UNIVERSITY OF ROCHESTER V. G.D. SEARLE & CO.: IN SEARCH OF A WRITTEN DESCRIPTION STANDARD

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The patent system strives to reward pioneering inventors for their efforts while simultaneously promoting subsequent research and innovation.[1] This balancing effort succeeds when the scope of the patent reward is commensurate with the inventor's contribution to society—namely, when the inventor receives exclusive rights to what he *actually invented* and nothing more.[2] The written description requirement of § 112[3] is one of the patent system's mechanisms of regulating this balance. A central purpose of the written description requirement is to ensure that "the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[4] The Federal Circuit and its predecessor courts have consistently held that, in order to satisfy the written description requirement, the inventor must demonstrate that he was in "possession" of the claimed invention when he filed the patent application.[5] The underlying assumption is that a sufficiently detailed description would not be possible if the inventor were speculating about the invention's features.[6]

While patent law theoretically governs the validity of all patents in a technology-neutral manner, application of the rules has in fact varied among technologies.[7] The biotechnology and pharmaceutical industries, in

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1. *See* Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J. L. & TECH. 267, 268 (2000).

2. *See* Paula K. Davis, *Questioning the Requirement for Written Description:* Enzo Biochem v. Gen-Probe *and Overly Broad Patent Cases*, 37 IND. L. REV. 467, 468 (2004); *see also* 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, 251-54 (2002) (discussing the pros and cons of a heightened written description standard).

3. 35 U.S.C. § 112 (2000).

4. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920 (Fed. Cir. 2004).

5. *See, e.g.*, Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); *In re* Edwards, 568 F.2d 1349, 1351 (C.C.P.A. 1978).

6. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1174 (2002).

7. *Id.* at 1156.

particular, have become subject to more stringent written description requirements than other disciplines.[8] In several pivotal decisions, the Federal Circuit addressed what constitutes "possession" in the context of biotechnology inventions and imposed a strict disclosure requirement for inventions involving DNA claims.[9] In the landmark case of *Regents of the University of California v. Eli Lilly and Co.*,[10] the court required disclosure of the precise nucleotide sequence of the claimed cDNA[11] to prove the inventor in fact possessed the invention.[12] The court's insistence that a DNA invention must be described by its precise structure has resulted in a stringent written description rule—the *Lilly* standard—specifically targeted at biotechnology patents.[13]

In its recent *University of Rochester v. G.D. Searle & Co.* decision,[14] the Federal Circuit solidified the *Lilly* standard and extended its stringent rule to all claims directed to biotechnology and pharmaceutical inventions. While the court rightly aimed to standardize the written description requirement, it missed the mark by choosing the *Lilly* rule as the standard for all DNA and chemical claims. The per se disclosure rule created by the *Rochester* court was not only unnecessary for reaching the proper outcome in the case, but it also strayed from a long line of precedent, promising to produce unreasonable outcomes and undermining the policy goals of the patent system. Most importantly, the rigid standard threatens to overshadow the fundamental inquiry when granting patent rights—whether or not the inventor *actually invented* that which he seeks to patent.[15]

Part I of this Note examines the historical development and evolution of the written description requirement in the United States patent system. Part II provides a summary of *Rochester* and examines the Federal Circuit's application of the written description requirement to chemical in-

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8. *See id.*

9. *See* Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566-67 (Fed. Cir. 1997); Fiers v. Revel, 984 F.2d 1164, 1170-71 (Fed. Cir. 1993).

10. 119 F.3d 1559.

11. *Id.* at 1566-67. cDNA is "complementary DNA," a type of DNA often used for cloning or as a DNA probe for locating specific genes. cDNA, MEDICINENET.COM, http://www.medterms.com/script/main/art.asp?articlekey=2656 (last visited Jan. 11, 2006).

12. *Lilly*, 119 F.3d at 1568-69.

13. *See* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 618 (1998).

14. 358 F.3d 916 (Fed. Cir. 2004).

15. *See In re* Barker, 559 F.2d 588, 592 n.4 (C.C.P.A. 1977) (explaining that the "essential goal" of the description of the invention is to clearly convey that the applicant has invented the subject matter he claims).

ventions. Part III contends that although *Rochester* was properly decided, the court's extension of the strict DNA-specific disclosure standard to all chemical inventions was unnecessary and improper in light of precedent and the policy goals of the patent system. This Note concludes that the "possession" test is the appropriate standard by which to harmonize the written description requirement and achieve the proper outcome among differing technologies.

I. BACKGROUND

The U.S. patent system aims to promote the progress of science and technology.[16] An inventor may be granted limited monopoly rights, in the form of patents, in exchange for contributing something of value to society.[17] In order for a patent to issue and withstand judicial scrutiny, the claimed subject matter must be useful, novel, nonobvious, and adequately described in the patent application.[18] Adequate disclosure is the "quid pro quo of the right to exclude";[19] it serves a teaching function in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.[20]

Section 112 sets forth the current standard for adequate disclosure:

> 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.[21]

The courts and the United States Patent and Trademark Office (PTO) interpret § 112 to contain three separate requirements: (1) the written description requirement; (2) the enablement requirement; and (3) the best mode requirement.[22]

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16. U.S. CONST. art. I, § 8, cl. 8.
17. *See generally* Bonito Boats v. Thunder Craft Boats, 489 U.S. 141 (1989).
18. 35 U.S.C. §§ 101-103, 112 (2000).
19. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974).
20. Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).
21. 35 U.S.C. § 112, ¶ 1 (2005).
22. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 566 (Fed. Cir. 2000); UNITED STATES PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161 (8th ed., rev. 2003) [hereinafter MPEP]. Although there

The following Part traces the development of the written description doctrine. Section A discusses the purpose and function of the written description requirement, detailing its evolution from a priority policing device with only procedural relevance into a substantive disclosure standard crucial to patentability and validity determinations.[23] Section B discusses the development of the "possession" standard as the test for adequate written description and the court's application of the possession standard to biotechnology inventions.

