WRITTEN DESCRIPTION AFTER *ARIAD V. ELI LILLY*: 35 USC §112'S THIRD WHEEL

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I. Introduction

The United States Constitution provides for the establishment of a patent system in order to promote scientific progress and development.[1] A patent grants the patent owner the right to exclude others from making, using, or selling his or her invention for a limited time in exchange for full disclosure of the invention to the public.[2] When the patent expires, the public can then use, develop, and profit from the information without infringing the rights of the inventor.[3]

The United States patent system reflects an effort to strike a balance between the societal interest in encouraging innovation and the rapid disclosure of this information, and an inventor's reasonable desire to profit from his or her work without having to compete with imitators who did not invest resources to develop the idea.[4] Disclosure to the public is viewed as key to promoting rapid advancement of science and innovation, but because it is often cheaper and easier to be an imitator rather

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1. U.S. CONST, art. 1, § 8, cl. 8. "The Congress shall have the power . . . [to] promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id*.

2. DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 9 (2009) (explaining incentives in filing a patent).

3. *See* BURK & LEMLEY, *supra* note 2, at 10 (articulating the purpose of disclosure when a patent expires).

4. *See* BURK & LEMLEY, *supra* note 2, at 7-8 (explaining the interest balancing implicit in the U.S. patent system).

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than an inventor, a limited monopoly in the form of a patent is the reward an inventor gets for making, and then disclosing, his or her invention.[5] Inventors naturally want to obtain the broadest possible patent protection, but granting broad patent protection can create monopolies on large swaths of information.[6] Broad patent rights granted to one party can limit the number of inventors who can profit by making improvements or new discoveries in an area covered by a broad patent, in turn stifling innovation.[7]

Conversely, exceedingly narrow patent rights can lack economic value because in some cases a competitor can easily design around a narrow patent without infringing it.[8] This is precisely the concern in the biotechnology industry where inventions can be difficult to describe fully, even when enabled, and are easily designed around.[9] Thus, patent protection that is too narrow to be meaningful can also stifle innovation.[10] Innovators in the biotechnology field believe that the current strict interpretation of the written description requirement of 35 U.S.C § 112 will leave them with just that: narrow patents that

5. *See* BURK & LEMLEY *supra* note 2, at 7-8.

6. *See* BURK & LEMLEY, *supra* note 2, at 73-74 (discussing various theories on an ideal incentive system).

7. *See* BURK & LEMLEY, *supra* note 2, at 73-74 (expounding on the idea that overbroad patent rights can limit innovation).

8. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 845 (1990). Narrow rights granted to many parties create patent thickets, which are groups of narrow, overlapping patents that a company must navigate via licensing agreements if they want to produce a technology in an area covered by many narrow patents. *Id.*; *see also* BURK & LEMLEY, *supra* note 2, at 26.

9. *See* BURK & LEMLEY, *supra* note 2, at 87. It is comparatively easy to obtain FDA approval for a generic imitation of a brand name drug. *Id.* All an imitator has to show is that the drug is a bioequivalent of the original drug, whereas the initial manufacturer must survive a long and expensive FDA approval process. *Id.* Similarly, because of the nature of DNA sequences and protein production, minor changes in an isolated cDNA sequence can be cheaply and easily produced without affecting the structure or function of the protein product. *Id.* "[T]he existence of numerous functional equivalents to a particular DNA sequence means that patent protection must be broad enough to effectively exclude simple design-arounds, just a as pharmaceutical patents must be broad enough to cover chemical analogs." *Id*.

10. *See* BURK & LEMLEY, *supra* note 2, at 73-74 (weighing different philosophies for intellectual property rights).

offer little real protection for their intellectual property because the patents are easily designed around or simply ignored.[11]

Despite the dangers associated with a mass of narrow patents, concerns also exist about granting overly broad patents rights.[12] Advocates for a strict written description requirement are concerned that the drawbacks of overly broad patents outweigh the negative aspects of narrow patents.[13] With the rapid advancements in biotechnology, patents on these inventions have proliferated and some companies have sought broad patent protection via functional descriptions.[14] Inventors are coaxed to broaden their claims to cover DNA sequences in other species via a functional description of what the protein does because DNA sequences—the proteins they encode and the protein functions— are similar across species.[15] These broad claims may not be warranted if the DNA sequences are highly variable across species.[16]

The first paragraph of 35 U.S.C. §112 dictates what a patent specification must contain,[17] and its interpretation is the

11. *See* BURK & LEMLEY, *supra* note 2, at 4 (stating the general view of biotechnology companies on the current patent system)..

12. *See* Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirement Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1261-65 (2000) (cautioning against overly broad patents); *see also* Wenrong Huang, Article, *Enzo's Written Description Requirement: Can It Be an Effective Check Against Overly Broad Biotechnology Claims?* 16 ALB. L.J. SCI. & TECH. 1, 12-13 (2006) (stating that the *Lilly* written description requirement was detrimentally relaxed); *see also* Shengfeng Chen, Note, *Pathways to Patents: Applying the Written Description Requirement Doctrine to Patents on Biological Pathways*, 30 HASTINGS COMM. & ENT. L.J. 559, 561 (2008) (stressing that broad patents would impede the progress of science).

13. *See* Sampson, *supra* note 12, at 1265 (describing risks and benefits associated with overly broad patents); *see also* Chen, *supra* note 12, at 561 (noting judges and scholars are concerned about overly broad patents).

14. *See* Huang, *supra* note 12, at 3 (stating that some biotech companies make broad claims based on functional descriptions).

15. *See* Huang, *supra* note 12, at 3 (characterizing biological functions as similar across species).

16. *See* Huang, *supra* note 12, at 3 (highlighting that the court required more detailed structural disclosure before granting a broad patent).

17. 35 U.S.C §112 (2009). 35 U.S.C §112 states:

The specification shall contain a written description of the invention,

subject of debate.[18] The current interpretation of 35 U.S.C. §112 is that the specification must meet three distinct requirements: describing the invention in sufficient detail to enable the public to make and use the invention, describing the best mode for making or using the invention, and providing a written description of the invention.[19] Before the creation of the Federal Circuit, precedent about whether the written description was a third requirement for the specification, separate and distinct from the best mode and enablement requirements, was inconsistent.[20] Many argued it was not a separate requirement at all.[21] The written description requirement was primarily applied to amended claims to insure that an inventor was in actual possession of the invention described in the amendment at the time of the original filing date.[22] The Federal Circuit reviewed its decision in *Ariad v. Eli Lilly*[23] *en banc* in order to settle the debate that was swirling

> 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.

Id.

18. *See* Jeffie A. Kopczynski, Note, *A New Era for § 112, Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 HARV. J.L. & TECH. 229, 261 (2002) (stating a debate exists regarding the nature of the written description requirement).

19. *See* Huang, *supra* note 12, at 5 (describing the current state of paragraph one of 35 U.S.C. 112). An enabling disclosure has been required under United States patent law since 1790 and requires that the patent specification enables a person of ordinary skill in the art be capable of making and using the invention based on the information disclosed in the patent specification. *See* Donald S. Chisum, CHISUM ON PATENTS § 7.03 (2010) (1978). The invention that must be enabled is defined by the claims, and while examples of specific embodiments of the invention are not required in the specification, the presence of specific examples is a factor in determining whether a patent specification is enabling. *Id.* The "best mode" requirement is analyzed under a subjective standard. *Id.* at §7.05. It is what the inventor believes in good faith to be the best way of carrying out the invention at the time he files the patent application. *Id.*

20. *See* Sampson, *supra* note 12, at 1252 (describing the history of the written description requirement).

21. *See* Sampson, *supra* note 12, at 1252.

22. *See* Huang, *supra* note 12, at 5 (detailing the process for applying the written description to amended claims).

23. *See* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009) [hereinafter "*Ariad I*"], *rev'd en banc*; Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) [hereinafter "*Ariad II*"].

around the interpretation of the written description requirement.[24]

This paper describes how the written description requirement has evolved over time. It shows that the Federal Circuit regarded the written description requirement as a third requirement under 35 U.S.C §112, but that written description was mainly applied to show that the inventor was in possession of the invention at the time of filing the patent application, and in a few other limited contexts. The development of today's strict written description requirement is traced. *Ariad v. Lilly*[25] is summarized along with the Federal Circuit's current interpretation of written description as a third requirement, distinct from enablement, to be applied in a rigorous manner in all contexts. This paper concludes that the written description requirement, as it is currently applied, is a superfluous third wheel. Judging the adequacy of the written description by whether a disclosure is enabling is a better standard to evaluate whether a disclosure meets the requirements of 35 U.S.C §112.

II. A Brief History of the Written Description Requirement Prior to *Lilly*

The history of the written description requirement can be traced through the five United States Patent Acts and the cases that interpreted these statutes.[26] The Patent Act of 1790 required that the specification "distinguish the invention or discovery from other things before known and used," and also required that the specification enable one skilled in the art to

24. *See Ariad II*, 598 F.3d at 1342 (explaining the court's reason in reviewing the case).

25. *Ariad II*, 598 F.3d at 1336.

