for FDA approval of their generic products while the corresponding original product was still under patent protection.[191] As a result of Hatch-Waxman, generic products were ready to hit the market as soon as the originator's patent expired.[192]

Under the Hatch-Waxman and Bayh-Dole Acts, private investors have tremendous financial incentives to collaborate with universities and other research institutions. Since Congress passed these Acts, academic institutions that previously relied almost entirely on federal funding are now able to transfer much of their biopharmaceutical research focus to industry-driven research.[193] As non-profit

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[187] Roche Products, Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984); Rowe, *supra* note 26, at 290.

[188] Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2000); 35 U.S.C. §§ 156, 271(2000)).

[189] Section 271(e) of Title 35 states

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product . . . which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e) (2006). Subsequent case law extended the exception to medical devices. *See* Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402 (Fed. Cir. 1989).

[190] Rowe, *supra* note 26, at 293–94.

[191] *Id.* at 294.

[192] *Id.*

[193] *See* Michael D. Witt & Susan K. Lehnhardt, *Transferring Innovations from Academic Research Institutions to Industry: Overview*, *in* 2 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY, *supra* note 153, at 1081, 1082.

institutions, academic research centers have traditionally pursued educational and basic research.[194] As federal support for research has decreased, the private-public collaborative effort has grown.[195] Consequently, universities are encouraged to target commercializable products over purely philosophical endeavors.[196] The pursuit of profit, however, might occasionally seem in conflict with an academic institution's mission to further progress and learning if the institution decides to focus on pure money-making projects instead of groundbreaking high-risk research.[197] Accordingly, private gain can at times work against the greater good of creating useful technologies.[198] Conversely, pursuing private gain also encourages the pursuit of products that might actually become available to the public as opposed to less productive research.[199] To balance these conflicting policies, universities must have incentives to pursue practical research and, at the same time, incentives to pursue groundbreaking research at the cost of profit. At the same time there must also be a balance between the incentives awarded to universities and the industry's ability to continually invest and compete.[200]

The experimental use exception provides an important incentive for universities to continue to improve the progress in an area of biopharmaceutical research. The CAFC at times, however, appears to be at odds with the congressional intent to encourage private-public collaboration through the exception. In *Merck KGaA v. Integra Lifesciences I, Ltd.*, the Supreme Court bolstered the Hatch-Waxman research exception, overturning the CAFC's narrow reading.[201] The Court interpreted § 271(e) as encompassing *all* research that is "reasonably related" to possible submissions under federal law and not merely research for generic products.[202] In another CAFC case, *Madey v. Duke University*, the court essentially

[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] *Id.* at 1082–83.
[198] *Id.*
[199] Witt & Lehnhardt, *supra* note 193, at 1082–83.
[200] *See infra* notes 333–47 and accompanying text.
[201] 545 U.S. 193 (2005); *see* Rowe, *supra* note 26, at 295. The CAFC would have excluded "(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA" from the § 271(e) safe harbor. *Merck*, 545 U.S. at 206. Effectively, the CAFC wanted to limit § 271 safe harbor to only generic products. *Id.*
[202] *Merck*, 545 U.S. at 206–07.

eliminated the common law experimental use exception for academic and other non-profit institutions.[203] The court held that even though universities often promote research projects that have "arguably no commercial application whatsoever," these projects still "further the institution's legitimate business objectives" through reputational benefits, the lure of research grants, and additional students and faculty.[204] Accordingly, academic institutions will rarely satisfy the experimental use exception unless they are performing § 271(e) biopharmaceutical research.[205] In light of these two cases, biopharmaceutical research provides a unique investment opportunity for private investors looking to tap into academic research institutions.

Overall, Bayh-Dole and Hatch-Waxman have fostered private-public collaboration. In general, however, the goals of private industry are to seek a profit, while the goals of university research are primarily to promote the pursuit of educational interests and high-cost groundbreaking research.[206] Accordingly, even though Bayh-Dole and Hatch-Waxman have largely been positive for biotechnology innovation, a significant imbalance occurs between the two sides if universities performing research are awarded too much protection against infringement and are granted broad patents for basic research.[207] Furthering the imbalance, universities rarely attack each other's patents or research.[208] A possible indicator of a growing imbalance is the fact that universities have begun winning large infringement suits against commercial companies in the pharmaceutical industry.[209] If universities receive broad patents for basic research, the biotechnology industry would likely face significant hurdles to its own research due to increased costs to either

[203] 307 F.3d 1351 (2002). The *Madey* case was an infringement action brought by Professor Madey, a former professor at Duke. *Id.* at 1361–62. The CAFC found Duke liable for using Madey's laser once Madey was no longer at Duke. *Id.*

[204] *Id.* at 1362.

[205] Rowe, *supra* note 26, at 293.

[206] Witt & Lehnhardt, *supra* note 193, at 1082.

[207] *See* Burk & Lemley, *supra* note 22, at 1611–13.

[208] *See* Rowe, *supra* note 26, at 301–04. Rowe notes that universities have little to gain by suing each other and much to lose. *Id.* at 298. A suit will fail if the infringing university is working purely for research and public universities have certain immunities from infringement suits altogether. *Id.* at 304 (citing Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 647–48 (1999)). Further, suing another university brings bad publicity and discourages collaborative projects with the attacking university and others, including the commercial industry. *Id.* at 303–04.

[209] *See* Rowe, *supra* note 27, at 301–04.

obtain licenses or settle infringement suits with universities.[210] Additionally, as basic research in particular is difficult to discover until disclosed, companies would have an even more difficult time knowing what patent they may have infringed upon.[211]

If the industry as a whole is to maintain its success, courts must find ways to preserve the balance between public and private research entities and limit the negative impact of broad biotechnology patents within the current system. The *Ariad* decision and the court's modern application of the written description requirement exemplify the CAFC's willingness to directly address these issues.[212] The *Ariad* case involved a number of extremely broad method claims included in a patent owned jointly by university researchers and the biotech company Ariad Pharmaceuticals.[213] Overall, the discovery was groundbreaking and tremendously helpful to other researchers.[214] The claims at issue, however, were more of a prediction of where the technology would progress as opposed to an actual product.[215]

In *Ariad*, the CAFC recognized that in unpredictable fields like biotechnology, improperly granted overbroad patents are of particular concern, and thus a high level of scrutiny is required.[216] Requirements that rely on the level of technology in the field, enablement in particular, may not catch every improper broad patent. The CAFC thus used the written description requirement to simplify its inquiry. Because Ariad did not include enough specific examples to identify its broad claims, the claims were invalid for failure to satisfy the written description requirement.[217] If private-public collaboration is to be encouraged, and the congressional intent of the Bayh-Dole and Hatch-Waxman Acts furthered, there must be greater protection for entities that are able to fully invest in developing a finalized product.[218] Following the trend dating back to *Evans*, *Morse*, and the more recent *Lilly* decision, the CAFC in *Ariad* used the written description requirement as a separate and distinct inquiry from the enablement requirement to provide this additional

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[210] *Id.* at 301.