A. Development of the Written Description Requirement

As early as 1822, the Supreme Court recognized the existence of separate enablement and written description requirements. In *Evans v. Eaton*,[24] the Court interpreted the purpose of the Patent Act of 1793 as being twofold: (1) to enable artisans to make and use the invention, and (2) to put the public in possession of the invention to prevent an inventor from "pretending that his invention is more than what it really is."[25] Early cases implied, however, that the written description requirement mattered only for policing priority of invention.[26] While the enablement requirement served as the substantive disclosure requirement for the original application, requiring that it enable artisans to make and use the invention, the written description requirement served the procedural function of preventing applicants from improperly amending claims after submitting the initial application.[27] Over time, however, the written description doctrine began to play a role in evaluating the substantive merit of originally filed claims,[28] making it difficult for the courts to clearly distinguish the written description and enablement requirements.[29]

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are three requirements, I do not discuss best mode because it is beyond the scope of this Note.

23. Kopczynski, *supra* note 2, at 236.

24. 20 U.S. (7 Wheat.) 356 (1822).

25. *In re* Barker, 559 F.2d 588, 592 n.4 (C.C.P.A 1977) (quoting *Evans*, 20 U.S. (7 Wheat.) at 434).

26. *See* Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d. Cir. 1981); *In re* Bowen, 492 F.2d 859, 864 (C.C.P.A. 1974); *see also* Guang Ming Whitley, *A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617, 619-20 (2004) (explaining that the original purpose of the written description requirement was to prevent a patent applicant from misusing the amendment process by introducing new matter into his claims while still retaining his original filing date, and therefore, his place in the "priority line"). *See generally* 3A DONALD S. CHISUM, CHISUM ON PATENTS §§ 10.01-.09 (2005) (offering a comprehensive explanation of priority).

27. Whitley, *supra* note 26, at 620.

28. Mueller, *supra* note 13, at 618-22.

29. *See* Mueller, *supra* note 13, at 634.

1. *The Purpose and Function of the Written Description Requirement*

In the early development of the written description doctrine, courts interpreted the requirement to prevent applicants from adding new disclosures to the patent through amendments while retaining the benefit of an earlier filing date.[30] In *In re Ruschig*,[31] the Court of Customs and Patent Appeals (CCPA) recognized a written description requirement that the court could use to deny priority in an interference proceeding where "new matter" was added to a patent application.[32] The inquiry in *Ruschig* was whether "the specification conveys clearly to those skilled in the art, to whom it is addressed, *in any way*, the information that appellants invented that specific compound."[33] The court rejected Ruschig's amended claim on the grounds that the compound added to the claim was never "named or otherwise exemplified" in the original application.[34] Because the specification failed to provide an adequate written description of the later-claimed species, the invention lacked a "written description" in the parent.[35]

The *Ruschig* court not only expressly recognized a written description requirement for claims filed or amended after an original filing date, but also established the standard by which to evaluate compliance with the requirement. The court made it clear that the *manner* in which a claimed invention is described is not critical, as long as the description conveys that the inventor had actually invented the claimed subject matter.[36] The CCPA developed this point further in *In re Smith*, explaining that the specification need not describe the claimed subject matter "*in haec*

30. Whitley, *supra* note 26, at 617-18.

31. 379 F.2d 990 (C.C.P.A. 1967).

32. *See id.* at 992, 996 (affirming rejection of an added claim to a patent application on the basis that the chemical compound was never "named or otherwise exemplified" in the original patent application even if it was within the literal scope of the originally filed claim, and observing that the specification would not "convey clearly to those skilled in the art" the information that applicants invented that specific compound); Harold C. Wegner, A New "Written Description" Requirement: Going Beyond the Statute, Address Before the American Intellectual Property Law Association (Apr. 19, 2002), *available at* http://www.foley.com/files/tbl_s31Publications/FileUpload137/819/enzo_wp_final.pdf.

33. *Ruschig*, 379 F.2d at 996 (emphasis added).

34. *Id.* at 992.

35. *See id.* at 995-96.

36. *Id.* at 996.

verba"[37] for it to satisfy the written description requirement.[38] The court described the "essential goal" of the description requirement as conveying "clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed."[39] When the original specification accomplishes this goal, the written description requirement is satisfied "regardless of how [the specification] accomplishes it."[40]

In *Regents of the University of California v. Eli Lilly and Co.*,[41] the Federal Circuit extended the scope of the written description requirement beyond the context of priority policing. In a case where the defendant never raised enablement, the court utilized the written description requirement to invalidate the University of California's originally filed claims.[42] The Federal Circuit thereby created a new substantive requirement for original claims by requiring patent applicants to show adequate disclosure through both the enablement and written description requirements.[43] As a result, the demarcation between the two requirements blurred.[44] The court has since struggled to articulate a function for the written description requirement that is distinct from that of the enablement requirement.[45]

2. *Written Description and Enablement are Separate and Distinct Requirements*

While the written description requirement traditionally served the procedural function of priority policing, the enablement requirement traditionally served to evaluate the substantive merit of the claims.[46] The enablement requirement ensures that the specification allows one skilled in the art "to make and use" the claimed invention without "undue experimentation."[47] The Federal Circuit, in *In re Wands*,[48] articulated a list of

37. *In haec verba* is Latin for "in these words," which refers to stating the exact language. LAW.COM: LAW DICTIONARY, http://dictionary.law.com/default2.asp?typed=in+haec+verba&type=1 (last visited Mar. 6, 2006).