26. *See* Patent Act of 1790, ch. 7, 1 Stat. 109–12 (Apr. 10, 1790) (repealed 1793); Patent Act of 1793, ch. 11, § 3, 1 Stat. 318 (repealed 1836); Patent Act of 1836, ch. 357, § 6, 5 Stat. 117 (repealed 1870); Patent Act of 1870, ch. 230, § 25, 16 Stat. 198 (repealed 1952); Patent Act of 1952, ch. 950, § 1, 66 Stat. 798 (amended 1975); *see also* Evans v. Eaton, 20 U.S. 356 (1822); *In re* Ruschig, 379 F.2d 990, 991 (C.C.P.A. 1967); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

make and use the invention.[27] The Patent Act of 1790 did not require claims, but the requirement to "distinguish the invention" served the same purpose: establishing the scope of what the inventor was claiming.[28] When the Patent Act of 1793 was enacted, the requirements for the specification essentially remained the same.[29]

In *Evans v. Eaton*,[30] the Supreme Court interpreted the Patent Act of 1793 to decide whether Evans's patent on an improvement to flour mill machinery was valid.[31] In this case, it was clear that Evans's patent was to an improvement upon the original machinery, but the specification did not expressly point out the nature of the improvement and distinguish it from the original invention.[32] The Court held that Evans could not obtain a

27. Patent Act of 1790, ch. 7, 1 Stat. 109–12 (Apr. 10, 1790) (repealed 1793).

> [T]he 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, and explanations and models . . . of the thing or things, by him or them invented or discovered. [The] 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 or manufacture, whereof it is a branch, or wherewith it may be nearest connected, 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 . . . .

Id.

28. *See* N. Scott Pierce, *University of Rochester v. G.D. Searle & Co.: Writing on the Wall*, 4 J. MARSHALL REV. INTELL. PROP. L. 406, 413-14 (2005) (articulating the express language and purpose of the Patent Act of 1790).

29. *See* Scott Pierce, *supra* note 28, at 414.

> [E]very inventor . . . 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 1793, ch. 11, § 3, 1 Stat. 318–23 (Feb. 21, 1793) (repealed 1836) (current version at 35 U.S.C.A. § 112 (2010)).

30. 20 U.S. 356 (1822).

31. *See id.* at 367. The original patent was for flour mill machinery called a Hopperboy, and the Stouffer Hopperboy was an improvement on the original. *Id.* at 357, 359. The improvement consisted of a change in shape of the mill shaft from a round to square profile, which allowed the shaft to turn the mill arm without the use of cords or pulleys. *Id*. at 360-61.

32. *See id*. at 363 (stating patents on improvements must specify the

patent on the entire machine because he did not invent the entire machine.[33] The Court stated that the written description has two functions: to enable an artisan to make and use the invention and to put the public on notice about the scope of the invention so that they can avoid inadvertent infringement.[34] In 1793, written description was serving the function that claims do today, putting the public on notice of the scope of the invention; once claims began to be required as part of the specification, the function of the written description requirement changed.[35]

The Patent Act of 1836 eliminated the requirement that the specification distinguish the invention from "other things known before," and added the requirement that claims specify exactly what the inventor was claiming.[36] The claims, not the

improvement over the original invention).

> A party cannot entitle himself to a patent for more than his own invention; and if the patent be for the whole of a machine, he can maintain a title to it only by establishing that it is substantially new in its structure and mode of operation. . . . When the patent is for an improvement, the nature and extent of the improvement must be stated in the specification, and it is not sufficient that it be made out and shown at the trial, or established by comparing the machine specified in the patent with former machines in use. *Id.*

33. *See id.* (denying the plaintiff's patent).

34. *See id*. at 433-34.

> The third section of the patent act requires, as has been already stated, that the party 'shall deliver a written description of his invention, 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, & c. &c [sic]. to make, compound, and use the same.' The specification, then, has two objects; one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims any thing [sic] 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.

Id.

35. Kopczynski, *supra* note 18, at 232 (comparing the function of the Patent Act of 1793 with the Patent Act of 1870).

36. *See* Patent Act of 1836, ch. 357, § 6, 5 Stat. 117 (July 4, 1836) (repealed 1870) (current version at 35U.S.C.A. § 112 (2010)).

[H]e shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the

language in the rest of the specification, now delineated the scope of the rights being claimed by the inventor.[37] The Patent Acts of 1870 and 1952 continued in the vein of the 1793 Act, requiring that the specification enable one skilled in the art to practice the invention, and requiring claims to define the scope of what was being claimed by "particularly point[ing] out" and "distinctly claim[ing]" the invention.[38]

In re Ruschig marks a shift in the role of the written description requirement from delineating the scope of what was

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 and use the same . . . . *Id*. Also added in this act was the requirement to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." *Id*.

37. *See* Pierce, *supra* note 28, at 415. (describing the distinct claims requirement of the Patent Act of 1870).

38. *See* Pierce, *supra* note 28, at 415-16 (observing the similarities between the Patent Act of 1870 and the Patent Act of 1952 with the Patent Act of 1793). "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Patent Act of 1952, ch. 950, § 1, 66 Stat. 798 (amended 1975), second paragraph:

> That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall . . . file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms 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, and use the same . . . and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery.

Id.

Patent Act of 1870, ch. 230, § 25, 16 Stat. 198–217 (July 8, 1870) (repealed 1952) (current version at 35 U.S.C.A. § 112 (2010)):

> 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.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Patent Act of 1952, ch. 950, § 1, 66 Stat. 798 (July 19, 1952) (current version at 35 U.S.C.A. § 112 (2010)).

claimed to insuring that the inventor was in possession of the invention at the time of the application for a patent.[39] The only issue in the case was whether the specification had a written description adequate to support a claim to the compound N-(p-chlorobenzenesulfonyl)-N-propylurea.[40] The claim was rejected because the specification only contained a general description of the compound, not a precise chemical formula.[41] The court held that the written description was inadequate without more direction to specific compounds than what was contained in the specification.[42] The court emphasized that the salient question was whether the "specification convey[s] clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound."[43] In other words, the applicant must show he or she possessed the invention at the time of filing.[44]

In *Vas-Cath Inc. v. Mahurkar*, the Court of Appeals for the Federal Circuit reviewed the development of the written description requirement in response to the district court's comment that "[u]nfortunately, it is not so easy to tell what the

39. *See* Sampson, s*upra* note 12, at 1252 (summarizing the evolution of the written description requirement in the federal courts).

40. *See In re* Ruschig, 379 F.2d at 991. Disputed claim 2 was to benzenesulphonylureas described via a general formula. *Id.* at 994. Benzenesulphonylureas consist of a hexane ring with an R group attached at one location and a group consisting of $-SO_2-NH-CO-NH-R_2$ attached to the benzene ring at a different location "wherein R is a member selected from the group consisting of chlorine and bromine and R_2 is a member selected from the group of alkyl-, alkenyl-, cycloalkyl- and cycloalkylalkyl radicals containing 2 to 7 carbon atoms." *Id.* This general description covered a large number of possible compounds. *Id.* The court stated that:

> Not having been specifically named or mentioned in any manner, one is left to select from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

Id.

41. *See id*. at 996 (concluding the patentee's specification does demonstrate possession of specific compound).

42. *See In re* Rushig, 279 F.2d at 994 (noting that the examiner computed more than 1,000 compounds would be covered by the claim).

43. *Id*. at 996 (emphasizing that the court required a showing of possession of the invention at the time of filing).

44. *See Id.* at 995.

law of the Federal Circuit is [with regard to written description]."[45] The Court of Appeals for the Federal Circuit responded by summarizing the relevant case law, stating that written description has been "frequently addressed" in the Federal Circuit and that a "fairly uniform standard for determining compliance with the 'written description' requirement has been maintained throughout."[46] The court in *Vas-Cath* concluded that written description is "separate and distinct from the enablement requirement" and that the written description must convey that the inventor was in possession of the invention at the time of filing.[47] The court explained that the function of the enablement requirement is to teach "how to make and use an invention without undue experimentation" but that showing possession of the invention at the time of filing would satisfy the written description requirement.[48] The court also stated that the written description requirement has been applied to guard against the addition of new matter when an applicant wanted to obtain the benefit of the original filing date when claims were later amended or to police priority during an

45. 935 F.2d at 1560. This case involved claims to a double-lumen catheter that were held to be invalid as anticipated by the district court under § 102(b). *Id*. at 1557. Mahurkar wanted to claim priority to an earlier filed design application that contained drawings of his design in order to overcome the rejection. *Id.* The district court held that priority could not be claimed because the drawings in the design application did not satisfy the written description requirement. *Id*. The Federal Circuit reversed this decision, holding that the drawings were an adequate written description. *Id*.

> Mahurkar's catheter comprises a pair of tubes (lumens) designed to allow blood to be removed from an artery, processed in an apparatus that removes impurities, and returned close to the place of removal. Prior art catheters utilized concentric circular lumens, while Mahurkar's employs joined semi-circular tubes that come to a single tapered tip. Advantageously, the puncture area of Mahurkar's semicircular catheter is 42% less than that of a coaxial catheter carrying the same quantity of blood, and its conical tip yields low rates of injury to the blood. The prior art coaxial catheters are now obsolete; Mahurkar's catheters appear to represent more than half of the world's sales.