[211] *Id.* at 309.

[212] *See* Ariad Pharm., Inc., v. Eli Lilly & Co., 598 F.3d 1336, 1358–60 (Fed. Cir. 2010) (Newman, J., concurring).

[213] *See infra* notes 228–31 and accompanying text.

[214] *See infra* notes 232–38 and accompanying text.

[215] *See infra* notes 236–48 and accompanying text.

[216] *See infra* notes 278–99 and accompanying text.

[217] *See infra* note 255 and accompanying text.

[218] *See* discussion *infra* Part V.

protection.[219] In order to fully understand how this requirement provides the necessary protection, the following section provides an in-depth look into the *Ariad* case. The following part looks at the CAFC's justifications for its holding and discusses why the court's use of the written description requirement was appropriate. Further, it discusses how the opinion specifically applies to certain biotechnology claims.

IV. *ARIAD V. ELI LILLY*

In order to manage the problematic rise in overbroad patents in biotechnology, the CAFC in *Ariad* reemphasized the need for a separate and distinct written description requirement as applied to original claims.[220] Thirteen years after the court's controversial reassertion of the requirement in *Lilly*, the CAFC finally weighed in *en banc* on the separate purpose and scope of the written description requirement. In *Ariad*, the court analyzed two key issues: "(1) [w]hether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement" and "(2) [i]f a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement."[221] The court came to the ultimate conclusion that the written description requirement is a separate and distinct requirement for patentability and that when claiming a broad generic invention, an inventor must show he has invented a sufficient number of species to support a broader claim.[222]

The *Ariad* case involved an allegation of patent infringement of U.S. patent 6,410,516 by, among other parties, Ariad Pharmaceuticals, Inc., against Eli Lilly & Company.[223] Ariad originally sued in the United States District Court for the District of Massachusetts.[224] At trial, a jury found infringement and did not invalidate any of the asserted claims in the patent.[225] On appeal, a panel of CAFC judges "reversed the district court's denial of Lilly's motion for judgment as a matter of law and held the asserted claims

[219] Ariad Pharm., Inc., v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010).
[220] *Id.* at 1336.
[221] *Id.* at 1342.
[222] *Id.* at 1349.
[223] *Id.* at 1340.
[224] *Id.*; *see* Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106, 112 (D. Mass. 2007).
[225] *Ariad*, 598 F.3d at 1340.

invalid for lack of written description."[226] The CAFC then accepted Ariad's petition for a rehearing en banc regarding the interpretation of § 112 and the written description requirement.[227]

Ariad alleged that two of Eli Lilly's "pharmaceutical products" infringed on several claims in Ariad's patent.[228] The overall scope of the claims effectively included "the desired result of reducing the binding of NF-K[B] to NF-[K]B recognition sites" without specific examples as to how this reduction was to be accomplished.[229] NF-[K]B is an inactive protein[230] found in many different cell types.[231] If NF-[K]B is activated through external stimuli, including diseases like cancer and AIDS, it travels and binds to other cells causing the cells to create proteins that help them survive against the infection.[232] While the NF-[K]B's primary purpose appears to be beneficial, the

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[226] *Id.*

[227] *Id.*

[228] *Id.* The claims were as follows:

> 80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-[K]B-mediated intracellular signaling, the method comprising altering NF-[K]B activity in the cells such that NF-[K]B-mediated effects of external influences are modified, wherein NF-[K]B activity in the cell is reduced] wherein reducing NF-[K]B activity comprises reducing binding of NF-[K]B to NF-[K]B recognition sites on genes which are transcriptionally regulated by NF-[K]B.
> 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-[K]B-mediated intracellular signaling, the method comprising reducing NF-[K]B activity in the cells such that expression of said genes is reduced], carried out on human cells.
> 144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-[K]B activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-[K]B activity comprises reducing binding of NF-[K]B to NF-[K]B recognition sites on genes which are transcriptionally regulated by NF-[K]B.
> 145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-[K]B activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

Id. at 1340–41.

[229] *Id.* at 1341; *see also infra* notes 236–48 and accompanying text.

[230] NF-[K]B is inhibited by a specific protein, "I[K]B" or "Inhibitor of kappa B." *Ariad*, 598 F.3d at 1340.

[231] Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106, 112 (D. Mass. 2007).

[232] Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1369–70 (Fed. Cir. 2009).

protein becomes harmful to the host if it is produced in excess.[233] Accordingly, any method that reduced the binding of NF-[K]B to NF-[K]B recognition sites, and thereby limited the production of the activated proteins, would have "enormous and wide-ranging therapeutic effects."[234] Ariad was not only the first to identify NF-[K]B, but also the first to discover the "mechanism" by which NF-[K]B is activated and responds to infections.[235] Despite Ariad's breakthrough discovery, it did not, at the time of filing, discover a specific method for achieving its desired result of reducing NF-[K]B activity.[236] Ariad disclosed three possible molecules that could "potentially" reduce NF-[K]B activity: specific inhibitors, dominantly interfering molecules, and decoy molecules.[237]

Regarding these molecules, first, Ariad listed only I-[K]B[238] as a specific inhibitor; however, Ariad only noted that if one of ordinary skill were to isolate natural I-[K]B, he could reduce NF-[K]B.[239] Isolation of I-[K]B would require further experimentation.[240] Ariad's "invitation for further research" showed that it did not have "possession" of a method to reduce NF-[K]B through specific inhibitors.[241] Second, Ariad failed to disclose a single "dominantly interfering molecule."[242] Ariad also admitted that it did not necessarily know how to create a specific dominantly interfering molecule.[243] Thus, Ariad was not in "possession" of the claimed method of reducing NF-[K]B through dominantly interfering molecules. Finally, Ariad did in fact disclose structural examples of "decoy molecules."[244] But, Ariad failed to describe the binding of

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[233] *Ariad*, 598 F.3d at 1340.

[234] *Ariad*, 529 F. Supp. 2d at 112.

[235] *Ariad*, 598 F.3d at 1340.

[236] *See Ariad*, 598 F.3d at 1355–58; *supra* note 10 and accompanying text.

[237] *Ariad*, 598 F.3d at 1355; *see also infra* notes 238–47 and accompanying text.