38. *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973).

39. *Id.*

40. *Id.*

41. 119 F.3d 1559 (Fed. Cir. 1997).

42. *Id.* at 1567.

43. *Id.*; *see also* Whitley, *supra* note 26, at 621 (observing that the Federal Circuit has had difficulty articulating a function for the written description requirement that is distinct from that of enablement, now that the written description requirement extends beyond the discrete sphere of priority and into the realm of adequate disclosure).

44. Mueller, *supra* note 13, at 634.

45. Whitley, *supra* note 26, at 621.

46. Whitley, *supra* note 26, at 617-18.

47. Adang v. Fischhoff, 286 F.3d 1346, 1355 (Fed. Cir. 2002).

factors that may be considered in determining whether or not the disclosure requires such "undue experimentation," including the "predictability" of the art.[49] The chemical and biotechnological arts, for example, are considered "unpredictable" because scientists are unable to predict how simple changes will affect chemical reactions or physiological activities.[50] While the scope of enablement theoretically varies inversely with the degree of unpredictability,[51] the *Wands* test failed to enumerate specific criteria for determining adequate disclosure in the unpredictable arts.[52] This inadequacy resulted in the granting of overbroad patents in unpredictable fields like biotechnology, and commentators have hypothesized that this deficiency eventually led the courts to demand higher levels of disclosure to satisfy both the enablement and written description requirements.[53]

As the written description requirement progressively assumed a larger role in determining the substantive validity of patents, the Federal Circuit grappled with whether the written description and enablement requirements were separate or intertwined.[54] In *In re Wilder*[55] the court explicitly stated: "The description requirement . . . is separate from the enablement requirement."[56] Upon revisiting the issue three years later, however, the

48. 858 F.2d 731 (Fed. Cir. 1988).

49. Factors to be considered in determining whether a disclosure would require undue experimentation . . . 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. at 737.

50. Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH L.J. 1233, 1240 (2000). The electrical and mechanical arts, in contrast to the chemical and biotechnological arts, are considered "predictable" because once a single embodiment of the invention is enabled, other embodiments can be made without difficulty and their performance characteristics can be predicted by known scientific laws. *Id.*

51. *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

52. Whitley, *supra* note 26, at 618.

53. *See* Whitley, *supra* note 26, at 618, 630; Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1, 27 (2005); *see, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991) (holding that the gene isolation methods disclosed were not enabling because conception of a DNA invention "has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated").

54. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (discussing conflicting precedents).

55. 736 F.2d 1516 (Fed. Cir. 1984).

56. *Id.* at 1520.

court determined that the purpose of the written description requirement is merely to "communicate that which is needed to enable the skilled artisan to make and use the claimed invention."[57] The court concluded that the requirements "may be viewed separately, but they are intertwined."[58]

In 1991, the Federal Circuit finally reviewed the requirements in *Vas-Cath, Inc. v. Mahurkar*[59] and stated that written description and enablement are two separate and distinct requirements.[60] The court explained that the purpose of the written description requirement goes beyond merely explaining how to "make and use" (i.e., enable) the invention.[61] Adequate description prevents the inventor's overreaching "by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."[62] In addition, the *Vas-Cath* court stated that to fulfill the written description requirement the applicant must "convey 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."[63]

B. The Possession Standard for Adequate Written Description

The "possession" standard that *Vas-Cath* articulated was adopted in subsequent cases[64] and embraced by the PTO.[65] *Lockwood v. American Airlines, Inc.*[66] further explained that an inventor demonstrates "possession" of the invention by describing the invention with "all its claimed limitations."[67] According to *Lockwood*, an applicant may comply with the disclosure requirement through such descriptive means as words, struc-

57. Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987).

58. *Id.*

59. 935 F.2d 1555 (Fed. Cir. 1991).

60. *Id.* at 1563-64.

61. *Id.* at 1563.

62. *Id.* at 1561 (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981)).

63. *Id.* at 1563-64 (emphasis added).

64. *See, e.g.*, Hyatt v. Boone, 146 F.3d 1348, 1354 (Fed. Cir. 1998) (affirming that the purpose of the written description requirement *in all cases* is to ensure that the inventor had possession of the subject matter claimed); Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996) ("the disclosure need only reasonably convey to persons skilled in the art that an inventor had possession of the subject matter in question"); Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993) (affirming that the legal standard for written description requires that the specification reasonably conveys to the artisan that the inventor had possession of the claimed subject matter).

65. *See* MPEP, *supra* note 22, §§ 2161, 2163.

66. 107 F.3d 1565 (Fed. Cir. 1997).

67. *Id.* at 1572.

tures, figures, diagrams, and formulas that fully set forth the claimed invention.[68]

In *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[69] the Federal Circuit applied a variation of the possession standard to invalidate claims to DNA inventions on grounds of insufficient enablement. The court defined possession in terms of "conception" of the complete and operable invention, which occurs when one has a "mental picture of the structure of the chemical" or is able to "define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it."[70] The court invalidated claims to gene isolation methods, concluding that conception of a DNA invention cannot be achieved until after the gene has been isolated, because an inventor would be unable to envision the detailed constitution of a gene until the gene had been cloned and characterized.[71] Thus, the court held that proof of conception of a DNA invention requires actual reduction to practice.[72]

While the court's analysis in *Amgen* pertained to enablement, it was not long before the new possession-by-completed-conception standard carried over into the written description context. Two years after *Amgen*, the Federal Circuit applied the new articulation of the possession standard, along with the heightened disclosure rule for DNA inventions, to evaluate the adequacy of written descriptions for biotechnology inventions.

