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## Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents

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# Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents

DUANE M. LINSTROM\*

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## I. INTRODUCTION

In April of 2002, the Court of Appeals for the Federal Circuit published

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a decision in the matter of *Enzo Biochem, Inc. v. Gen-Probe Inc.*<sup>1</sup> The decision was an important precedent in the application of the 35 U.S.C. § 112 written description requirement for patents on genetic material. The holding was unremarkable and followed logically from the Federal Circuit's previous application of the written description requirement to DNA patents.<sup>2</sup> What was surprising was that by July 2002, in a rare example of a court's overruling itself, the court had reversed its April 2002 decision.<sup>3</sup> The subsequent decision was, in many aspects, a fundamental departure not only from the prior holding but also from recent decisions relating to the written description requirement.<sup>4</sup> Of particular interest in the second ruling were the following: the court's unusual reliance on the Patent and Trademark Office Guidelines (PTO Guidelines) rather than prior case law, the allowance of a biological deposit as sufficient for compliance with the written description requirement, the possible allowance of a description by function, and a new articulation of the written description requirement as more than a showing of possession. This Article will examine the recent history of the ways in which courts have applied the written description requirement to gene patents with a particular focus on the changes in the law wrought by the *Enzo* decision.

## II. THE WRITTEN DESCRIPTION REQUIREMENT

The United States patent system functions on the rationale of quid pro quo, by which the law grants a temporary monopoly on the production and use of an invention in exchange for the knowledge of the invention's being made public.<sup>5</sup> This quid pro quo depends upon the inventor's providing adequate disclosure of the invention, which includes a written description of the invention<sup>6</sup> and information on how to make and use it.<sup>7</sup> In order to ensure adequate disclosure, the first paragraph of 35 U.S.C. § 112 requires that a patent application disclose a written description of the following: the invention, how to make and use the invention, and the best mode for use of the invention.<sup>8</sup> This written description aspect of

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1. 285 F.3d 1013 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002).

2. *See infra* text accompanying notes 71–77.

3. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002).

4. *See infra* Part IV.B.

5. DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (2002).

6. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 131 (1996).

7. CHISUM, *supra* note 5, § 7.01.

8. 35 U.S.C. § 112 (2000). Paragraph one states:

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

§ 112 is commonly referred to as the “written description requirement.”<sup>9</sup> The written description requirement originated with the Patent Act of 1790,<sup>10</sup> which required that each patent have “a specification in writing, containing a description.”<sup>11</sup> Because certain aspects of the Patent Act of 1790 were perceived as inefficient,<sup>12</sup> it was replaced just three years later by the similarly titled Patent Act of 1793.<sup>13</sup> The new act slightly modified the language of the written description requirement<sup>14</sup> by requiring a party that wished to obtain a patent to “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 . . . to make, compound and use the same.”<sup>15</sup> In 1822, the U.S. Supreme Court in *Evans v. Eaton* construed this language as containing two separate requirements.<sup>16</sup> In modern usage, these requirements are known as the enablement requirement and the written description requirement.<sup>17</sup> The Court stated that the objective of the written description requirement is “to put the public in possession of what the party claims as his own invention.”<sup>18</sup> The Court also determined that the written description must define the limits of what had been patented, explaining that the inventor “ought to describe what his own

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forth the best mode contemplated by the inventor of carrying out his invention.

*Id.*

9. *Williams v. Gen. Surgical Innovations, Inc.*, 178 F. Supp. 2d 698, 704 (E.D. Tex. 2002). “[T]he three requirements of § 112 . . . in patent law parlance are commonly referred to as the written description requirement, the enablement requirement, and the best mode requirement.” *Id.*

10. Patent Act of 1790, ch. 7, § 2, 2 Stat. 109 (1790) (repealed 1793).

11. *Id.* at 110.

12. Amusingly, the Patent Act of 1790 required the Secretary of State, the Secretary for the Department of War, and the Attorney General to examine every patent petition and vote as to whether it was “sufficiently useful and important.” E.C. Walterscheid, *Thomas Jefferson and the Patent Act of 1793*, 40 *ESSAYS IN HIST.* 3 (1998), at <http://etext.lib.virginia.edu/journals/EH/EH40/walter40.html>. If the Patent Act of 1790 were still in effect today, Colin Powell, Donald Rumsfeld, and John Ashcroft would be required to examine and vote on all patents.