Id. at 1558.

46. See *Vas-Cath Inc.,* 935 F.2d at 1562-63 (summarizing written description precedent).

47. *See id*. at 1563-64 (reaffirming a distinct written description requirement).

48. *See id*. (distinguishing the written description requirement from the enablement requirement).

interference when an applicant wished to obtain the benefit of an earlier filed application.[49] While this illustrated how the written description requirement had historically been applied, the court did not preclude the application of the written description requirement for other purposes.[50]

III. Advent of the Heightened Written Description Requirement

What is characterized as the "heightened" or "Lilly" written description requirement sprang from the decision in *Regents of California v. Eli Lilly* (*Lilly*),[51] which signaled a shift in how the Federal Circuit applied the written description requirement was applied in the Federal Circuit.[52] Because *Lilly* required disclosing chemical structures to satisfy the written description requirement, instead of allowing the description of a compound by its function, some have called it a "super-enablement" requirement[53] and feared this would fatally weaken biotechnology patents.[54] Limiting a patent only to those embodiments disclosed creates rights that are narrow and easily invented around with minor changes to a DNA or amino acid sequence, leading to a patent that lacks economic value.[55] Patent protection is a large part of a company's value and significant in spurring innovation in the rapidly changing field of biotechnology.[56] Consequently, concerns within the biotechnology industry that courts will narrow the scope of patents via a strict written description requirement and weaken

49. *See id.* at 1560 (providing examples of common disputes involving the written description requirement).
50. *See id.*
51. 119 F.3d 1559 (Fed. Cir. 1997).
52. *See* 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, 4 (2007) (introducing the article).
53. *See id*. Functional claiming is using language "describing an invention in terms of what it *accomplishes* rather than in terms of what it *is*." CHISUM, *supra* note 19, at § 8.04. Functional language is of concern because it may cause a claim to encompass more than what an inventor has contributed to the public, or fail to clearly delineate what an inventor is claiming by only "defining the invention in a vague and ambiguous manner." CHISUM, supra note 19.
54. *See* HOLMAN, *supra* note52, at 4.
55. *See* MERGES & NELSON, *supra* note 8, at 845.
56. *See* BURK & LEMLEY, *supra* note 2, at 49-50.

patent protection are understandable.[57]

The patents at issue in *Lilly* related to recombinant DNA technology for the production of human insulin.[58] The researchers at the University of California (UC) developed techniques that could be used to produce human insulin via incorporation of the PPI and PI complimentary DNA (cDNA) sequences into plasmids.[59] The plasmids could, in turn, be

57. *See* Alison E. Cantor, Note, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 269-70 (2000) (discussing difficulties of "pioneer" patents which are patents based on entirely novel ideas).

58. *See Lilly*, 119 F.3d at 1562. Type 2 diabetes results when a person fails to produce enough insulin to metabolize the sugar he or she needs for energy. *Id*. Treatment of diabetes used to be effected with animal insulin, but the allergic reactions that resulted from animal insulin made human insulin more desirable for treatment. *Id*. Insulin is made up of two amino acid chains: 21 amino acid chain A and 30 amino acid chain B. *Id*. Human insulin is produced in the body via a metabolic pathway that produces an amino acid insulin precursor called pre-proinsulin (PPI). *Id*. PPI is further metabolized to produce proinsulin, which is in turn cleaved to produce insulin. *Id*.

59. *See Lilly,* 119 F.3d at 1563 (describing in detail the process of researchers to produce human DNA). Transcription is a multistep process through which the information contained in the gene is used to create the proteins needed by the cell. *See also* NEIL A. CAMPBELL et al., BIOLOGY CONCEPTS AND CONNECTIONS 191-215, 234 (5th ed. 2006). Genes are composed of long chains of four distinct nucleic acids (abbreviated as G, C, T and A), while proteins are composed of long chains of amino acids that fold into functional proteins as they are produced. *Id.*at 191. DNA is a double stranded molecule that forms when complementary nucleic acids pair up; G always binds with C, and A with T. *Id.* Transcription is initiated when a specialized protein complex called RNA polymerase binds to a promoter sequence on the DNA molecule. *Id.* at 193. RNA polymerase reads the DNA strand and creates a complementary RNA molecule. *Id.* RNA, like DNA, is composed of nucleic acids that only pair with their counterpart, but in RNA thyamine (T) is replaced by uracil (U). *Id..* When RNA is synthesized from a DNA molecule: G pairs with C, T in the DNA molecule pairs with A in the RNA, and A in the DNA molecule will pair with U in RNA. *Id*. Ribosomes, specialized protein complexes, then translate the RNA molecule into a protein. *Id.* Plasmids are small, circular pieces of DNA that exist within bacterial cells, separate from the bacterial chromosome. *Id*. at 205. All plasmids have a start sequence that can initiate the translation of the genetic material contained within the plasmid. *Id.* Plasmids can be used to induce bacterial cells to produce foreign proteins by making a recombinant plasmid that includes the bacterial plasmid DNA, the start sequence, and the foreign DNA that encodes the protein of interest. *Id*. When this recombinant plasmid is incorporated back into the bacterial cell, the bacteria's cellular machinery will begin to transcribe foreign DNA along with the plasmid, producing the protein of interest. *Id.* In the *Lilly* case, that protein was human insulin for the treatment of diabetes. *See Lilly,* 119 F.3d at

incorporated into microorganisms that would then express these DNA sequences and produce the protein insulin.[60] UC obtained two patents.[61] The '525 patent included claims to a plasmid encoding for vertebrate insulin, claims to microorganisms containing the plasmid that could produce vertebrate insulin, and claims to mammalian and human insulin cDNA.[62] The '740 patent was based on human PPI and PI cDNA sequences.[63] The claims were to the transfer vectors that would insert the insulin cDNA sequences into host cells, to the recombinant organism that contained the transfer vectors, and to the recombinant plasmids containing the PPI and PI cDNA sequences.[64]

1263.

60. *See Lilly*, 119 F.3d at 1563 (describing the processes the UC researchers patented).

61. *See id.* at 1562-63 (detailing the patent claims).

62. *See id*.

> Claim 1 of the '525 patent reads as follows: 'A recombinant *plasmid* replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a *vertebrate,* which mRNA encodes insulin." (emphasis added). Claim 2 relates to a recombinant procaryotic *microorganism* containing *vertebrate* insulin-encoding cDNA. Claims 4 and 5 depend from claim 2, and are limited, respectively, to *mammalian* and *human* insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain "at least one genetic determinant of the plasmid col E1.' Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

Id.

63. *See id.* at 1563 (describing the basis for the '740 patent claim). cDNA is the DNA sequence that is complementary to the DNA sequence of interest, which codes for the amino acid sequence that forms a PPI molecule. *Id.*

64. *See id.* (setting forth the '740 patent claims).

> Claim 2 of the '740 patent reads: "A DNA transfer vector *comprising* an inserted cDNA *consisting essentially of* a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide of the sequence coding for said proinsulin." (emphasis added). Dependent claim 3 is directed, *inter alia,* to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector *comprising* a deoxynucleotide sequence coding for human proinsulin *consisting essentially of* a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." (emphasis added). Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are

Eli Lilly produced human insulin via a semi-synthetic DNA that produced a bacterial protein linked to human PI by a single amino acid (methionine).[65] When the methionine is cleaved, human insulin is the resulting product.[66] UC sued Eli Lilly for infringing the '525 and'740 patents.[67] The court did not need to consider whether Lilly infringed the '525 patent because UC's claims to mammalian, vertebrate and human cDNA were found to be invalid due to an inadequate written description, although the rat cDNA was adequately described.[68] The court quoted *Fiers v. Revel* holding that and adequate written description requires "a precise definition, such as by structure, formula, chemical name, or physical properties."[69]

A method for isolating the DNA was not sufficient to describe the human cDNA that was claimed.[70] Nor could the amino acid sequence of the human insulin A and B chains describe the human cDNA itself.[71] The court stated that the cDNA molecule was not adequately described because no distinguishing information such as a sequence or structural or physical characteristics of the cDNA molecule was provided.[72]

> Whether or not [the specification] provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin...

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directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

Lilly, 119 F.3d at 1263.

65. *See id.* at 1563 (describing Lilly's process for making the human insulin).

66. *See id.*.

67. *See id.* at 1562 (setting forth the issue at bar).

68. *See id.* at 1566-1568 (holding the '525 patent inadequately described the claims)..

69. *See id.* at 1566 (*quoting* Fiers v. Revel 984 F.2d 1164, 1171 (C.A.Fed. 1993) (listing the requirements for an adequate written description for DNA).

70. *See id*. at 1567 (showing how the description of an isolation method was inadequate).

71. *See Lilly*, 119 F.3d at 1567 (showing how describing the amino acid sequence was inadequate).

72. *See id.* (holding the patentee only described a general method for producing the insulin and not the insulin itself).

> Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.... Accordingly, the specification does not provide a written description of the invention of claim 5.[73]

So although 'a' functional cDNA sequence that would encode for the insulin A and B chains can be determined by looking at the amino acid sequence of the protein, the redundancy of the genetic code does not allow determination of 'the' exact DNA sequence used by the inventors using knowledge of the protein sequence.[74] The court would not settle for any description other than the precise DNA sequence of human insulin cDNA.[75] The '740 patent was not infringed by Lilly because the methods for producing human insulin were not equivalent.[76] This strict requirement that a DNA sequence is the only way to describe an invention claiming a DNA molecule is what is known as the Lilly or heightened written description requirement.[77]

Enzo Biochem, Inc. v. Gen-Probe, Inc. (*Enzo I*) followed *Lilly*, and was the first post-*Lilly* application of the heightened written

73. *See id*. at 1567.

74. *See* CAMPBELL, et al., *supra* note 59, at 192. The genetic code is described as 'redundant.' *Id.* Proteins are composed of amino acids which are encoded by the RNA sequence transcribed from a strand of DNA. *Id.* Recall that the nucleic acids comprising RNA are abbreviated G, C, A, and U. *Id.* A set of three nucleic acids, called a codon, codes for a single amino acid. *Id.* at 191. There are sixty-four possible codons, but only twenty amino acids combine to form proteins. *Id.* There is not a one to one correspondence between amino acids and codons because multiple codons encode for one amino acid. *Id.* For example, the codons GCU, GCC, GCA and GCG all code for the amino acid alanine. Campbell, et al., *supra* note 60, at 192. Recalling that the researchers in *Regents v. Lilly* determined the human insulin amino acid sequence, not the DNA sequence, one can see that researchers could determine which nucleic acids in the DNA sequence would produce a functional DNA sequence, but could not determine the exact DNA sequence for human insulin by looking at a human insulin amino acid sequence. *See id.*

75. *See Lilly*, 119 F.3d at 1567 (invalidating claim 5).

76. *See id.* at 1571-72 (outlining the differences between the methods of producing insulin).

77. *See id.* at 1568-69 (creating the heightened description requirement).

description requirement.[78] Enzo Biochem Inc. was the assignee of a patent for a diagnostic tool useful for diagnosing gonorrhea (the '659 patent) while avoiding the false positives associated with tests that could not distinguish between disease causing and harmless forms of the bacteria.[79] In *Enzo I* the court invalidated Enzo's patents for lack of an adequate written description.[80] Enzo's three DNA probes preferentially hybridized to the common strains of *N. gonorrhoeae*.[81] The probes were deposited at the American Type Culture Collection as recombinant DNA molecules within an *E. coli* bacterial host.[82] The claims to the specific probes contained references to the accession numbers of the bacteria and described how to isolate the DNA sequences from the deposited bacteria.[83] Upon suit for infringement of the '659 patent, Gen-Probe's motion for summary judgment, arguing that Enzo's claims were invalid for lack of written description, was granted.[84]

The Federal Circuit court reiterated that written description is a "fact based inquiry that will necessarily vary depending on the nature of the invention claimed" and the court upheld the validity of the circuit court's summary judgment.[85] The Federal Circuit relied on its holding in *Lilly* and required that a DNA sequence be provided in order to satisfy the written

78. Enzo Biochem Inc. v. Gen-Probe, Inc., 285 F.3d 1013 (Fed. Cir. Apr. 2, 2002) [hereinafter "*Enzo I"*], rev'd by Enzo Biochem Inc. v. Gen-Probe, Inc., 323 F.3d 956, 960 (Fed. Cir. Jul 15, 2002) [hereinafter "*Enzo II"*].

79. *See Enzo I*, 285 F.3d at 1015 (introducing the patent that had been granted for a tool diagnosing gonorrhea). Accurately diagnosing gonorrhea can be difficult because the disease causing bacteria, *Neisseria gonorrhoeae*, is homologous to *Neisseria meningitidis*, which does not cause disease, causing a high rate of false positives. *Id.*

80. See *id.* at 1015-16 (setting forth the basis for the patent claims).

81. *See id.* at 1016 (explaining Enzo's process for deriving strains of *N. gonorrhoeae*). The inventors theorized that a preferential hybridization ratio greater than five to one would hybridize to only *N. gonorrhoeae*. *Id.* The actual hybridization ratio of the probes was greater than fifty. *Id.*

82. *Id.* (discussing the three probes derived by Enzo).

83. *Enzo I*, 285 F.3d at 1016 (articulating Enzo's claims relating to the probes).

84. *Id.* (stating the claims were invalid for failure to meet requirements pursuant to 35 U.S.C. § 112, ¶ 1).

85. *Enzo I*, 285 F.3d at 1016-18 (affirming the district court's holding that the specification failed to provide an adequate written description).

description requirement.[86] The court concluded that the specification only described the DNA sequence by its functionality, "binding to *N. gonorrhoeae* in a preferential ratio of "greater than about five" with respect to *N. meningitidis.*"[87] The court further rejected Enzo's argument that the hybridization ratio is a chemical property that distinguishes the sequences that were claimed from those that were not.[88] Enzo also argued that their case was distinguishable from *Lilly* because the DNA probes were hybridizing to *N. gonorrheoeae*, rather than encoding proteins.[89] The court rejected all of these arguments, characterizing them as attempts to describe the DNA probes via their function, rather than providing a distinct chemical formula.[90]

Enzo's argument that the Patent and Trademark Office (PTO) Guidelines allow sufficiently detailed disclosure of functional characteristics of some biological molecules to satisfy the written description requirement was also rejected.[91] Enzo went on to argue that they possessed the invention claimed as demonstrated by their reduction to practice and deposit of the genetic materials, in compliance with the holding in *Vas-Cath*.[92]

86. *Id*. (stating "that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention").

87. *Id*. at 1018 (affirming the District Court's holding).

88. *Id.* (discussing Enzo's attempt at distinguishing the facts of his case from the facts of *Lilly*).

89. *Enzo I*, 285 F.3d at 1016-18 (detailing Enzo's argument distinguishing *Lilly*).

90. *Enzo I*, 285 F.3d at 1018-19 (discussing the reasons for rejecting Enzo's arguments).

91. *Id.* (stating that PTO guidelines are not binding). The PTO Guidelines state:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.

Id. at 1019.

92. *Enzo I*, 285 F.3d at 1020 (explaining how Enzo has complied with § 112, ¶ 1 possession test set forth in *Vas-Cath*).

The court rejected this argument and held that *Vas-Cath* was only stating the purpose of the written description requirement, not stating that possession satisfies the written description requirement.[93] The court stated that "a showing of 'possession' is secondary to the *statutory mandate* that 'the specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention."[94]

In his dissent, Judge Dyk argues that because written description is a matter of fact, the circuit court should have relied on the testimony of those skilled in the art to determine whether the DNA sequences were adequately described.[95] He reasons that Enzo disclosed well known methods for isolating DNA sequences in great detail and that one skilled in the art, not the court, should have evaluated the adequacy of the written description.[96] Judge Dyk questioned not only the holding in this case, but also the *Lilly* decision on which the court relied.[97]

> *Eli Lilly*, in departing from the general rule that an applicant satisfies the written description requirement by 'convey[ing] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and imposing a unique written description requirement in the field of biotechnology, is open to serious question. But even *Eli Lilly* does not sanction the approach taken here.[98]

93. *Id.* (articulating the court's reasoning for rejecting Enzo's *Vas-Cath* argument).
94. *Id*. at 1021.
95. *Id*. at 1024-25 (agreeing with Enzo regarding the holding in *Lilly*).
96. *Enzo I*, 285 F.3d at 1024-25 (asserting that those skilled in the art are who should evaluate the adequacy of a written description).
97. *Id*. at 1025 (explaining the reason for questioning the holding of *Lilly* as applied to the facts of this case).
98. *Id*.

Judge Dyk stated that the claims in *Enzo I* are distinguished from those in *Lilly* because selective hybridization is indicative of the structure that is claimed, a fact conceded by both sides in the case.[99] He also states that a deposit is an "ideal" way to fulfill the goal of putting the public on notice of the scope of what is claimed.[100] The majority pointed out that the written description must also be sufficient to allow the patent examiner to understand the invention in sufficient detail to examine the application.[101] Judge Dyk countered that the examiner was able to conduct his examination of the patent and that while there were rejections of the '659 patent on other grounds before the patent was granted, the examiner never issued rejection based on inadequate written description.[102] He suggests that the court "should not be second-guessing the PTO's own judgment" or subject the applicant to the unfairness of rendering a deposit inadequate when it is too late to amend the claims if the PTO is satisfied with reliance on a deposit.[103]

99. *Enzo I*, 285 F.3d at 1026 (arguing that *Enzo* should be distinguished from *Eli Lilly*).

> The degree of hybridization between a probe and a target depends on the degree of complementarity between the chemical structure between the probe and the target. To be sure, the sequences and the chemical structure of the targets were not disclosed in the specification, but the targets were not novel, and the "Background" section of the patent states that the degree of homology between the *N. gonorrhoeae* and *N. meningitidis* DNA targets was known to be between 80% to 93%. This indicates that the structure of the targets was at least somewhat known to those of skill in the art. Thus, by describing the degree of hybridization of the claimed nucleotide sequences, the specification may adequately describe the structure of the claimed sequences. At least one of ordinary skill in the art might so conclude.