[238] I-[K]B occurs naturally in the body and keeps NF-[K]B inactive until the cell receives external influences, such as infections. *Id.* at 1356.

[239] *Id.*

[240] *Id.*

[241] *Id.*

[242] *Id.* A dominantly interfering molecule is in effect part of an NF-[K]B molecule which would bind in place of NF-[K]B but not have the negative properties of NF-[K]B. *Id.*

[243] *Id.*

[244] *Ariad*, 598 F.3d at 1357. Decoy molecules are different molecules from NF-[K]B that would "mimic" NF-[K]B and bind in place of NF-[K]B receptors, thereby blocking the binding of the NF-[K]B molecules themselves. *Id.*

these decoy molecules or whether or not they would be effective.[245] After analyzing all three of Ariad's claimed methods for reducing NF-[K]B, the court concluded that the claims merely described general molecular structures and hypothesized how they might reduce NF-[K]B activity.[246] Ariad's claims, covering nearly any method to reduce NF-[K]B, were significantly broader than anything it had disclosed, and therefore the claims were invalid for failure to satisfy the written description requirement of § 112.[247]

Before specifically analyzing Ariad's claims under the written description requirement, the court first had to answer Ariad's assertion that the written description requirement, as articulated by the CAFC, was not separate from the enablement requirement.[248] The court would then have to establish the scope of the written description requirement before going forward with analyzing the claims themselves.[249] To address the first issue, the court looked to the language of § 112, Supreme Court precedent, stare decisis, the CCPA case *In re Ruschig*,[250] the application of the written description requirement to original claims, and finally, to its own precedent.[251]

First, the CAFC looked to the language of § 112 to determine the meaning of the written description requirement as separate from the enablement requirement.[252] Again, the relevant statutory text is as follows:

> 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 . . . to make and use the same.[253]

Ariad argued that the statute merely required a written description "(i) of the invention, and (ii) of the manner and process of making and using it," which should be "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use

[245] *Id.* The court noted that "there is no descriptive link between the table of decoy molecules and reducing NF-[K]B activity." *Id.*

[246] *Id.* at 1358.

[247] *Id.*

[248] *Id.* at 1342.

[249] *Id.*

[250] *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).

[251] *Id.* at 1342–51.

[252] *Ariad*, 598 F.3d at 1343.

[253] 35 U.S.C. § 112 (2006); *see also Ariad*, 598 F.3d at 1343.

the same."[254] Thus, Ariad's reading merged the written description requirement and the enablement requirement. The court, however, disagreed with this reading and confirmed that the specification must contain (i) a written description of the invention and (ii) a written description of the manner and process of making and using the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."[255] The court further explained that the written description requirement has been "expressly" included in the Patent Act as early as 1793.[256] The court noted that Congress has never indicated any intention to remove or amend the requirement despite numerous recodifications of the Patent Act.[257] Finally, the court also noted that the separate written description requirement has been a staple of the "quid pro quo" of patent law where one must describe what his invention is.[258] Without this description, the public would not know an inventor possessed his claimed invention, and it would not know the breadth of the patent and whether or not it was infringing on the patent.

Second, the CAFC examined Supreme Court precedent and agreed with Lilly's argument that the Supreme Court has "continually confirmed the existence of a separate written description requirement."[259] The CAFC looked to *Morse*, noting that the Court rejected the inventor's broad claim because he had not described and could not show possession of the process that he was claiming, which indicated that he had not invented what he claimed.[260] Looking to *Schriber-Schroth Co. v. Cleveland Trust Co.*, the CAFC discussed the Supreme Court's post-1836 interpretation of § 112.[261] In *Schriber-Schroth*, the Court held that § 112 required a patent application to satisfy enablement *and* "to inform the public during the life of the patent of the limits of the monopoly asserted, so that it

[254] *Ariad*, 598 F.3d at 1343 (internal quotation marks omitted).

[255] *Id.* at 1344. Part "(i)" is the written description requirement and part "(ii)" is enablement. *See id.*

[256] *Id.* at 1345.

[257] *Id.*

[258] *Id.*

[259] *Ariad*, 598 F.3d at 1345. (citing O'Reilly v. Morse, 56 U.S. 62 (1853); Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47 (1938); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002)). *Schriber* involved a patent for an improvement of the pistons in a gas engine. *Schriber–Schroth* , 305 U.S. at 57. The Court examined an amendment to the patent that described "flexible" webs where the original claim only described "extremely rigid" webs. *Id.* at 54–55.

[260] *Ariad*, 598 F.3d at 1346 (citing *Morse*, 56 U.S. (15 How.) at 113).

[261] *Id.*

may be known which features may be safely used or manufactured without a license and which may not."[262] Finally, the CAFC looked to the more recent *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* decision.[263] The Court in *Festo* noted that a patent application must "describe, enable, and set forth the best mode of carrying out the invention."[264] Further, the Court noted that an inventor's claim must be the same as the disclosed specification.[265] Essentially, the specification cannot be broader than the actual invention. If this is the case, the claims should not issue.[266] Once again, the CAFC reiterated that the purpose of the written description is "to provide notice of the boundaries of the [patentee's] right to exclude and to define limits," or in other words, to "disclose and teach[]."[267]

Third, the CAFC briefly noted that it was obligated to uphold the separate written description requirement under the doctrine of stare decisis.[268] To that end, the court expressed the common

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[262] *Id.*

[263] *Id.* at 1347.

[264] *Festo*, 535 U.S. at 736. The primary issues in *Festo* involved prosecution history estoppel and the doctrine of equivalents. *Id.* at 726. The inventor in *Festo* amended his original claims in order to avoid a rejection from the Patent Office under § 112. *Id.* at 728. The original application contained a method of operation that was "unclear." *Id.* Prosecution history estoppel arises when a patent applicant amends his claims during patent prosecution in order to ensure patentability. *Id.* at 735. When a patent applicant amends his claims, he is estopped from using the doctrine of equivalents with regard to the amended claim in a subsequent infringement suit. *Id.* at 734–35. The doctrine of equivalents is a court-made doctrine that allows a patent to cover not only the literal meanings of a patentee's claims, but also equivalents that a court could infer the patentee intended to cover; it provides the patentee with additional protection. *Id.* at 731–32. *See generally* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605 (1950) (discussing the doctrine of equivalents). Even though these amendments are usually designed to avoid potentially invalidating prior art under 35 U.S.C. § 102, additional reasons will also give rise to prosecution history estoppel. *Festo*, 535 U.S. at 735–36. Amendments designed to obtain patent approval under § 112 will give rise to prosecution history estoppel. *Id.* at 736. If a patentee amends his claims to narrow the scope of his patent, it is possible that he initially claimed more than he was entitled to. *Id.* at 736–37. *Festo* looks to all the potential reasons a claim might not issue or be found invalid during the patent prosecution, including the written description. *Id.* Accordingly, *Festo* supports the CAFC's holding that the written description is not only a separate and distinct requirement but also that it can be used to invalidate overbroad original claims that should not have been issued in the first place. *See* Warner-Jenkinson v. Hilton Davis Chem. Co., 520 U.S. 17, 33 (1997) (holding that a patentee may rebut a presumption of prosecution history estoppel if he shows that the amendments were not substantially related to patentability).