13. Patent Act of 1793, ch. 11, § 3, 2 Stat. 318, 321–22 (1793) (repealed 1836).

14. See, e.g., Lisa A. Karczewski, Comment, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 *MCGEORGE L. REV.* 1043, 1061 (2000).

15. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433 (1822) (quoting Patent Act of 1793 § 3) (alterations in original).

16. *Id.* at 433–34.

17. *CHISUM*, *supra* note 5, §§ 7.03–.04.

18. *Evans*, 20 U.S. at 434.

improvement is, and to limit his patent to such improvement.”<sup>19</sup>

After *Evans*, courts began to develop the practice of drafting central claims that succinctly state what has been invented and define the limits of the invention with reference to more substantial descriptions contained elsewhere within the application.<sup>20</sup> The Patent Act of 1836 codified this practice of drafting claims.<sup>21</sup> After 1836, the importance of claims continued to increase although the written description was still considered the central feature of the patent document.<sup>22</sup> Ultimately, the role of the written description in delineating the limits of the invention was usurped entirely by the use of claims with the Patent Act of 1870.<sup>23</sup> Stripped of its role of defining the limits of the patent, the written description requirement became a historical anachronism for almost one hundred years until it was resurrected by *In re Ruschig*<sup>24</sup> in 1967.<sup>25</sup> In *Ruschig*, the court used the written description not to determine the limits of the patent, but to ascertain whether the patent conveyed “clearly to those skilled in the art” that the inventor had invented what was claimed.<sup>26</sup>

Since *Ruschig*, the understanding that the written description requirement “must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed” has endured.<sup>27</sup> *Ruschig*’s conceptualization of the purpose of the written description requirement has evolved in the common law into a specific test: In order to satisfy the requirement, the application must describe the invention with adequate specificity to allow a person skilled in the art to know that the inventor had been in possession of the claimed subject matter at the time of the application.<sup>28</sup> Until *Enzo Biochem, Inc. v. Gen-Probe Inc.*,<sup>29</sup>

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19. *Id.* at 435.

20. Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 619–20 (1998).

21. Patent Act of 1836, ch. 357, § 5, 1 Stat. 117, 119 (repealed 1870). When the practice of claims drafting was codified by the Patent Act of 1836, “it was understood as merely codifying the existing law which had been developed by the courts.” Karl B. Lutz, *Evolution of the Claims of U.S. Patents*, 20 J. PAT. OFF. SOC’Y 134, 143 (1938); Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1, 12 n.50 (2000).

22. See, e.g., Jason M. Okun, Note, *To Thine Own Claim Be True: The Federal Circuit Disaster in Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 21 CARDOZO L. REV. 1335, 1344 (2000).

23. Zhibin Ren, Note, *Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the University of California v. Eli Lilly & Company*, 1999 WIS. L. REV. 1297, 1301 (1999).

24. 379 F.2d 990 (C.C.P.A. 1967).

25. Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 620 (1998).

26. *Ruschig*, 379 F.2d at 996.

27. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991) (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)); see *infra* text accompanying note 121.

28. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

29. 285 F.3d 1013 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002).

recent case law had continually reinforced the understanding that, as applied to patents on genetic material, the written description requirement was satisfied by a showing of possession.<sup>30</sup>

### III. THE RECENT CASE LAW

*Amgen, Inc. v. Chugai Pharmaceutical Co.*<sup>31</sup> was one of the earliest cases to influence the evolution of the written description requirement for patenting genetic material. In *Amgen*, the plaintiff alleged that Genetics Institute, in collaboration with Chugai Pharmaceuticals, had infringed a patent held by Amgen that claimed the nucleotide sequence that expressed human erythropoietin (EPO), a protein that stimulates the production of red blood cells.<sup>32</sup> The Amgen patent claimed “[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human [EPO].”<sup>33</sup> Genetics Institute argued that it had been the first to invent the disputed nucleotide sequence because it had conceived a method for the isolation of the DNA for EPO prior to Amgen.<sup>34</sup> The court found that, although Genetics Institute had conceived of a potential method for isolating the EPO gene prior to the Amgen patent, the company did not have “an adequate conception of the DNA sequence.”<sup>35</sup> The court further noted that the inventor for Genetics Institute did not have adequate conception at the time of application because “he did not then know the sequence of the gene encoding EPO.”<sup>36</sup> The court held that “when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method

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30. See *infra* Part III.