1. *The Strict Possession Standard for Biotechnology Inventions*

In *Fiers v. Revel*,[73] the Federal Circuit co-opted the *Amgen* standard to evaluate compliance with the written description requirement, reasoning that "one cannot describe what one has not conceived."[74] In a three-way interference case regarding claims to DNA encoding human beta-interferon, Revel and Fiers lost the priority battle to Sugano, the party who was first to set forth "the complete and correct nucleotide sequence" of the

68. *Id.*

69. 927 F.2d 1200, 1206, 1212, 1214 (Fed. Cir. 2001) (invalidating claims for insufficient enablement because conception had not been proven where patentee generically claimed all possible DNA sequences that would encode a protein "sufficiently duplicative" of erythropoietin).

70. *Id.* at 1206.

71. *Id.*

72. *Id.*

73. 984 F.2d 1164 (Fed. Cir. 1993).

74. *Id.* at 1171.

claimed DNA.[75] The court equated the *Amgen* standard for conception with the possession test for written description, demanding actual reduction to practice (i.e., isolation and sequencing) to prove possession of the DNA claimed.[76] Although the court established a DNA-specific standard for written description compliance, it preserved a crucial degree of flexibility by leaving open other ways of claiming DNA.[77]

The Federal Circuit revisited the issue of the written description requirement for original claims to DNA sequences in *Regents of the University of California v. Eli Lilly and Co.*[78] Relying on its reasoning in *Fiers*, the court invalidated the University of California's patent on human insulin-encoding cDNA because the specification only recited the nucleotide sequence of rat insulin-encoding cDNA.[79] Even though the University's inventors had isolated a cDNA gene for rat insulin and described a general method of producing human insulin cDNA in the specification, the court found the University's written description inadequate for failure to provide the specific nucleotide sequence of the human cDNA.[80] In the words of the court: "[A]n adequate written description of a DNA . . . '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."[81] The court demanded a showing of possession through recitation of nucleotide sequences, and accordingly, limited the patent to only those cDNA sequences the University had in fact isolated and specifically described.[82] The court further elaborated on the written description re-

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75. *Id.* at 1172. Human fibroblast beta-interferon (B-IF) is a protein that promotes viral resistance in human tissue. Interferon, ANSWERS.COM, http://www.answers.com/topic/interferon (last visited Jan. 17, 2006).

76. 984 F.2d at 1170-71. DNA sequencing is the process of determining the order of nucleotides (base sequences) in a segment of DNA. DNA sequence, MEDICINENET.COM, http://www.medterms.com/script/main/art.asp?articlekey=3101 (last visited Jan. 17, 2006).

77. 984 F.2d at 1169-70; *see* Mueller, *supra* note 13, at 624 ("Prior to the Federal Circuit's decision in Lilly, adequate written description of chemical and biotechnological compounds . . . could be described in terms of their function, properties, method of making, or any other manner sufficient . . . to convey possession by the inventor.").

78. 119 F.3d 1559 (Fed. Cir. 1997).

79. *Id.* at 1567-68. cDNA is "complementary DNA," a type of DNA often used for cloning or as a DNA probe for locating specific genes. *See* cDNA, MEDICINENET.COM, http://www.medterms.com/script/main/art.asp?articlekey=2656 (last visited Jan. 11, 2006).

80. 119 F.3d at 1567-68.

81. *Id.* at 1566 (quoting and upholding a standard established in *Fiers*, 984 F.2d at 1171).

82. *Id.* at 1567-69.

quirement, stating that a description of what a material does, rather than what it is, usually does not suffice, because the disclosure must allow one skilled in the art to distinguish between the claimed subject matter and other materials with the same function or activity.[83]

After the *Lilly* court tightened the disclosure standard for biotechnology inventions, the Federal Circuit returned five years later in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*[84] to relax the written description requirement.[85] In an earlier opinion in this case,[86] the Federal Circuit applied the *Lilly* standard and invalidated claims to polypeptides that detect the gonorrhea bacteria, despite the fact that the inventor of these DNA probes deposited three polypeptides at a public depository.[87] The court concluded that merely depositing the material did not satisfy the nucleotide-by-nucleotide recitation required by *Lilly*.[88]

Within a few months, the court vacated its original opinion and reversed the result, remedying the inappropriate outcome that had resulted from applying the rigid *Lilly* standard.[89] The court in *Enzo II* resurrected the possession test from *Vas-Cath*, affirming that the purpose of the written description requirement is to demonstrate that the inventor did in fact possess what he sought to claim.[90] The court declared that functional descriptions of genetic material *can* establish possession, if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."[91] The court held that Enzo's patent claims, describing the functional ability of the probes and referring to a deposit of the biological material in a public depository, satisfied the written description requirement. Accordingly, *Enzo II* not only rejected the strict *Lilly* disclosure standard and reinstated

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83. *Id.* at 1568.

84. 323 F.3d 956 (Fed. Cir. 2002) [hereinafter *Enzo II*].

85. *Id.* at 964 ("It is not correct . . . that all functional descriptions of genetic material fail to meet the written description requirement."). *But see* Chandra Garry, Note, *Written Description:* Enzo Biochem, Inc. v. Gen-Probe, Inc., 18 BERKELEY TECH. L.J. 195, 202 (2003) (arguing that *Enzo* does not relax, but rather redefines the written description requirement).