Id.

100. *See Enzo*, 285 F.3d at 1027 (describing the best way of informing the public of the scope of an invention).

101. *See id.* (outlining one use of the patent specification).

102. *See id*. at 1028 (explaining the '659 patent prosecution history).

103. *See id.* at 1028-29 (suggesting the court's opinion should not supersede that of the PTO).

In *Enzo II*,[104] shortly after *Enzo I*,[105] the court vacated its decision and remanded the case "because genuine issues of material fact exist[ed] regarding satisfaction of the written description requirement...."[106] The court stated that while the holding in *Lilly* required a "precise definition, such as by structure, formula, chemical name or physical properties... it is not correct... that all functional descriptions of genetic material fail to meet the written description requirement."[107] The court went on to adopt the PTO's standard allowing functional claiming of genetic material.[108]

The court held that reference in the specification to a deposit, when a description of the contents is not otherwise available in written form, complies with the written description requirement.[109] So although the exact nucleotide sequence was not included in the specification, reference to the deposited material in the specification was sufficient to describe the sequences that were deposited.[110] The '659 patent also

104. *Enzo,* 323 F.3d 956, 960 (Fed. Cir. Jul 15, 2002).
105. *Enzo I*, 285 F.3d at 1013.
106. *Enzo II,* 323 F.3d at 960 (Fed. Cir. Jul 15, 2002).
107. *Id.* at 964.
108. *See id.* The court adopted the PTO Guidelines for the written description requirement:

> show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure,* or some combination of such characteristic.. . . Thus, under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.

Id.
109. *See id.* at 965 (describing the court's holding that deposits comply with the written description requirement).
110. *See Enzo II,* 323 F.3d at 966. The court made allowances for the fact that the sequence may not have been reasonably obtainable at the time of filing because of the investment of time required to sequence DNA at the time of filing and found that the public could obtain the sequence by accessing the deposited samples. *Id.* Therefore, the written description requirement was satisfied. *Id.*

> The sequences are thus accessible from the disclosure in the

contained broad generic claims to all sequences that would bind to *N. gonorrhoeae* with the required affinity.[111] The court distinguished *Enzo* from *Lilly*, stating that the sequence for rat cDNA in *Lilly* did not describe common features within the genus claimed, or describe a sufficient number of species in order to claim the genus.[112] Enzo argued that all of its claims, both broad and narrow, were adequately described because of the functional hybridization with the deposited sequences.[113] This allowed for the possibility that functional description can be sufficient to support broad claims, holding that whether the deposited sequences described the broad claims was at least an issue of material fact to be decided by a reasonable fact finder on remand.[114]

Enzo filed a petition for rehearing of this case *en banc*, which was denied.[115] The judges concurring in this decision emphasized the importance of a strict interpretation of the written description requirement.[116] They pointed out that just because written description has typically been an issue in priority cases, nothing in the law states written description should only be applied in priority cases, and that disclosure, the primary role of a patent, is thwarted when the written description requirement is lax.[117]

> specification. Although the structures of those sequences, *i.e.,* the exact nucleotide base pairs, are not expressly set forth in the specification, those structures may not have been reasonably obtainable and in any event were not known to Enzo when it filed its application in 1986. *See* '659 patent, col. 3, ll. 40-46 (noting severe time constraints in sequencing DNA).

Id.

111. *See id.* Enzo's expert testified that this could conceivably encompass "astronomical" numbers of variations on the sequences that were deposited. *Id.*

112. *Id.* at 967 (recognizing that the court addressed a similar issue in Eli Lilly but that the facts were different).

113. *Enzo II*, 323 F.3d at 966-67 (discussing Enzo's additional, broad claims).

114. *Id*. at 968 (holding that the district courts granting of summary judgment was an error).

115. *Id.* at 971 (discussing the reasons for the denial of the petition).

116. *Id*. at 971-75 (re-emphasizing the majority opinion that the purpose of the written description requirement is multi-faceted).

117. *Enzo II*, 323 F.3d at 971-75 (discussing the purposes of the written description requirement).

In his vigorous dissent to the decision to deny rehearing of *Enzo II en banc*, Judge Rader emphasized the origin, history, and legal precedent leading up to the current written description requirement.[118] He stated that the application of written description as a general disclosure doctrine in *Lilly* deviated from thirty years of precedent in which written description was used to police priority.[119] He went on to say that because priority and new matter were not issues in *Lilly* or the *Enzo* cases, whether the claims are enabled was the sole issue.[120] Rader states that the claims in *Lilly* clearly exceeded the scope of what was enabled in the specification and the claims should have been invalidated on that basis.[121] Judge Rader also warns against disrupting established case law and the settled expectations of inventors

118. *Id*. at 976-77 (emphasizing the legal precedent behind the written description requirement).

119. *Id.* at 979-80 (critiquing the new way in which the court is applying the written description requirement).

> In fact, this Circuit's test for written description required assessment of the specification to check 'later claimed subject matter.' . . . [T]his standard emphasizes that WD does not examine the specification for "literal support" of the claim language unless priority is in question. In any event, this Circuit did not apply WD to claims without priority problems because the doctrine had no purpose beyond policing priority.

Id.

120. *Enzo II*, 323 F.3d at 980-82 (discussing the progression of the written description requirement by pointing out how the court deviated in *Lilly* and *Enzo*).

121. *Id.* at 980-81. Judge Rader views enablement, not written description, as the appropriate gatekeeper to guard against claims that exceed what an inventor discloses to the public because it better protects an inventor's property right while still insuring adequate disclosure to the public. *Id*.

> Although it should not be necessary, a brief defense of the statutory standard for adequate disclosure shows the flaws of the new form of WD. Enablement already requires inventors to disclose how to *make* (reproduce, replicate, manufacture) and how to *use* the invention (by definition rendering it a "useful art"). Therefore, because the competitor can make the invention, it can then acquire the DNA sequence or any other characteristic whenever it desires. Meantime the competitor can use, exploit, commercialize (outside the patent term) or improve upon and design around (within the patent term) as much of the invention as it cares to make. In other words, the statutory standard for sufficiency of disclosure serves masterfully the values of the patent system.

Id.

when the enablement requirement serves to prevent claims that are overly broad and exceed the scope of an applicant's disclosure.[122]

IV. Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company

The first hearing of the *Ariad* case occurred when Ariad sued Eli Lilly for infringement of patent number 6,410,516 (the '516 patent), which was related to regulation of gene expression via modification of the activity of transcription factors (called NF-KB).[123] The proteins that are produced when NF-KB is activated can be helpful in fighting infection, but are harmful in excess.[124] The inventors of the '516 patent realized that if NF-KB activity could be regulated, they could minimize the damaging effects of excessive amounts of the proteins while maintaining its beneficial effects.[125]

The claims at issue in Ariad's '516 patent were to non-specific methods for reducing external effects on cells that induce NF-KB signaling in cells, methods for reducing expression of cytokines by reducing binding to the NF-KB activation sites on genes, and methods for reducing NF-KB expression in eukaryotic cells.[126] On the day the '516 patent issued, Ariad filed suit against

122. *Id.* at 981-83 (cautioning against the negative effects of the courts treatment of written disclosure in *Lilly* and *Enzo*).

123. *Ariad I,* 560 F.3d at 1369. Transcription factors are biological molecules that help RNA polymerase produce mRNA from the DNA template. *See* CAMPBELL, et al., *supra* note 59, at 214. Some transcription factors are activators which act to promote RNA, and thus, protein synthesis, while some are inhibitors which prevent RNA polymerase from functioning. *Id.* Ariad discovered a transcription factor called NF-KB which becomes activated in response to stress or damage to the cell. *See Ariad I.*, 560 F.3d at 1369. Upon activation, NF-KB induces genes encoding the proteins that will ameliorate the harmful extracellular influence to be transcribed. *Id.* The proteins that are produced in upon activation of the genes by NF-KB, help the cell survive infection, but can be harmful in excess. *Id.*

124. *See Ariad I*, 560 F.3d at 1369 (describing the effects of NF-KB).

125. *Id*. at 1370 (analogizing the role of NF-KB to that of aspirin in that they both limit symptoms without treating underlying infections).