31. 927 F.2d 1200 (Fed. Cir. 1991).

32. *Id.* at 1203.

33. *Id.* at 1204. Genetic information is stored in DNA in the form of a sequence of nucleotide bases, either adenine, thymine, cytosine, or guanine. Each nucleotide will only recognize its complementary base, so that adenine complements thymine and cytosine complements guanine. The nucleotides are organized in codons, sequences of three base molecules that each correspond to a specific amino acid. The sequence of codons in a gene therefore only codes for the sequence of amino acids in the protein. In order for a protein to be expressed by the host organism, the genetic information contained in its strand of DNA is first transcribed to a strand of complementary messenger RNA (mRNA). The mRNA is then “translated” or read by tRNA molecules in the ribosome, leading to the assembly of the corresponding amino acid sequence and expression of the protein product. See OFFICE OF HEALTH & ENVTL. RESEARCH, U.S. DEP’T OF ENERGY, PRIMER ON MOLECULAR GENETICS 6–9 (1992).

34. *Amgen*, 927 F.2d at 1205.

35. *Id.* at 1207.

36. *Id.*

for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.”<sup>37</sup> Stated in other terms, *Amgen* allowed two methods of conception of a gene: (1) actual knowledge of the nucleotide sequence sufficient to distinguish it from others with a method for obtaining it, or (2) actual isolation of the gene.<sup>38</sup>

The requirements for conception articulated in *Amgen* were joined specifically to the written description requirement for patents on genetic material in *Fiers v. Revel*.<sup>39</sup> In *Fiers*, three separate inventors all claimed patent rights to DNA encoding “human fibroblast beta-interferon [], a protein that promotes viral resistance in human tissue.”<sup>40</sup> The *Fiers* court applied the conception standards for DNA patents that had been defined in *Amgen* directly to the written description requirement by stating, “one cannot describe what one has not conceived.”<sup>41</sup> The court understood *Amgen* to hold that “conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.”<sup>42</sup> The clear implication was that one could not adequately describe a DNA by its function.<sup>43</sup> According to the *Fiers* court, conception required a description based on “structure, formula, chemical name, or physical properties.”<sup>44</sup>

The *Fiers* court also emphasized that the written description must establish that the inventor had been in possession of the claimed DNA at the time of the patent application.<sup>45</sup> The court specified criterion for

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37. *Id.* at 1206.

38. Although the *Amgen* decision discusses “conception” rather than the “written description requirement,” this decision relates to the written description requirement because the concept of conception essentially stood as a proxy for the more commonly used term of “possession.” Establishment of possession is the purpose of the modern written description requirement. This connection is articulated by *Fiers v. Revel*, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993). See *infra* text accompanying notes 34–43.

39. 984 F.2d 1164.

40. *Id.* at 1166. *Fiers* was an interference involving three groups of foreign inventors: Walter C. Fiers of the United Kingdom; Michel Revel and Pierre Tiollais of Israel; and Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi of Japan. *Id.* at 1166–67. All three groups sought priority for their patent applications based on the filing date of the foreign patent applications they filed in their respective countries. *Id.*

41. *Id.* at 1171.

42. *Id.* at 1169.

43. *Id.* at 1171. In reference to a description that purported to cover all DNA that coded for beta-interferon, the court held, “Claiming all DNA’s that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.” *Id.*

44. *Id.*

45. *Id.* at 1170. The court stated that the patent board had correctly set forth the legal standard for sufficiency of description. *Id.* The patent board had held:

[W]hat is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed. The test for sufficiency of support is whether the disclosure of the application relied upon “reasonably

establishing possession, stating that “[a]n adequate written description of DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.”<sup>46</sup> Ultimately, the *Fiers* court awarded patent rights to the one inventor of the three who had described the exact nucleotide sequence of the DNA.<sup>47</sup> Although the court did not state that the written description requirement required an inventor to disclose the exact nucleotide sequence, the facts of the case tended to support that interpretation.<sup>48</sup>

Prior to *Enzo*, the last case to define the written description requirement as it relates to patents on genetic material is *Regents of the University of California v. Eli Lilly & Co.*<sup>49</sup> In *Eli Lilly*, the court invalidated a University of California-owned patent, which claimed a prokaryotic host containing insulin encoding DNA for mammals, vertebrates, or humans, for failure to satisfy the written description requirement.<sup>50</sup> The patent described the nucleotide sequence for insulin DNA in a rat, but described the rest of the genus, including human, only by function.<sup>51</sup> Citing *Fiers*, the court held that a description of the

conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.”