86. Enzo Biochem, Inc. v. Gen-Probe, Inc., 285 F.3d 1013 (Fed. Cir. 2002) [hereinafter *Enzo I*], *vacated*, 323 F.3d 956 (Fed. Cir. 2002).

87. *Id.* at 1022. A polypeptide is a chain of linked amino acids, also known as a protein molecule. Polypeptide, EVERYTHINGBIO.COM, http://www.everythingbio.com/glos/definition.php?word=polypeptide (last visited Jan. 17, 2006).

88. 285 F.3d at 1022.

89. *See Enzo II*, 323 F.3d at 960; Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1308 (Fed. Cir. 2004) (Newman, J., dissenting).

90. 323 F.3d at 969 (citing *Vas-Cath*, 935 F.2d at 1563-64).

91. *Id.* at 964.

the possession test, but it also proffered an example of an invention successfully described by its functional characteristics.[92]

II. *UNIVERSITY OF ROCHESTER V. G.D. SEARLE & CO.*

The University of Rochester received U.S. Patent No. 6,048,850 (the '850 patent) for a method of producing and administering a compound to relieve inflammation.[93] The day the '850 patent issued, Rochester sued several pharmaceutical companies, alleging that their sale of the anti-inflammatory drugs Celebrex and Bextra infringed the patent.[94] On appeal, the Federal Circuit assessed the validity of the '850 patent based on the written description requirement of Section 112 and examined the written description standard for all DNA and chemical inventions.[95]

A. Facts and Procedural History

Scientists from the University of Rochester developed a screening assay to determine whether a particular drug selectively inhibits the enzyme responsible for inflammation, without also inhibiting the enzyme responsible for protecting the stomach lining.[96] Traditional non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin, ibuprofen, ketoprofen, and naproxen are believed to function by inhibiting the activity of enzymes called cyclooxygenases (COX).[97] Specifically, NSAIDs inhibit both COX-1 (also called PGHS-1), which provides protection for the stomach lining, and COX-2 (also called PGHS-2), which is responsible for the inflammation associated with diseases such as arthritis.[98] As a result, NSAIDs not only reduce inflammation, but can also cause gastrointestinal side effects including upset stomach, ulcers, and bleeding.[99] After the separate functions of COX-1 and COX-2 were discovered, it was hypothesized that the side effects of NSAIDS could be prevented if a method could be found for selectively inhibiting the activity of COX-2.[100] To this end, Rochester scientists developed a screening assay to identify com-

92. *Id.* at 970.
93. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 918 (Fed. Cir. 2004).
94. *Id.* at 918-19.
95. *See id.*
96. *Id.* An assay is a test used to determine the presence of a substance and the amount of that substance or to analyze the biological or pharmacological potency of a drug. Assay, BIOLOGY-ONLINE.ORG, http://www.biology-online.org/dictionary/assay (last visited Jan. 17, 2006).
97. *Rochester*, 358 F.3d at 917.
98. *Id.*
99. *Id.* at 917-18.
100. *Id.* at 918.

pounds with such selective inhibition capabilities, and in 1998 obtained United States Patent No. 5,837,479 (the '479 patent) covering the methods.[101]

Two years later, the University obtained another patent, the '850 patent, from a division of the application that led to the '479 patent.[102] The '850 patent claimed a method of treating humans by administering a selectively inhibiting compound.[103] The specification described the compound necessary to practice the treatment method only in terms of its function: "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product."[104] The day the '850 patent issued, Rochester brought suit against G.D. Searle & Co., Inc., Monsanto Co., Pharmacia Corp., and Pfizer Inc. (collectively, "Searle") for infringement of the '850 patent by Celebrex and Bextra, which treat inflammation.[105]

B. The District Court Decision

The District Court for the Western District of New York granted summary judgment to the manufacturers, declaring the '850 patent invalid for failure to meet the written description and enablement requirements of 35 U.S.C. § 112.[106] The court found that although all eight claims of the '850 patent require the use of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene," the '850 patent neither disclosed any such compound nor provided any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research.[107] The court concluded that the specification failed to provide evidence that the inventors themselves knew of any such compound at the time their patent application was filed and accordingly held that the claims were invalid for lack of written description.[108] In addition, the court held that the claims were also invalid for lack of enablement, because the prac-

101. *Id.* In 1998, the '479 patent issued, covering methods for identifying a compound "that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2)." U.S. Patent No. 5,837,479 (filed June 7, 1995). The validity of the '479 patent was not at issue in this case.

102. *Rochester*, 358 F.3d at 918.

103. *Id.* More specifically, all eight claims of the '850 patent were directed to methods "for selectively inhibiting PGHS-2 activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment." U.S. Patent No. 6,048,850 (filed June 7, 1995).

104. *Rochester*, 358 F.3d at 918.

105. *Id.* at 918-19.

106. *Id.* at 919.