126. *Id.* Cytokines are regulatory proteins that are important in generating an immune response. Definition of cytokine, YAHOO! EDUCATION, *archived at* http://www.webcitation.org/5oFjNN5pk. The actual claims are as follows:

[Claim] 80. [A method for modifying effects of external influences on a

Lilly alleging that Lilly's drug Evista® infringed claims 80 and 95 and that Lilly's drug Xigris® infringed claims 144 and 145.[127] The Federal Circuit court held that all of Ariad's claims were invalid due to lack of an adequate written description.[128]

The court emphasized that the written description requirement serves the dual functions of demonstrating that the applicant for a patent was in possession of the invention at the time of filing, and ensuring that the scope of the patent protection granted does not exceed the scope of what is disclosed to the public.[129] The court stated that there is no particular form of disclosure required to satisfy the written description requirement, but that more disclosure than that which would render the claim obvious is required.[130] The court reiterated that

> eukaryotic cell, which external influences induce NF-KB-mediated intracellular signaling, the method comprising altering NF-KB activity in the cells such that NF-KB-mediated effects of external influences are modified, wherein NF-KB activity in the cell is reduced] wherein *reducing NF-KB activity* comprises reducing binding of NF-KB to NF-KB recognition sites on genes which are transcriptionally regulated by NF-KB.
>
> [Claim] 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-KB-mediated intracellular signaling, the method comprising *reducing NF-KB activity* in the cells such that expression of said genes is reduced], carried out on human cells.
>
> [Claim] 144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-KB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein *reducing NF-KB activity* comprises reducing binding of NF-KB to NF-KB recognition sites on genes which are transcriptionally regulated by NF-KB.
>
> [Claim] 14[5]. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises *reducing NF-KB* activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

Ariad I, 560 F.3d at 1370.

127. *Ariad I*, 560 F.3d at 1370- (laying out the procedural history of the case).

128. *Id*. at 1380 (noting the law does not specify the form that a written description must take).

129. *See id*. at 1371 (explaining the dual functions of the written description requirement).

130. *See id*. at 1371-72 (noting no specific form required but the description must not make the claim obvious).

while the question of whether the written description requirement is satisfied is a fact based inquiry, "[a] description of what a material does, rather than of what it is, usually does not suffice."[131]

In response, Ariad emphasized the significance of their scientific discoveries, the fact that Ariad never claimed a compound, only methods, and that their methods were adequately described.[132] The court rejected Ariad's arguments, stating that by Ariad's admission three classes of molecules (specific inhibitors, dominantly interfering, and decoy) were suggested "to achieve NF-KB reduction."[133] The court required that Ariad indicate it possessed the claimed methods by sufficiently disclosing specific molecules capable of reducing NF-KB activity."[134] The court also required that Ariad provide a method for using the hypothesized molecules that would reduce NF-KB activity in order to prove possession at the time of filing and found that no such method was provided.[135]

> Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement. But this

131. *Ariad I*, 560 F.3d at 1372.
132. *See id.* at 1372-73 (stating Ariad's position).
133. *See id.* at 1373. Ariad hypothesized three classes of molecules to potentially reduce NF-KB activity: specific inhibitors, dominantly interfering and decoy molecules. *Id*. The specification did not provide specific examples of the specific inhibitors, dominantly interfering molecules, or binding domains on the target DNA, but it did provide specific sequences for decoy molecules. *Id.* at 1374-75. Specific inhibitors prevent the transcription factor, NF-KB, from binding to DNA. *Id* at 1375. If the transcription factor does not bind, the cellular machinery will not receive the signal required to initiate protein synthesis. *See Ariad I*, 560 F.3d at 1369-70. Dominantly interfering molecules consist of the portion of NF-KB that binds to DNA, but lack the portion that initiates transcription of the protein, again preventing transcription. *Id.* Decoy molecules are designed to mimic the NF-KB binding site of the natural DNA molecule. *Id.* at 1375. Instead of binding cellular DNA and initiating protein production, NF-KB would bind a decoy and become inactive. *Id.*
134. *See Ariad I*, 560 F.3d at 1374-75 (holding that Ariad must prove possession through sufficient disclosure).
135. *See id.* at 1375-76 (noting that Ariad lacked a proven method for reduction in NF-KB activity).

> disclosure is not so much an "example" as it is a mere mention of a desired outcome.... [T]here is no descriptive link between the table of decoy molecules and reducing NF-KB activity.[136]

The court stated that the "thin thread" of support provided by the decoy molecules could not support the "vast scope of these generic claims."[137]

Circuit Judge Linn concurred with the opinion of the court because it was supported by the existing precedent, as established by *Lilly*, but wrote a separate opinion to emphasize his belief that the creation of a separate written description requirement was "misguided.[138] He stressed that the salient question with regard to 35 U.S.C. § 112, first paragraph is whether the specification enables one skilled in the art to make and use the claimed invention, and that prior to *Lilly* precedent demanded no more.[139] He noted that both the Federal Circuit and the Supreme Court have recognized that the claims define the scope of the invention, not the specification, and that the current interpretation of the written description requirement has:

> "create[d] confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude,"... causing uncertainty "in how inventions are protected, in how the [Patent & Trademark Office] discharges its responsibilities, and in how business is conducted in emerging fields of law[.]"[140]

He characterized the fact that Ariad's claims were probably not

136. *Id.* at 1375.
137. *Id*. at 1376. Decoy molecule structures were described, but there were no examples given of how to use decoy molecules to reduce NF-KB activity. *See id.* at 1375.
138. *See Ariad I*, 560 F.3d at 1380 (Linn, J., concurring) (disagreeing with the creation of a separate written description requirement).
139. *See id.* at 1380-81 (considering the precedential limits prior to *Lilly*).
140. *Id.* at 1381.

enabled as "an important issue... left unresolved," because of the focus being placed on the written description requirement.[141]

V. State of the Law Prior to En Banc Review of *Ariad I*

Although the written description cases from *Lilly* onward engendered confusion, there are certain requirements with regard to written description that are clear based on these cases. While *Lilly* required an exact molecular sequence to provide a written description of a cDNA, this extremely strict interpretation of the written description requirement was eroded in subsequent cases.[142] Recognizing the difficulty in describing biological material, the policies underlying patent law, and the historical use of biological deposits, the court in *Enzo II* held that a biological deposit satisfies the written description requirement for the deposited material.[143] The court specifically adopted the PTO guidelines and stated that functional descriptions of genetic material can meet the written description requirement.[144] The *Enzo II* court also held that a biological deposit can adequately describe claims to a broader genus if enough species are described.[145] The court distinguished the *Enzo* cases from *Lilly*,

141. *See id.* (pointing out flaws in the court's focus).

142. *See* Holman, *supra* note 52, at 23-26 (describing the subsequent cases which limited the *Lilly* written description requirement).

143. *See Enzo II*, 323 F.3d at 965 (holding biological deposits satisfy the written description requirement).

144. *See id.* at 964 (adopting the PTO guidelines).

> In its Guidelines, the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure,* or some combination of such characteristics. (emphasis added). . . . Thus, under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement.

Id.

145. *See Enzo II*, 323 F.3d at 966-67. "If those sequences are representative

stating that *Lilly's* generic claims to all cDNA's encoding for vertebrate failed because features common to the genus were not described and because an inadequate number of species were described.[146]

Although *Enzo II* was remanded for a determination of whether the functional descriptions provided in the specification were adequate to describe the genus in this particular case, the court clearly held that deposited samples combined with functional descriptions can describe a genus.[147] The court was careful to point out that while the deposit can serve as proof of reduction to practice that can help establish a priority date, the purpose of the deposit is to satisfy the quid pro quo patent law requires.[148] The holding that a deposit satisfies the written description requirement is based on the fact that the accession number of the deposit puts the invention in the public's possession.[149]

In the '516 patent, Ariad claimed a method for reducing NF-KB activity in cells, but did not provide examples of specific molecules capable of reducing NF-KB activity.[150] Instead, Ariad disclosed three classes of molecules that they believed would be effective, but only provided specific sequences for decoy molecules.[151] Sequences were not provided for the other two

of the scope of the genus claims, *i.e.,* if they indicate that the patentee has invented species sufficient to constitute the genera, they may be representative of the scope of those claims." *Id*.

146. *See id.* at 967 (distinguishing *Lilly* from *Enzo II*).

In *Eli Lilly,* the specification and generic claims to all cDNAs encoding for vertebrate or mammalian insulin did not describe the claimed genus because they did not set forth any common features possessed by members of the genus that distinguished them from others . . . Nor did the specification describe a sufficient number of species within the very broad genus to indicate that the inventors had made a generic invention, *i.e.,* that they had possession of the breadth of the genus, as opposed to merely one or two such species. *Id*.

147. *See id.* at 967 (holding deposited samples and functional descriptions can adequately describe a genus).

148. *See Enzo II*, 323 F.3d at 969-70 (clarifying the purposes of the deposit).

149. *See id.* at 970 (noting the public deposit satisfies the written description requirement).

150. *See Ariad I*, 560 F.3d at 1375 (recognizing Ariad's lack of specificity).