[265] *Festo*, 535 U.S. at 736.

[266] *Id.*

[267] *Ariad*, 598 F.3d at 1347.

[268] *Id.*

sentiment in patent law that, to encourage innovation, the courts should not alter the "settled expectations of the inventing and investing community."[269] This is particularly true regarding claims for biotechnology patents, such as the one in *Ariad*, because the biotechnology industry is particularly susceptible to changes in expectations due to the high-risk nature of investment.[270]

Fourth, the CAFC looked to the 1967 CCPA case *In re Ruschig*.[271] In *In re Ruschig*, the CCPA specifically distinguished written description as a distinct requirement of § 112.[272] The inventors in *In re Ruschig* attempted to amend their broad original claim to include a specific chemical compound that they had not originally disclosed.[273] In rejecting the broad claim, the CCPA explained that enablement was "beside the point."[274] Because the specification failed to describe the specific chemical compound that the inventors were claiming, the inventors clearly did not disclose what they actually invented.[275] Ariad argued that the *In re Ruschig* rejection relied on either enablement or § 132's rejection of new matter.[276] The CAFC, however, interpreted *In re Ruschig* as focusing on the inventor's failure to describe the claim itself, which would have evidenced possession of the invention, not necessarily the subsequent amendments to the claim.[277]

Fifth, the CAFC rejected Ariad's argument that the written description was always satisfied in the original claims because that initial disclosure itself is the written description that must then be used to determine the validity of future amendments.[278] The CAFC,

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[269] *Id.* at 1347; *see* Burk & Lemley, *supra* note 22, at 1668–75; Kelly, *supra* note 7, at 252; *see also* Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) ("In the area of patents, it is especially important that the law remain stable and clear.") (Stevens, J., concurring).

[270] *Ariad*, 598 F.3d at 1343.

[271] *Ariad*, 598 F.3d at 1347.

[272] *In re Ruschig*, 379 F.2d at 995–96.

[273] *Id.* at 991.

[274] *Id.* at 995.

[275] *Id.* at 995–96.

[276] *Ariad*, 598 F.3d at 1348; *see also* 35 U.S.C. § 132 (2006). Section 132 'allows patent examiners to disallow an amendment if a party seeks to add something new to their original claim on reissue. *Id.*; § 251.

[277] *Ariad*, 598 F.3d at 1348. Notably, in *In re Ruschig*, the court explained:

> It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared—or have not yet been made . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

379 F.2d at 994–95.

[278] *Ariad*, 598 F.3d at 1349.

however, quickly noted that there is no statutory language that limits the written description to Ariad's interpretation.[279] The court explained that the written description requirement was necessary to ensure that an inventor actually invented a generic (genus) claim.[280] The disclosure must include a sufficient number of species within the genus or "structural features common to the members of a genus so that one of skill in the art can 'visualize or recognize' the members of the genus" to demonstrate that the inventor actually possessed, or invented, the generic invention.[281] The written description might also be satisfied if, in a functional claim, those in the art can establish a correlation between structure and function.[282] Ariad's claim failed to satisfy the written description because Ariad's method claims described a genus method for accomplishing a result but did not disclose any specific species that would accomplish the desired results.[283]

Finally, the court looked to its own precedent to describe the scope and purpose of the written description requirement.[284] The court articulated its' test for written description as "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."[285] More specifically, one must show "possession as shown in the disclosure" or that a person skilled in the art would know "that the inventor actually invented the invention claimed."[286] Because the written description inquiry is a question of fact, the requirements for each claim will vary depending on '"the existing knowledge in the particular field, the extent and

[279] *Id.* at 1349. The CAFC explained: "[T]he statute does not say 'The specification shall contain a written description of the invention *for purposes of determining priority*.'" *Id.*

[280] *Id.* at 1349–50.

[281] *Id* at 1350 (citing Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568–69 (Fed. Cir. 1997)).

[282] *Ariad*, 598 F.3d at 1350 (citing Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002)). The correlation might be more recognizable as the technology and level of sophistication in the art improves, however the written description would still only be satisfied if those of ordinary skill in the art could see that the inventor actually possessed the full scope of the invention that he claimed.

[283] *Ariad*, 598 F.3d at 1350.

[284] *Id.* at 1351.

[285] *Id.* (citing *In re* Gosteli, 872 F.3d 1008, 1012 (Fed. Cir. 1989)).

[286] *Ariad*, 598 F.3d at 1351 (internal quotation marks omitted).

content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue."[287]

The court further noted that, while specific examples were not always required and that a "constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description," the specification still must demonstrate possession of the invention.[288] Even if an inventor actually possessed an invention, failure to articulate this possession in the specification would prevent the patent from satisfying the written description requirement.[289] The written description requirement must satisfy the purpose of accurately and specifically disclosing the scope of the claim so that there is no confusion as to what the invention is and whether a subsequent invention will infringe upon it. Additionally, the written description requirement ensures that those who actually invent an invention and have it in their possession are awarded the benefits of the patent system.[290] While Ariad argued that a strict written description requirement might hinder basic biotechnology research performed at universities, the CAFC pointed out that the balance between incentive and reward must be maintained.[291] Broad, preemptive claims on inventions not yet invented would have a stifling effect on any industry, and the biotechnology industry in particular.[292]

V. PROMOTING INNOVATION THROUGH *ARIAD*

Overbroad patents stifle innovation in the biotechnology industry.[293] The written description requirement can further innovation by limiting overbroad patents on a basic level by requiring the actual description of a patent to outline the scope and purpose of an invention.[294] Currently, the extent of the impact of the written description requirement as articulated in *Ariad* remains unclear.[295] By placing limits on original claims, however, the written description

[287] *Id.* (quoting Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005)) (internal quotation marks omitted).

[288] *Ariad*, 598 F.3d at 1352.

[289] *Id.*

[290] *Ariad*, 598 F.3d at 1353. For a description of the trade-offs of the patent system's exclusive rights, see *supra* Part I.

[291] *Ariad*, 598 F.3d at 1353.

[292] *Id.* at 1353–54.