107. *Id.*

108. *Id.*

tice of the claimed methods would require a person of ordinary skill in the art "to engage in undue experimentation, with no assurance of success."[109] Finding no genuine issue of material fact concerning either written description or enablement, the court granted Searle's motions for summary judgment and denied Rochester's cross-motion.[110]

Rochester appealed, arguing that the district court erred on three grounds: (1) granting Searle's motion for summary judgment of invalidity for lack of written description; (2) granting Searle's motion for summary judgment of invalidity for lack of enablement; and (3) denying Rochester's cross-motion for summary judgment with regard to written description.[111]

C. The Federal Circuit's Analysis

The Federal Circuit affirmed the district court's invalidation of the '850 patent for lack of written description and affirmed summary judgment in favor of Searle on that ground.[112] Upon finding the patent invalid on its face, the court held the enablement issue to be moot.[113] The court also affirmed the district court's denial of Rochester's cross-motion for summary judgment, holding that no evidence to rebut the presumption of validity is necessary where a patent is, as a matter of law, invalid for failure of description.[114]

Focusing on the possession aspect of the written description requirement, the court reaffirmed that a patent application must "describe the claimed subject matter in terms that establish that the applicant was in *possession* of the . . . claimed invention, including all the elements and limitations."[115] Stated another way, the specification must provide sufficient description to show one of ordinary skill in the art that the inventor possessed the claimed invention at the time of filing.[116]

The court observed that Rochester's claimed method depended upon finding a compound that selectively inhibits PGHS-2 activity; without such a compound, it is impossible to practice the claimed method of treatment.[117] The Federal Circuit agreed with the district court's finding

109. *Id.*
110. *Id.*
111. *Id.*
112. *Id.* at 929-30.
113. *Id.* at 930.
114. *Id.*
115. *Id.* at 926 (emphasis added).
116. *Id.* at 928.
117. *Id.* at 926.

that "one critical aspect of the method—a compound that selectively inhibits PGHS-2 activity—was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound."[118] The '850 patent disclosed nothing more than a "hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it."[119] To that end, the Federal Circuit affirmed invalidation of Rochester's '850 patent.[120]

But, the Federal Circuit did not stop there. After acknowledging the undisputed fact that the '850 patent does not disclose any compounds that can be used in its claimed methods, and that the patent was therefore invalid on its face, the court went on to articulate a more stringent disclosure standard for future chemical inventions. The court recited the *Lilly* standard for demonstrating possession of biotechnology inventions: "an adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,'" and added, "that requirement applies just as well to non-DNA (or -RNA) chemical inventions."[121] The Federal Circuit held that because the '850 patent did not disclose just "which 'peptides, polynucleotides, and small organic molecules' have the desired characteristic of selectively inhibiting PGHS-2," the claimed methods were not adequately described.[122]

III. DISCUSSION

While *Rochester* was properly decided, the court's extension of the strict biotech-specific disclosure standard to all chemical inventions was unnecessary and improper in light of precedent and the policy goals of the patent system. Section A explains why extension of the *Lilly* standard was unnecessary. Section B examines *Capon v. Eshhar*,[123] a biotechnology case decided six months after *Rochester*, to illuminate the problems the rigid standard has already caused. Section C addresses the undue burden placed on patentees and argues that the "possession" test is the appropriate standard by which to harmonize the written description requirement and achieve the proper outcome among differing technologies.

118. *Id.*
119. *Id.* at 926-27.
120. *Id.* at 929.
121. *Id.* at 927.
122. *Id.*
123. 418 F.3d 1349 (Fed. Cir. 2005).

A. Extending the *Lilly* Standard to all Chemical Inventions was Unnecessary

According to the *Lilly* standard, inventions involving claims to DNA require disclosure of the specific nucleotide sequence.[124] By applying this strict standard across the board to all chemical inventions, the *Rochester* court declared that proof of possession necessarily requires description of the *precise structure* of the compound required to practice the claimed method.[125] Stated another way, the court assumes that the written description requirement in the chemical arts cannot be satisfied by describing compounds in terms of their function, properties, method of making, or any other manner, regardless of whether or not that description is sufficient to convey possession.[126] While it may have been the case in *Lilly* that disclosure of the specific nucleotide sequence was necessary to prove possession of the human insulin cDNA, the *Rochester* court's assumption that this will *always* be the case for claims involving DNA or chemical inventions contradicts a long line of precedent. Ironically, the Federal Circuit acknowledged this in its own reasoning.

The *Rochester* court recognized that historically courts have afforded patent applicants flexibility in the mode selected for compliance with the written description requirement.[127] In *In re Edwards*, for example, the CCPA held that the written description requirement was satisfied by a specification describing a water-insoluble polyol by the process by which it was made, rather than by its chemical structure.[128] The court found that Edwards' application, "taken as a whole, reasonably leads persons skilled in the art to the [recited reactions] and, concomitantly, to the claimed compound."[129] In *Union Oil Co. v. Atlantic Richfield Co.*, the Federal Circuit rejected the argument that Unocal's patent was invalid because it described claimed gasoline mixtures by their "desired characteristics," rather than by their "exact chemical components."[130] The court held that the disclosure was sufficient because artisans in petroleum refining knew how to

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124. Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566-67 (Fed. Cir. 1997).

125. 358 F.3d at 927; *see Lilly*, 119 F.3d at 1567-69.

126. *See* Mueller, *supra* note 13, at 624.

127. *Rochester*, 358 F.3d at 928.

128. *In re* Edwards, 568 F.2d 1349, 1354 (C.C.P.A. 1978). A polyol is an alcohol containing more than two hydroxyl groups. The polyol claimed in *Edwards* had sufficient self-catalytic activity to react with organic compounds to form fire-retardant polyurethane foams. *Id.* at 1350.