151. *See id.* (highlighting that only decoy molecules were provided).

classes of molecules, or for the target NF-KB DNA sequence.[152] The court stated that "because the specification discloses specific example sequences [for decoy molecules], there is little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art."[153] Provision of these sequences alone was not adequate to meet the written description requirement for the methods claimed in the '516 patent because there was no descriptive link between the decoy molecules and reducing NF-KB activity.[154] The court stated that prophetic examples can satisfy the written description requirement, but that the particular specification in *Ariad* "merely" disclosed a "desired outcome."[155]

An extensive review of Federal Circuit cases, district court cases, and Board of Patent Appeals and Interferences decisions analyzing how the *Lilly* written description requirement was being applied after *Enzo II* indicated that trends have developed in how the written description requirement was being applied prior to en banc review of *Ariad*.[156] The conclusion was that *Lilly* was not being applied as a super enablement requirement.[157] A single Board of Patent Appeals and Interferences (BPAI) decision in which written description was treated as a super-enablement requirement was documented, but the Federal Circuit overturned that decision.[158] In addition, the study revealed that the enablement requirement was invalidating overly broad claims as effectively as the written description requirement, and that enablement and written description were functioning interchangeably.[159] As technology moves away from obtaining

152. *See id.* (detailing a lack of sequences for the three classes of molecules).
153. *Id.*
154. *See Ariad I*, 560 F.3d at 1375 (discussing whether the specification adequately describes the method claimed).
155. *Id.* Ironically, in a 1990 publication, Ariad disclosed the successful use of decoy molecules to reduce NF-KB activity, but because the '516 patent relied on a 1989 filing date, Ariad could not obtain a benefit from this 1990 disclosure. *Id.* at 1375-76.
156. Holman, *supra* note 52, at 25-26 (detailing the author's methodology).
157. Holman, *supra* note 52, at 78 (noting that no judicial decisions exist applying *Lilly* to invalidate an otherwise enabled claim).
158. Holman, *supra* note 52, at 78.
159. Holman, *supra* note 52, at 79-80 (analyzing the cases following *Lilly*).

protein sequences prior to obtaining a DNA sequence, the importance of the *Lilly* written description requirement is likely to diminish further.[160]

VI. *En banc* Review of *Ariad v. Lilly*

The Federal Circuit granted Ariad's petition for en banc review of *Ariad I* to consider whether 35 U.S.C. § 112, first paragraph, contains a written requirement that is divorced from enablement.[161] The court reaffirmed that 35 U.S.C. § 112, first paragraph, does contain a separate written description requirement, and that Ariad's '516 patent is invalid for failing to meet it.[162] The fundamental issue in the case was the standard by which written description is measured.[163] Ariad argued that written description does not exist independent of the enablement requirement, therefore an enabling disclosure meets the written description requirement.[164] Lilly maintained their argument that a separate and distinct written description requirement exists apart from enablement and that it should be universally applied, even when priority is not an issue.[165]

In this ruling, which is consistent with post-*Lilly* written description precedent,[166] the Federal Circuit affirmed that satisfying the written description requirement is a fact based inquiry that "varies depending on the nature and scope of the

160. Holman, *supra* note 52, at 80 (concluding that even if there were a "super-enablement" requirement, its applicability will diminish).
161. *Ariad II*, 598 F.3d at 1340 (detailing basis for en banc review).
162. *Id.* (affirming the holding of *Ariad I*).
163. *Id.* at 1342 (outlining the parties' position and the question presented).
164. *Id.* (summarizing Ariad's postion).
165. *Id.* (summarizing Lilly's position).
166. *See Lilly*, 119 F.3d at 1567; *Enzo II*, 323 F.3d at 965. The court affirmed the standards for written description, as set out in *Lilly* and *Enzo II*, that an inventor shows possession of an invention at filing by reciting an exact molecular sequence or by making a deposit of a biological material in a public depository. *See Lilly*, 119 F.3d at 1567; *Enzo II*, 323 F.3d at 965. The current written description standard does not preclude the use of functional descriptions of what is claimed to meet the written description requirement, but there are no clear standards for what level of functional description will be adequate. *See Enzo II*, 323 F.3d 964 (citing USPTO Guidelines and allowing functional claiming).

claims and on the complexity and predictability of the relevant technology."[167] No bright line rules were elucidated, but the court articulated a number of broad principles to assist in evaluating whether the written description requirement is met by the specification.[168] The court stated that no actual reduction to practice is required to satisfy the written description requirement, that the specification must demonstrate possession by the inventor, and that merely describing an invention in enough detail to render it obvious does not meet the written description requirement.[169]

The court also stated that the written description problem is most often arises when a patentee attempts to claim a broad genus with functional language.[170] The court explained that functional claims can still meet the written description requirement when there is correlation between structure and function.[171] Under the ruling in *Ariad II*, an adequate written description will continue to be measured by whether the inventor had possession of the invention upon filing.[172] Thus an inventor who seeks to claim a broad genus must show that he or she was in possession of enough species at the time of filing to prove possession of the genus.[173]

In her concurring opinion in *Ariad II*, Judge Newman

167. *Ariad II*, 598 F.3d at 1351.
168. *See id.* at 1351-52 (declining to establish a bright line rule due to complex factual scenarios common in patent cases).
169. *Id.*at 1352 (listing principles that apply in all cases).
170. *Id.* at 1349. The court acknowledged that:

> [t]he problem [of written description] is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Id.
171. *Ariad II*, 598 F.3d. at 1350 (delineating methods for claiming a genus).
172. *Id.* at 1351 (restating the written description standard).
173. *Ariad II*, 598 F.3d at 1350 (setting forth the requirements for claiming a genus). .

asserts that the court's holding will insure that the patentee is granted an "exclusionary right" that is "commensurate in scope" with what the patentee discloses.[174] Judge Newman emphasizes that the policy of patent law should drive these decisions, not agonizing over the "placement of commas" in 35 U.S.C. §112.[175] The goal of patent policy is to move products to the public in a form the public can use, therefore the Federal Circuit is correct to disallow patents on discoveries related to basic science that are too far upstream in the research process to quickly translate into a marketable product.[176] A policy driven decision is probably wise, but sound policy dictates using enablement to insure that an inventor does not receive more in a patent grant than what he or she gives to the public in a patent specification.

VII. Analysis: Enablement Is a Better Standard by Which to Judge the Adequacy of a Written Description Under 35 U.S.C. § 112

The purpose of patent law is to promote progress by granting patents in which the scope of the patent right is broad enough to protect the inventor's interests, avoiding a mass of narrow, valueless patents, while insuring the patent right is commensurate with what the inventor discloses to the public. Written description became an issue in the area of biotechnology because it is relatively easy to claim functional characteristics of a protein or DNA sequence that cover a broad scope without defining a precise sequence.[177] Those who support the heightened written description standard in Lilly believe that broad patents will stifle innovation and allow inventors to claim more than they disclose to the public.[178] These broad, blocking

174. *Id.* at 1359-60 (Newman, J., concurring).
175. *Id.* at 1360 (rejecting parsing of the language of 35 U.S.C §112 as a method for determining how to best define the written description requirement).
176. *See id.* at 1359 (explaining the limited patentability of basic scientific principles).
177. Chen, *supra* note 12, at 561.
178. Sampson, *supra* note 12, at 1261 (warning of the effects of overbroad patent grants); *see also* Chen, *supra* note 12, at 567 (arguing that written description may be the best way to reign in overly broad patents because it limits patent scope based on disclosure in the specification).

patents can deter innovation because they cover a large swath of technology, and make any second-comers subject to the original, broad patent.[179] When a broad patent exists that keeps others out of an area of technology, the incentive to innovate in that area is reduced.[180] Thus, some argue that the bright-line rule elucidated in *Lilly* and requiring recitation of an exact molecular sequence is the only way to avoid overly broad claims.[181]

In addition, there are those who assert that the written description requirement was detrimentally relaxed in *Enzo II* when the court reasoned that generically described sequences met the written description requirement because the sequences could be obtained via hybridization to the deposited sequence.[182] They argue a deposit should only satisfy the written description requirement for the specific material deposited, and that *Enzo II* should not have allowed a deposit to satisfy broader claims to a genus: another bright-line rule.[183]

Written description as an independent requirement under 35 U.S.C §112 is an unnecessary third wheel. Innovation could remain vibrant under pre-*Lilly* precedent, where written description was tied to an enabling disclosure and was satisfied when the specification showed that the inventor was in possession of the invention at the time of filing. The *Lilly* written description requirement is not only superfluous, but could be a threat to the "vitality of the biotechnology industry."[184]

179. Hugh McTavish, Note, *Enabling Genus Patent Claims to DNA*, 2 MINN. INTELL. PROP. REV. 121, 143-44 (2001) (suggesting why the Federal Circuit blocked broad patent claims in recombinant DNA).
180. McTavish, *supra* note 179, at 143-44.
181. Sampson, *supra* note 12, at 1261 (listing ways a patent on a gene can block further innovation).
182. Huang, *supra* note 12, at 12-13 (analyzing the court's decision in *Enzo II*).
183. Huang, *supra* note 12, at 15-16 (concluding that *Enzo II* went too far in its holding).
184. Holman, *supra* note 52, at 17.