[293] *See infra* notes 323–41 and accompanying text.

[294] *See infra* notes 311–53 and accompanying text.

[295] *See, e.g.*, Crouch, *supra* note 109, at 396–97; Holman, *supra* note 79, at 80–81.

requirement could have its largest impact on an inventor's decision whether to patent a claim.[296] Additionally, the requirement encourages inventors to finalize their inventions and pursue an end product before seeking patent protection and public disclosure. Through these methods, the CAFC's requirement seems to be a positive step towards limiting the problems associated with patents in the biotechnology industry.

Critics of written description argue that the *Ariad* standard is merely an excessive and mutated form of the enablement requirement, or a "super enablement" requirement.[297] As Professor Christopher Holman noted in his discussion of *Lilly*, "[t]he court appears to be requiring a precise, nucleotide-by-nucleotide recitation of chemical structure . . . while enablement merely requires a 'reasonable correlation' between the scope of disclosure and the scope of the claims."[298] Holman argues that to meet the "super enablement" requirement, certain biotechnology genus claims must include a "structure-based definition" which can only be satisfied by describing a '"representative number' of structurally defined examples" or by describing "common structural features."[299] Holman further argues that recent enablement and written description jurisprudence shows no indication that there is a meaningful distinction between these two doctrines.[300] Essentially, Holman argues that every claim that fails to satisfy the written description requirement would also fail to satisfy the enablement requirement.[301] Thus, Holman's primary stance is that the written description requirement has not been sufficiently separated from enablement since *Lilly*.[302] Other studies seem to support Holman's assertions.[303]

Overall, the primary arguments against the written description requirement are that it is too strict and that it is not sufficiently separated from the enablement requirement.[304] Contrary to Professor

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[296] *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 840–41 (2001).

[297] *See* Holman, *supra* note 79, at 17; *see also Regents Amicus Brief*, *supra* note 4, at 15–16.

[298] Holman, *supra* note 79, at 15.

[299] *Id.*

[300] *Id.* at 80.

[301] *Id.* at 78.

[302] *Id.* at 80; *see also* Brief for Christopher M. Holman, Inc. as Amicus Curiae Supporting Neither Party, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (No. 02-CV-11280) [hereinafter Holman Amicus Brief].

[303] *See* Crouch, *supra* note 109.

[304] *See, e.g.*, *Regents Amicus Brief*, *supra* note 4, at 8–10; Holman, *supra* note 79, at 15.

Holman's assertions, a reasonable distinction between the enablement and the written description requirements seems apparent: enablement is necessary to ensure that a person of reasonable skill in the art can make and use the invention by reading the claims, while the written description requirement provides notice to the public about what the invention is. Since the first Patent Act, the written description requirement and the enablement requirement have stood side-by-side as equally important but separate patent provisions.[305] As innovations in the biotechnology industry become increasingly complex, additional detail in patent claims is required to outline the scope of an invention. Otherwise, patents that are easily enabled by improving technology but, at the time of filing, are not the true scope of the inventor's actual invention may be approved.

The most recent U.S. Patent Office guidelines highlight how the written description requirement is separate from enablement and adequately limits the scope of biotechnology inventions.[306] One example in the guidelines discusses a hypothetical claim for "[a]n isolated antibody capable of binding to antigen X."[307] The guidelines note that this claim would satisfy the written description requirement even if the antibody were not described; it was essential that the antigen would be described in detail.[308] Because there are only a small number of antibodies capable of binding to antigen X and because the process to obtain these antibodies is routine, a person of ordinary skill in the art would know that the claimant would easily be in possession of the antibodies.[309] This narrow claim appropriately includes the inventor's actual invention and shows that the inventor had possession at the time of filing.[310]

Broad claims, on the other hand, require additional scrutiny. In another example, the USPTO guidelines list two separate written descriptions[311] that relate to a claim for "[a]n isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity X."[312]

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[305] *See supra* notes 1–2, 13–19 and accompanying text.

[306] U.S. PATENT & TRADEMARK OFFICE, WRITTEN DESCRIPTION TRAINING MATERIALS (2008), *available at* http://www.uspto.gov/web/menu/written.pdf.

[307] *Id.* at 45.

[308] *Id.* at 45–46.

[309] *Id.*

[310] *Id.*

[311] They are labeled "Specification" in the guidelines. *Id.* at 37, 39–40.

[312] U.S. PATENT & TRADEMARK OFFICE, *supra* note 311, at 37, 40.

Specification B includes two specific locations in the sequence that account for activity X and conservatively predicts that most mutations of the sequence will not impact that activity.[313] Specification A contains no such information.[314] While both descriptions enable a person of ordinary skill in the art to make and use the sequence that produces activity X,[315] only specification B indicates that the inventor possessed the broad claim of sequences with at least eighty-five percent sequence identity that could still produce activity X.[316] Specification B removes the chance that an inventor will be awarded a broad patent merely on an assumption that similar sequences will produce the same function as the disclosed sequence. As in *Ariad*, the inventor must finalize his invention by disclosing a specific correlation between the structure and function of his claims. A broad patent should not be granted merely because an inventor lists a few examples that will likely result in a desirable function, even if those examples are enabling.

Through *Ariad*, the CAFC has taken a positive step towards negating the problematic overexpansion of patents in the biotechnology industry. By enforcing the written description requirement, the CAFC encourages actual invention and stifles broad patent claims. While other recent Federal Circuit restrictions on biotechnology patents may directly stifle research the written

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[313] *Id.* at 39–42.

[314] *Id.* at 37.

[315] The inventors would be able to use a computer to identify all the sequences that have eighty-five percent sequence identity with the disclosed sequence. *Id.* at 38.

[316] *Id.* at 39–42. This example is described in the *Ex parte Kubin* at the time when it was before the Board of Patent Appeals and Interferences. *Ex parte* Kubin, 83 U.S.P.Q.2d 1410 (B.P.A.I. 2007). In *Ex parte Kubin*, the patentee claimed a sequence that had the function of binding to the protein CD48. *Id.* at 1412. The claim, however, was a broad genus claim that included all sequences having "at least 80%" sequence identity. *Id.* at 1417. Following *Johns Hopkins*, the court concluded that enablement would have been satisfied because "the amount of experimentation to practice the full scope of the claimed invention . . . would have been routine." *Id.* at 1416 (citing Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998)). The written description requirement, however, was not satisfied because the patentee did not disclose sufficient working variations of the claimed sequence that could maintain the function of binding to CD48. *Id.* at 1417. The court made its conclusion based on prior federal circuit case law, which later led to the en banc *Ariad* decision. *Id.* at 1416 (citing Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004); Enzo Biochem., Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002); Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Fiers v. Revel, 984 F.2d 1164, (Fed. Cir. 1993)). Notably, the court also rejected the claim under § 103 for obviousness. *Id.* at 1415. A subsequent federal circuit ruling affirmed the obviousness rejection and accordingly did not need to address the written description rejection. *In re* Kubin, 561 F.3d 1351, 1361 (Fed. Cir. 2009).

description doctrine itself will neither stop nor slow down research at universities.[317] Rather, because the written description requirement protects actual invention through full investment over theoretical research at its early stages, the industry should be further encouraged to invest in both basic research at universities, which can still lead to profitable breakthroughs, and in specific products that will actually have practical use when released to the public.[318] Eventually, once these products are fully disclosed, further research can be performed without concerns about infringement, and the successful patentee will have the benefit of his completed invention.