129. *Id.*

130. Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000) [hereinafter *Unocal*].

mix the sources to achieve a final product with the desired characteristics.[131] Finally, the *Rochester* court discussed *In re Herschler*, which found adequate written description support for broad claims to processes for topically administering a steroidal agent to a human or animal by concurrently administering the steroid and dimethyl sulfoxide ("DMSO").[132] The specification only disclosed one example of "a physiologically active steroidal agent," but the court upheld the claims nonetheless because many such steroidal agents were known in the art.[133]

The Federal Circuit went to great lengths to distinguish the facts of *Rochester* from cases that had allowed diverse forms of disclosure.[134] In "marked contrast to the *Edwards* application," the court reasoned, Rochester's patent failed to disclose any method for making even a single compound that can achieve the claimed effect.[135] The court distinguished *Unocal* by the fact that artisans skilled in petroleum refining could recognize what Unocal claimed based on the disclosed ranges of gasoline properties, whereas Rochester presented no evidence that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description as "a non-steroidal compound that selectively inhibits . . . PGHS-2."[136] Finally, the *Rochester* court distinguished *Herschler* based on the fact that, unlike "non-steroidal compounds that selectively inhibit . . . PGHS-2," there is no question that numerous physiologically active steroidal agents were known to those of ordinary skill in the art.[137] The *Herschler* court allowed the broad claims because the novelty in that invention was the DMSO solvent, not the steroids.[138]

After distinguishing *Rochester*, the court properly concluded that the '850 patent specification failed to establish a necessary link between the functional characteristics disclosed and a corresponding structure that would uniquely identify a compound. Furthermore, Rochester presented no evidence at trial that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description.[139] The court properly held that, because the '850 patent specifications disclosed nothing more than an elaborate research plan and provided no evidence

131. *Unocal*, 208 F.3d at 1000-01.
132. 358 F.3d at 928; *In re* Herschler, 591 F.2d 693, 701 (C.C.P.A 1979).
133. *Herschler*, 591 F.2d at 700-01.
134. *Rochester*, 358 F.3d at 926-28.
135. *Id.* at 928.
136. *Id.*
137. *Id.*
138. *Id.*
139. *Id.*

that the patentees ever possessed a compound necessary for the process, the written description was inadequate.[140] However, by taking the analysis one unnecessary step further and declaring that the strict DNA disclosure standard from *Lilly* "applies just as well" to all chemical inventions,[141] the court diverged from all of its cited precedents.

The Federal Circuit seems to have forgotten its own warning in *Vas-Cath* that each case involving the issue of written description must be decided on its own facts, because "the primary consideration . . . depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure."[142] The court has lost sight of a critical characteristic of the written description requirement—flexibility, both in the methods of disclosure available to patentees for proving possession and in the court's discretion to determine the extent of disclosure necessary to demonstrate possession of the specific technology. The new rigidity of the written description standard proved problematic shortly thereafter.

B. The Rigid Standard Has Already Proven Problematic: *Capon v. Eshhar*

The August 2005 decision in *Capon v. Eshhar*[143] reveals the inherent problem with the *Rochester* court's creation of a rigid per se rule: the Federal Circuit will continually have to carve out exceptions to the rule in order to rectify the illogical outcomes that will result from the lower court's application of the inflexible standard. In *Capon*, both of the parties to a patent interference proceeding appealed the decision of the Board of Patent Appeals and Interferences ("Board") regarding claims directed to the production of chimeric genes designed to enhance immune responses.[144] Both Eshhar and Capon claimed novel genetic material described in terms of the functional characteristics of the protein encoded by the chimeric gene.[145] The specifications of both applications described procedures for identifying and obtaining the desired immune-related DNA segments and linking them into the desired chimeric genes.[146] In addition, both pointed to the specific examples of chimeric DNA prepared using identified

140. *Id.* at 926-27.

141. *Id.* at 927.

142. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (quoting *In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976)).

143. 418 F.3d 1349 (Fed. Cir. 2005).

144. *Id.* at 1350. A chimeric gene is an artificial gene that combines segments of DNA in a way that does not occur in nature. *Id.* at 1351.

145. *Id.* at 1355.

146. *Id.*

known procedures, along with citations to the scientific literature for every step of the preparative method.[147]

Despite the elaborate disclosures, the Board held that neither party's specification met the written description requirement for failure to provide "the requisite description of the full scope of the chimeric DNA or encoded proteins, by reference to knowledge in the art of the 'structure, formula, chemical name, or physical properties' of the DNA or the proteins."[148] The Board stated that "controlling precedent" required inclusion in the specification of the complete nucleotide sequence of "at least one" chimeric gene.[149]

On appeal, the Federal Circuit concluded that the Board erred in holding that the specifications did not meet the written description requirement.[150] The court held that there is not a per se rule requiring nucleotide-by-nucleotide analysis when the structure of the component DNA segments is already known, or readily determined by known procedures.[151] Rather, the written description requirement must be applied in the context of the particular invention and the state of the knowledge in the art.[152] In the words of the court:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process . . . its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.[153]

The court concluded that the written description requirement does not mandate that every invention be described in the same way and found the Board's demand that the sequences be reported precisely would not have added descriptive substance.[154] As each field evolves, the "balance also evolves between what is known and what is added by each inventive con-

147. *Id.*

148. *Id.* at 1354.

149. *Id.* at 1356 (quoting the Board). As controlling precedent, the Board cited Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993), Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991), and Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316 (Fed. Cir. 2002).

150. *Capon*, 418 F.3d at 1358.

151. *Id.*

152. *Id.*

153. *Id.* at 1357.

154. *Id.* at 1358.

tribution."[155] Because the chimeric genes at issue in the case are prepared from known DNA sequences of known function, the Board erred in holding that the specifications do not meet the written description requirement simply because they do not reiterate the structure, formula, or chemical name for the nucleotide sequences of the claimed chimeric genes.[156]

Capon makes it clear that even in the case of DNA inventions, the strict standard cannot be applied across the board. Extension of the standard to chemical inventions promises to generate even more problems for the Federal Circuit, as there will certainly be similar cases in the chemical arts in which the per se rule leads to the wrong result. Precedent cited by the *Rochester* court illustrates precisely those scenarios in which application of the strict standard would have led to the invalidation of meritorious patents.[157] The court is likely to find itself carving out more and more exceptions to the *Lilly* standard in order to rectify illogical outcomes. As a result, the written description standard will gradually approach the pre-*Lilly* standard that directly addressed the question of whether or not the description proves that the inventor was *in possession* of the invention.