> [C]ommentators have characterized LWD as a "super-enablement requirement" substantially limiting the ability of inventors to patent biotechnological inventions, some going so far as to suggest that the doctrine actually poses a substantial threat to the vitality of the biotechnology industry. Typical of the tone in the immediate

Requiring a DNA sequence can be economically wasteful and divert energy away from innovation because sequencing DNA is time consuming and expensive, but routine.[185] The narrow patent scope *Lilly* requires, although relaxed by *Enzo II*, could lead to large numbers of patents that are easily designed around via small, non-functional changes in a DNA sequence.[186] These narrow patents have little economic value and offer little protection for a company who must make significant investment to bring a product to market.[187] Innovation can suffer when patentees, faced with navigating numerous narrow patents, instead elect to forgo research in a particular area.[188]

Whether claims are broad or narrow, the scope of patent rights should be limited to what an inventor contributes to the public, and there is justifiable concern that patentees making broad functional claims will not satisfy patent law's quid pro quo.[189] Although sound policy would seem to dictate that patent scope must be precisely commensurate with an inventor's contribution to society, strictly limiting a patentee to embodiments that are "actually created at the time the patent application is filed... would soon render a patent useless" because

> aftermath of Lilly [sic] was an article, published in 1998, which lambasted Lilly [sic] as "an unmitigated disaster that if followed, has the potential for causing untold havoc in the biotechnology field."

Id.

185. McTavish, *supra* note 179, at 155-56 (arguing that the *Lilly* rule leads to economic inefficiency).

186. *See* Holman, *supra* note 52, at 19-20 (discussing the effects of the written description requirement after *Lilly*).

187. *See* Holman, *supra* note 52, at 22. DNA sequences are almost always found non-obvious and can receive a patent, but that numerous patents on different sequences held by different owners can constrain the freedom to work in a particular area. Id. Patent protection for DNA sequences must be broad enough to effectively exclude "design-arounds," just as pharmaceutical patents must be broad enough to cover chemical analogs. Id. at 11.

188. *See* Holman, *supra* note 52, at 19-20 (explaining that a single disease is rarely caused by a single DNA sequence, and that effective products and cures will result more and more frequently from therapies that require the use of multiple DNA sequences).

189. *See* Merges & Nelson, *supra* note 8, at 848 (highlighting the argument that a broad set of claims is a disincentive for invention).

such patents can be easily designed around with minor, non-functional changes.[190]

An enabling disclosure is required under 35 U.S.C. § 112, and what constitutes an enabling disclosure is defined in the statute.[191] An enabling disclosure allows a person skilled in the art "to make and use" the invention[192] without undue experimentation.[193] The factors from *In re Wands* provide a well defined standard for enablement.[194] In contrast to the clear *Wands* factors, whether a written description meets the requirements of 35 U.S.C. § 112 under *Ariad II* is a question of fact that varies on a case by case basis, creating considerable uncertainty for inventors and practitioners.[195] Thus, tying the adequacy of the written description requirement to whether a disclosure is enabling, provides a standard that is less ambiguous.

Enablement can function as the means for determining whether the inventor's contribution to society is commensurate with the scope of what is claimed, and whether the specification meets the written description requirement.[196] The well-known cases of *O'Reilly v. Morse* and Edison's Incandescent Lamp Patent illustrate how enablement can function to invalidate overly broad claims.[197] In his eighth, and most broad claim, Morse attempted

190. Merges & Nelson, *supra* note 8, at 845 (stating that determining how broad the disclosure should be is an important issue in patent law).
191. 35 U.S.C. §112 (codifying the specifications required in the written description).
192. *Id.* (requiring that the written description include language sufficient for others to make and use invention).
193. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir., 1988) (explaining that the words undue experimentation do not appear in the statute, but it is "well established" that a lack of undue experimentation is required for a disclosure to be enabling).
194. *Id.* The *Wands* 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." *Id.*
195. *See Ariad*, 598 F.3d at 1355 (reviewing Ariad's written description evidence).
196. *See* Merges & Nelson, *supra* note 8, 844-45 (evaluating the function of the enablement requirement).
197. *See* Merges & Nelson, *supra* note 8, at 849-51 (discussing the *O'Reilly*,

to claim all methods of using electromagnetism to communicate at a distance, but the court invalidated this claim as non-enabled because he did not disclose all methods in his patent.[198] Similarly, when Edison challenged Sawyer and Mann's patent claims on all "carbonized fibrous or textile material" used as light bulb filaments, the court struck down those claims as non-enabled because undue experimentation would be required to practice the broad claims.[199]

Although enablement can limit overly broad claims, the Federal Circuit did not consider enablement in *Lilly*.[200] The methods described in University of California's patent specification were complex, but they were quite possibly enabled because a person of ordinary skill in the art would have been able to use the techniques described to isolate any other mammalian cDNA sequence.[201] Thus, in this case, one can argue that the policy goal of patent law was obstructed by the *Lilly* written description requirement because an inventor could not claim what they contributed to the public.[202]

Enzo Biochem Inc., v. Calgene, Inc. also provides an example of the enablement requirement working to invalidate overly broad claims.[203] Enzo claimed antisense technology to regulate gene expression in all organisms, but only provided a successful example of regulating the expression of three genes in E. coli.[204] Despite failing to regulate gene expression in any other

Morse and *Edison* cases).

198. *See* Merges & Nelson, *supra* note 8, at 850-51 (describing the scope of Morse's claim).

199. *See* Merges & Nelson, *supra* note 8, at 849-50 (holding the claims were non-enabled because of undue experimentation).

200. *See* McTavish, *supra* note 179, at 136 (articulating the courts reasons for not considering enablement in *Lilly*).

201. *See* McTavish, *supra* note 179, at 136-37 (evaluating the reasonableness of using rat cDNA to isolate any other mammalian cDNA).

202. *See* McTavish, *supra* note 179, at 136-37 (highlighting policy implications of a heightened written description requirement versus relying on enablement).

203. 188 F.3d 1362, 1381 (Fed. Cir. 1999).

204. *See* McTavish, *supra* note 179, at 133 (describing Enzo's patent claims). Antisense technology blocks the translation of an mRNA into a protein by introducing a nucleic acid strand into a cell that is complementary to the

genes in E. coli or in any other organisms, the patentee received a patent on broad claims.[205] The court evaluated the claims in *Enzo v. Calgene* according to the *Wands* standards and found that extremely broad claims were being made in the unpredictable art of antisense technology, that a great deal of experimentation was required to successfully employ the patentees methods, and that few examples were provided.[206] The *Wands* factors were equal to the task of invalidating overly broad claims.[207]

Limiting inventors to what they contribute to the public is certainly sound policy, but providing some certainty for inventors is also important for promoting innovation. The written description standard appears to be a moving target: a question of fact with no clear standards for what will satisfy the requirement.[208] As Judge Rader stated in his dissenting opinion in *Ariad II*, the *Lilly* written description requirement is a new, judicially created requirement that will impede innovation.[209] Enablement is a strong, statutory test that provides for neutral, predictable application. The superfluous nature of written description as a separate requirement under 35 U.S.C. § 112 is perhaps best illustrated by the fact that since *Lilly* was decided the USPTO has been successfully using lack of enablement, not

sequence of the mRNA strand. *See* Enzo v. Calgene, 188 F.3d at 1366-67. This double stranded complex cannot be translated into a protein, and therefore the expression of the gene is halted. *Id.* at 1367.

205. *See* McTavish, *supra* note 179, at 133 (asserting that broad claims were granted absent gene regulation in any other organisms).

206. *See* McTavish, *supra* note 179 (listing and applying the *Wands* standards to Enzo's claims).

207. *See* Enzo v. Calgene, 188 F.3d at 1381 (concluding that the claims were overly broad and invalid).

208. *See Ariad II*, 598 F.3d at 1361. In his dissent in *Enzo II*, Judge Rader comments that the fact based nature of the current written description requirement is too subjective to provide clarity for inventors. *Id.* (citing Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (Rader, J., dissenting)). "As it stands, the court's inadequate description of its written description requirement acts as a wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection." *Id.* at 1366.

209. *See Ariad II*, 598 F.3d at 1362. "If this court perceives a need for renewed attention to description requirements, it should strengthen its enablement jurisprudence instead of making new rules. Invention of new technologies strengthens and advances the "useful arts," but invention of new doctrines frustrates and confuses the law." *Id.* at 1366-67.

inadequate written description, to invalidate overly broad claims.[210]

VII. Conclusion

It is unfortunate that the Federal circuit focused on written description in the *Lilly* written description line of cases. The Federal Circuit declined to consider enablement in *Lilly* and *Enzo*, passing up a golden opportunity to fortify enablement case law. Recent decisions regarding written description upset existing case law and the settled expectations of inventors, potentially impeding innovation. This is especially troublesome in the biotechnology industry where patent protection is vital in moving new products to market. Although *Ariad* has solidified, and affirmed the post-*Lilly* precedent, providing some certainty for inventors, satisfying the written description under *Ariad* remains a fact based inquiry where the rules appear unclear and potentially fluid. Judging the adequacy of a written description by whether a disclosure is enabling would have been a superior standard because the *in re Wands* factors are well established. Providing clarity for innovators will allow them to more confidently invest the resources essential for moving a biotechnological innovation to market in the form of a useful product, thereby "promot[ing] the progress of science and useful arts," [211] and meeting the goal of United States patent law.

210. *See Ariad II*, 598 F.3d at 1371. The government's amicus brief stated that the written description requirement is essential for examining patent applications, but at "at oral argument . . . could not cite the number of applications that the PTO annually rejects on written description grounds and cannot reject on another basis." *Id.*

211. U.S. CONST, art. 1, § 8, cl. 8.