Restrictions on broad patents and a strict written description requirement should lead to more detailed disclosures, appropriately awarding actual invention. When inventions are appropriately awarded, investors know that they have a fair chance to earn a return on their investment and thus would be encouraged to partner with university researchers. These restrictions, however, can sometimes have the opposite effect. One significant problem is the increasing tendency of universities and researchers to withhold disclosure of their research until they have completed their inventions.[319] Increased funding from pharmaceutical companies can put pressure on academic researchers to avoid releasing information that might hurt the companies financially.[320] Academic researchers are motivated by a desire to publish their findings.[321] Accordingly, a conflict of interest arises when those researchers are contractually obligated to withhold information in order to receive funding from a commercial company.[322] While *Ariad* does not seem to directly address this issue, it promotes innovation by resolving similar conflicts that have emerged since the enactment of Bayh-Dole between industry and university research.

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[317] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09-Civ.-4515, 2010 U.S. Dist. LEXIS 35418, at *147–16 (S.D.N.Y. Apr. 5, 2010); Moore, *supra* note 164, at 158–61 (explaining how the CAFC's restrictions on the experimental use doctrine have severely limited its potential and possibly even removed its viability altogether).

[318] *See also* Michael J. Remington, *The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future*, 17-1 J. ASS'N U. TECH. MANAGERS 1, 14 (2005), *available at* http://www.drinkerbiddle.com/files/Publication/e225136e-6ac8-476a-b11c-01cde4b795be/Presentation/PublicationAttachment/98997d01-1def-4dd9-9f68-026d2d0faa4f/Remington_AUTM.pdf.

[319] JEREMY RIFKIN, THE BIOTECH CENTURY 56 (1998).

[320] *See, e.g.*, *In re* Synthroid Mktg. Litig., 201 F. Supp. 2d 861 (N.D. Ill. 2002).

[321] *See* Witt & Lehnhardt, *supra* note 193, at 1086.

[322] *Id.*

Similar conflicts arise when biotechnology companies, seeking a return on their investment, refuse to license essential research tools.[323] A recent case involving the biotechnology company Myriad Genetics exemplifies potential problems and potential court-offered solutions.[324] In *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, Myriad held crucial patents over certain gene sequences that are linked to breast and ovarian cancer.[325] Myriad's patents also covered any diagnostic or therapeutic use of the genes.[326] Due to Myriad's refusal to license its patents, patients who needed genetic sequencing of their tissue samples to screen for the mutations were required to send all samples to Myriad.[327] Screening for the mutation is an essential step in detecting and treating the highly frequent form of cancer that the mutation causes.[328] The negative

[323] *See* Schmieder, *supra* note 135, at 180–81.

[324] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09-Civ-4515, 2010 U.S. Dist. LEXIS 35418, at *1–2 (S.D.N.Y. Apr. 5, 2010). The controversy in this case primarily focused on the patentability of isolated DNA sequences and not specifically on the written description requirement. *Id.* at *3. The policy concerns surrounding the case, however, are similar to those presented to the biotechnology industry with regard to patent protection. For a more in depth look at the Myriad controversy, see, e.g., Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 Food Drug L.J. 133 (2004).

[325] The genes where the mutations are located are called BRCA1 and BRCA2. *Id.* at *56–57.

[326] *See id.*; *see also* Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257, 2296 (2010).

[327] Bernstein, *supra* note 326, at 2296.

[328] *See Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 35418, at *55–58. Discussing the importance of the Myriad screening test, the court noted:

> Women with *BRCAl* and *BRCA2* mutations face up to an 85% cumulative risk of breast cancer, as well as up to a 50% cumulative risk of ovarian cancer. In addition, among the 10-15% of ovarian cancer cases that are inherited genetically, 80% of women diagnosed under the age of 50 carry mutations in their *BRCAl* genes and 20% carry mutations in their *BRCA2* genes. . . . Male carriers of mutations are also at an increased risk for breast and prostate cancer. . . . The existence of *BRCA1/2* mutations is therefore an important consideration in the provision of clinical care for breast and/or ovarian cancer. A patient will not only learn of her risk for hereditary breast and ovarian cancer, but also can gain information that may be useful in determining prevention and treatment options. This information is useful for women who are facing difficult decisions regarding whether or not to undergo prophylactic surgery, hormonal therapy, chemotherapy, and other measures. Testing results for the *BRCA1/2* genes can be an important factor in structuring an appropriate course of cancer treatment, since certain forms of chemotherapy can be more effective in treating cancers related to *BRCA l/2* mutations.

consequences of Myriad's refusal to license were felt by both individual patients[329] and researchers who examine the genes.[330] The latter, unable to perform the screenings independently, were restricted in their ability to improve upon the existing technology, correct errors by Myriad, or discover additional mutations.[331] Researchers at the University of Pennsylvania and the Yale DNA Diagnostics Laboratory are two of a number of research institutions whom Myriad forced to cease BRCA genetic testing.[332] In order to correct the negative consequences of the Myriad patents, Judge Sweet in the Southern District of New York held that patents on genetic sequences similar to the Myriad patents are categorically unpatentable subject matter under § 101.[333]

Judge Sweet's ruling appears to be a potential solution to Myriad's attempt to hinder further innovation. But while the negative impact to further innovative research, particularly at universities, seems apparent in the *Association for Molecular Pathology* case, the reality is far more complex. Much of Myriad's research was performed in conjunction with universities, primarily the University of Utah.[334] Further, Myriad collaborated with, and received significant funding from, the U.S. government for its research.[335] Similarly to *Ariad*, public entities who currently receive little financial benefit from patents funded and performed much of the groundbreaking research that led to Myriad's patented gene.[336] If, however, private companies that do not receive significant federal support are unable to recover their investments through patent protection, the incentive for these companies to invest in high-risk yet groundbreaking research like the BRCA project would be greatly diminished.[337] Despite Myriad's questionable actions, overall research

Id. at *56–57 (internal citations omitted).