C. The Traditional Possession Test is the Appropriate Standard for Harmonizing the Written Description Requirement

While the court was justified in trying to harmonize the written description standard between DNA and chemical inventions,[158] the rigid standard it chose to apply was inappropriate in light of precedent, policy, and the unreasonable outcomes it will produce. As the Federal Circuit acknowledged in both *Capon* and *Enzo*, applying a rigid per se disclosure rule that fails to account for the context of the particular invention, indus-

155. *Id.*

156. *Id.*

157. *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 928 (Fed. Cir. 2004) (discussing precedent cases which upheld claims disclosed by diverse forms of description, including description based on functional characteristics, description by deposit, and description by method of making); *supra* Section III.A.

158. *See* Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries?*, 61 N.Y.U. ANN. SURV. AM. L. 317, 336-37 (2005) (discussing the benefits of harmonization in light of the problems associated with creating specially-tailored patent standards for different technologies). Shi addresses the difficulties of technology classification and synchronization of the rules with rapidly changing technologies, arguing that the patent law can be "technologically responsive" without being "technologically different" by applying established patent standards which have "intrinsic technology-responsive hinges" rather than tailor-making standards for every technology. *Id.* at 337-38.

try, and knowledge among inventors in that field can lead to illogical outcomes.[159]

The *Lilly* standard imposes an undue burden on inventors who are able to demonstrate possession of their DNA or chemical invention by means other than disclosing the precise structure of each component. This encourages superfluous disclosure, undermining the well-established principle of the patent system that a patent "need not teach, *and preferably omits*, what is well known in the art."[160] Demanding that such unnecessary information be disclosed threatens to elicit voluminous disclosures, create validity problems for patents issued prior to *Rochester*, and discourage development, thereby frustrating the patent system's policy goal of encouraging prompt disclosure of new inventions.[161]

A standard that is too lenient, on the other hand, can be equally detrimental. Granting overbroad patents stifles the competition necessary for creative development and valuable downstream innovation.[162] Patents should therefore be limited in scope to encourage other inventors to continue researching and inventing in the same area without fear of infringing previous patents.[163] Even more problematic than overbroad patents is granting exclusive rights to an invention *not yet in existence*. *University of Rochester* is a prime example, as the claimants likely did not yet possess what they sought to claim.[164] If Rochester's patent had been upheld, the competitors that ultimately produced and supplied the useful drugs to the public would have been penalized. Furthermore, competitors would have been discouraged from committing the vast resources necessary to continue pursuing innovations in the same field. Granting an inventor rights to something he does not possess can thus erect upstream obstacles that ultimately deprive society of the benefits of valuable downstream innovation.

The proper standard by which to harmonize the written description requirement must be just strict enough to grant patent rights to that which an inventor can prove he actually invented, but nothing more. The classic *Vas-Cath* possession standard accomplishes precisely that; it naturally adjusts the amount of disclosure necessary depending on the facts and cir-

159. *See Capon*, 418 F.3d at 1360-61; *Enzo II*, 323 F.3d 956, 960.

160. Hybritech, Inc. v Monoclonal Antibodies, Inc, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (emphasis added); Whitley, *supra* note 26, at 622.

161. Mueller, *supra* note 13, at 617.

162. *See* Cantor, *supra* note 1, at 270. *See generally* Aljalian, *supra* note 53.

163. *See* Cantor, *supra* note 1, at 270.

164. *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926-27 (Fed. Cir. 2004).

cumstances of the case.[165] The standard automatically requires more disclosure in cases like *Lilly*, where disclosure of anything less than the actual nucleotide sequence would be insufficient to prove that the inventor in fact possessed the compound.[166] On the other hand, it requires less in cases like *Enzo*, where an inventor clearly evidenced possession by depositing the compound in a public depository,[167] or *Capon*, where the compound is clearly recognizable in the art by disclosure of its method of making.[168] Thus, the possession standard provides for a degree of technology specificity without imposing an undue burden on all patentees.

IV. CONCLUSION

The Federal Circuit properly invalidated the University of Rochester's '850 patent. A patent that claims a method of achieving a biological effect, which discloses no compound that can accomplish that result, clearly fails to satisfy the patent disclosure requirements. The Federal Circuit went beyond what was necessary to resolve *Rochester*, however, and imposed an unnecessarily stringent per se disclosure rule on all pharmaceutical and biotechnology patentees. To the detriment of future applicants, current patent owners, and the patent system as a whole, the court chose the *Lilly* rule as the standard by which to harmonize the written description requirement across technologies.

While the *Lilly* standard frustrates the policy goals of the patent system by imposing undue burdens on all patentees, producing unreasonable outcomes, and discouraging innovation, the *Vas-Cath* possession standard ensures that the scope of the patent reward is commensurate with the inventor's contribution to society. Patent jurisprudence has demonstrated that the *Vas-Cath* possession standard achieves the desired balance between rewarding pioneering inventors for their efforts and promoting subsequent research and innovation. Possession, therefore, serves as the appropriate standard by which to harmonize the written description requirement among technologies.

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165. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561-64 (Fed. Cir. 1991).

166. *See* Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567-69 (Fed. Cir. 1997).

167. *See Enzo II*, 323 F.3d 965 (Fed. Cir. 2002).

168. *See Capon*, 418 F.3d 1349.