[329] Many patients could not afford the screening test, even if their treatment providers had the capability to perform the screening. *Id.* at *58–61.

[330] *Id.* at *58–61, *75–83.

[331] *Id.* at *65. Some labs even had access to better technology than Myriad and could perform "more comprehensive testing than Myriad's standard testing services." *Id.* at *66.

[332] *Id.* at *61–64.

[333] *Id.* at *147–64.

[334] *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 35418, at *51–52.

[335] *Id.* at *50–54.

[336] *Id.* at *53–54. The federal researchers involved in the BRCA1 research were excluded as co-inventors of the BRCA1 patents and Myriad has not paid royalties to other parties. *Id.*

[337] *Id.* at *27.

would likely be hindered more than it would be promoted if companies like Myriad were to be refused patents for finalized inventions.

Unlike the categorical ban on the genetic sequence patent in the *Association for Molecular Pathology* case under § 101, the *Ariad* decision maintains a better balance between preventing companies like Myriad from abusing broad or crucial patents, while at the same time allowing investors in biotechnology research to recover their investments for finalized products. The written description requirement gives courts the discretion to decide if a broad patent is rightfully obtained and actually possessed, or if a claim is merely an attempt to predict where research will go in the future and prematurely corner the market.[338] For example, in 2000, Human Genome Sciences Incorporated (HGS) was awarded a patent for an important gene related to identifying and eventually treating HIV.[339] At the time of filing, HGS was unaware of the many functions and the general utility of the gene.[340] To identify the gene, HGS used computer analysis to generally predict the utility of the gene and its function.[341] Shortly after HGS received its gene patent, several independent researchers demonstrated the actual function of the gene as it related to the HIV virus.[342] Unlike Myriad, however, HGS has allowed universities to perform unlicensed research on the gene, and is involved in several licensing agreements.[343] In situations like the HGS gene patent where courts—other than the *Association for Molecular Pathology* court—have been unwilling to use § 101 to limit broad predictive biotechnology patents,[344] the written description requirement may provide a solution. A court could look to a broad claim for a multi-functioning gene and use the written description requirement to appropriately limit the scope of the patent or invalidate it altogether upon a finding that the patentee did not truly posses the actual invention that he is claiming. The written description requirement curbs abuse of the patent system while

[338] *See supra* notes 278–99 and accompanying text.

[339] *See* Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1661–62 (2001).

[340] *Id.* at 1625–26.

[341] *Id.* at 1625 n.11.

[342] *Id.* at 1625–26. Additional functions were also later identified. *Id.*

[343] Richard Li-dar, *Biomedical Upstream Patenting Scientific Research: The Case for Compulsory Licensing Bearing Reach-Through Royalties*, 10 YALE J. L. & TECH. 251, 273 (2008).

[344] *See* Gitter, *supra* note 339, at 1662; Wang, supra note 343, at 272–73.

avoiding categorical bans on biotechnology patents that are essential to promoting further private-public collaboration and future innovation.

In addition, even if the written description requirement furthers the incentive for universities to withhold research for their corporate investor until the research is completed (and it seems unclear if this is a significant problem at all), the end result includes a finalized product by the researchers and increased confidence for investors. It would be much more problematic to grant broad patents prematurely to universities that are neither tied to industry nor supported by adequate funding, who then might refuse to license essential research technologies.[345] Such a policy would greatly lower the industry's incentive to continue funding research at universities or other research institutions. A possible middle ground may involve allowing entities like Ariad to somehow share in the rewards of the finalized product that results from the groundbreaking discovery.[346] The written description requirement could accomplish this goal by encouraging researchers to develop narrower patents that they can license for more reasonable fees, as opposed to the excessive charges that can result from broad patents that corner too much of the market. Lowering overall costs should encourage greater investment and provide further opportunity for public-private collaboration.

The intent of the Bayh-Dole and Hatch-Waxman Acts is to encourage innovation through public-private collaboration, primarily by tapping into university research.[347] If the system focuses too greatly on obtaining patents for profit and less on promoting cooperative research, innovation will be stifled. Under the Bayh-Dole Act, researchers at federally funded universities continue to have an obligation to disclose their work.[348] Knowing of this disclosure obligation, the biotechnology industry has continued to invest in university research, and technology transfer at universities also continues to grow.[349] Even with potential conflicts between the entities, universities and the biotechnology industry are still

[345] *See* Schmieder, *supra* note 135, at 180–81.

[346] *See, e.g.*, Carol M. Nielsen & Michael R. Samardzija, *Compulsory Patent Licensing: Is it a Viable Solution in the United States?*, 13 MICH. TELECOMM. & TECH. L. REV. 509 (2007); Simone A. Rose, *On Purple Pills, Stem Cells, and Other Market Failures: A Case for a Limited Compulsory Licensing Scheme for Patent Property*, 48 HOWARD L.J. 579 (2005).

[347] *See supra* notes 151–83 and accompanying text.

[348] *See* Witt & Lehnhardt, *supra* note 193, at 1082.

[349] *See, e.g.*, Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, 2 SCIENCE TRANSLATIONAL MED. 52, Oct. 6, 2010, *available at* http://stm.sciencemag.org/content/2/52/52cm27.full.pdf.

interdependent[350] when it comes to biotechnology research.[351] The written description requirement articulated in *Ariad* shows the CAFC is aware of the negative incentives associated with overbroad patents, particularly those for DNA.[352] Granting overbroad patents for unidentified DNA sequences, particularly those whose function may vary greatly, would hinder innovation. As in the *Ariad* case, companies like Ariad would be able to prevent others from completing the necessary research to develop an actual product for the described concept.

The relationship between the three major players in the development of biotechnology—the government, the private industry, and the universities—has been described as "antagonistic" and at the same time "cooperative and even symbiotic."[353] For this reason, maintaining a balance between encouraging basic research and promoting patent protection to recoup profits is a difficult task.[354] If universities obtain more power to protect their broad basic research, there will be fewer opportunities for private industries to invest. Accordingly, there would be a negative impact on universities if they were to oppose the interests of the pharmaceutical industry to develop finalized workable products. Further, public funding and the academic researchers' desire to advance in their field preserve the potential to develop breakthrough products.[355] Similarly, groundbreaking discoveries will always provide universities with reputational benefits, which draws additional investors, students, and distinguished faculty members.[356] While Congress designed the Bayh-Dole and Hatch-Waxman Acts to give researchers further incentive to perform high-risk biotechnology research, the benefits presented

[350] Research universities rely on investment and funding to support further academic research, while the biotechnology industry relies on the manpower and risk management of universities to complete complex research projects. Brief for the Biotechnology Industry Organization and the Association of University Technology Managers as Amicus Curiae Supporting Respondent, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 2010 U.S. App. LEXIS 24248 at *24–26 (Fed. Cir. Filed Nov. 23, 2010) (No. 2010-1406).

[351] *Id.*

[352] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349–53 (noting that *Ariad* illustrates the problems associated with generic claims, particularly those in the "biological arts," and how these broad patents, merely by describing a function, cover compounds that are only later "actually invented" through the subsequent work of the pharmaceutical industry); *Id.* at 1358–59 (Newman, J., concurring).

[353] *See* Golden, *supra* note 153, at 131.

[354] *Id.* at 135–36.

[355] *Id.* at 148–51.

[356] Madley v. Duke Univ., 307 F.3d 1351, 1362 (2002).

have always been for meaningful discoveries that actually contribute to innovation.[357]

To that end, the *Ariad* decision is a step in the right direction to fix some of the imbalances arising from the current trends in the biotechnology industry and biotechnology patents. Disclosure continues to be an essential requirement of university-funded research,[358] and the written description requirement in *Ariad* requires a specific disclosure of the patented invention.[359] A specific DNA sequence, even slightly altered, may have a significantly different function than the claimed invention.[360] A specific description both encourages streamlined research into useful products and discourages inventors who might attempt to game the system by teaching others to make something that the inventor did not yet possess. Accordingly, the written description requirement articulated in *Ariad* gives judges another method to police abuses and promote innovation of the patent system by basic researchers, particularly in biotechnology where patents are so essential to future research.

Ariad merely solidifies the proposition that only those who make meaningful contributions to the useful arts should obtain patents. There is little to suggest that university researchers will avoid performing research if they are restricted to patents on products that they actually invented instead of receiving broad genus patents that may cover discoveries that they have not yet made.[361] If a patent is worthy of a genus claim, it should be granted the rights to that invention and all the benefits that come with it. Because universities have additional legal protection, continue to receive public and private funding, and receive broad discretion with the use of those funds, there is nothing to indicate that they may not allocate those funds to additional research that will lead to breakthrough discoveries and the spoils of that research.[362] Because academic researchers are motivated by financial and personal incentives, a better incentive for research is to allow both motivating factors, the pursuit of knowledge and the pursuit of profit, to co-exist.[363] Without

[357] *See* Moore, *supra* note 164, at 153.

[358] *See supra* notes 182, 319–30 and accompanying text.

[359] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1355 (Fed. Cir. 2010).

[360] *See* Holman Amicus Brief, *supra* note 79, at 12.

[361] *See generally* Regents Amicus Brief, *supra* note 4 (discussing the major benefits granted by Bayh-Dole yet failing to note setbacks since the application of the written description requirement as articulated in *Ariad*).

[362] *See* Rowe, *supra* note 26, at 301–09.

[363] *See* Golden, *supra* note 153, at 153–54.

restrictions on patents like the written description requirement articulated in *Ariad*, the ability for researchers to innovate would be severely restricted by the constant threat of infringement and the over-patenting of inventions not yet invented.

Further, due to the nature of the biotechnology industry, where there is uncertainty today there is unlikely to be uncertainty tomorrow. As the biotechnology industry improves, it should become easier for researchers to disclose the number of species that they actually invented, thus allowing legitimate genus claims. The level of technology, however, is not the focus of the written description requirement. The written description simply looks to the breadth of the claims and determines whether the claimed scope is what the inventor possessed on the day he filed for a patent application. The requirement places less emphasis on what others could accomplish based on the inventor's claims (an expansive enablement approach) but places more pressure on the inventor to fully articulate the boundaries of the invention (a limiting approach). At the same time, inventors are encouraged to provide more detailed disclosure, rewarding the public with more information that other researchers can use for further innovation. Accordingly, with fewer restrictive patents issued and more specific disclosures from university researchers, more opportunities for investment should become available. This will foster further public-private collaboration. Far from discouraging the congressional motivations for Bayh-Dole and Hatch-Waxman, the written description requirement should only encourage researchers to fully develop techniques that identify potentially useful products and mechanisms and to not simply look for an easy way to obtain overreaching patent rights.

VI. CONCLUSION

After *Ariad*, there undoubtedly is a distinct and separate written description requirement in U.S. patent law under 35 U.S.C. § 112. The overall impact of the written description requirement to modern technology, however, is unclear thus far. Regardless, *Ariad* as a whole reasserted the notion that to gain the benefit of the exclusive rights of a patent, an inventor is obligated to specifically describe the invention that was actually invented. This not only maintains the quid pro quo of the patent monopoly but also notifies members of the public of the scope of the invention so that they can avoid infringement. An inventor should only receive a broad patent if the inventor can show that he made the broad discovery and not just a small fraction of what he allegedly claims. The written description

requirement is an essential tool in preventing inventors from abusing the patent system by claiming more than they have a right to claim.

The patent system rewards those who perform their due diligence and actually contribute to the useful arts. In the biotechnology industry, with high risk comes high reward. Through public funding, special protections, and out-of-market motivations, universities are in a unique position to bear the high risk associated with developing novel biotechnology products. Congress acknowledged the need to support such entities by passing the Bayh-Dole and Hatch-Waxman Acts. These Acts sought to promote and continue to promote innovation, particularly in the biotechnology industry. While these Acts have had a positive impact on innovation, the complexity of the technology and the rate at which the technology has advanced make it difficult for the patent system to keep pace. Blocking technologies and excessive costs for licensing are just two of the major problems that arose out of a system that was unable to adequately comprehend the scope and significance of particular inventions.

Ariad and the written description requirement further the intent of the Bayh-Dole and Hatch-Waxman Acts to promote innovation and encourage cooperation between public and private actors. By rewarding actual invention, the Federal Circuit further encourages the symbiotic relationship between the biotechnology industry and universities. Even though some commentators criticize the written description requirement for being a mere extension of enablement and for having a negligible impact, *Ariad* has greater significance for the policies that the requirement advances and its more targeted inquiry. The written description requirement in *Ariad* avoids an inquiry into what others can accomplish based on a disclosure, and instead encourages an inventor to set the specific boundaries of his actual invention. For an unpredictable field like biotechnology, it is important to emphasize limitations as opposed to allowing inventors to advantageously use unpredictability to claim more than they are entitled to. Patents reward invention. Innovation is to be encouraged and not stifled. The detail that the written description requirement mandates not only informs other inventors of the claimed invention so that they can innovate further but also provides the proper incentive to those who work to create a truly useful technology.