*Id.* The court rejected the patent application of Revel because the description did not establish possession. *Id.* at 1171. “A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA.” *Id.*

46. *Id.* at 1170.

47. *Id.* at 1172. The court gave priority to Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi of Japan, stating:

We also conclude that Sugano’s application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for  $\beta$ -IF and thus “convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for  $\beta$ -IF].”

*Id.* (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)) (alterations in original).

48. The conclusion that a description of the nucleotide sequence of a DNA patent was required by the holding in *Fiers* is supported by the fact that all three patent applications disclosed a means of isolating the DNA, but priority was granted to the one patent that actually described the nucleotide sequence. *Id.* The court clearly stated that to fulfill the written description requirement, a plan for isolating the DNA was not enough, holding that “what is required is a description of the DNA itself.” *Id.* at 1170. The court gave no indication of what would suffice as a “description of the DNA itself” except description of the nucleotide sequence. *Id.* at 1172.

49. 119 F.3d 1559 (Fed. Cir. 1997).

50. *Id.* at 1562.

51. *Id.* at 1567. Although the University of California patent did provide a general



DNA's function was not sufficient, stating that "definition by function . . . is only a definition of a useful result rather than a definition of what achieves that result."<sup>52</sup>

*Eli Lilly* also seemed to further establish the rule that a DNA can only be described by a recitation of the nucleotide sequence.<sup>53</sup> The court in *Eli Lilly* understood *Fiers* as requiring "[the] kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA."<sup>54</sup> In terms of patenting a genus, the court stated:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.<sup>55</sup>

In other words, the applicant must disclose the entire sequence of a sufficient number of cDNA's to represent the entire genus or a substantial portion of the nucleotide sequence for every member of the genus. Beyond that, the court refused to speculate about other ways by which DNA could be properly described.<sup>56</sup>

After *Eli Lilly*, a wide variety of commentators anticipated that a recitation of the exact nucleotide sequence was now necessary to fulfill the written description requirement for patents on genetic material.<sup>57</sup> Although the court in *Eli Lilly* did not explicitly adopt a bright-line rule that disclosure of the nucleotide sequence was required, the wording of the case effectively left disclosure of the sequence, or at least large portions of the sequence, as the only certain option. In the exact

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method for obtaining the cDNA that encodes for human insulin, the court did not consider it to be a written description of the DNA itself, but rather a potential disclosure of enablement. *Id.* The cDNA itself was only described by the protein that it encoded, which is a description by function. *Id.* at 1568.

52. *Id.* (citing *Fiers*, 984 F.2d at 1169–71).

53. See, e.g., Courtney J. Miller, Comment, *Patent Law and Human Genomics*, 26 CAP. U. L. REV. 893, 917 (1997). "The decision in *Lilly* appears to foreclose any further gene claims methods other than disclosure of the actual gene sequence." *Id.*

54. *Eli Lilly*, 119 F.3d at 1569.

55. *Id.*

56. *Id.*

57. See, e.g., Miller, *supra* note 53, at 917 ("The decision in *Lilly* appears to foreclose any further gene claims methods other than disclosure of the actual gene sequence."); Margaret Sampson, Comment, *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, 1259 (2000); Emanuel Vacchiano, Comment, *It's a Wonderful Genome: The Written-Description Requirement Protects the Human Genome from Overly-Broad Patents*, 32 J. MARSHALL L. REV. 805, 817 (1999); Dorothy R. Auth, *Are ESTs Patentable?*, 15 NATURE BIOTECHNOLOGY 911, 912 (1997) (stating that the *Lilly* decision "suggests that the new standard for the written description requirement—at least in the courts—may well be that sequences claimed must be provided in the specification"); Eliot Marshall, *Courts Take a Narrow View of UC's Claims*, 277 SCIENCE 1029, 1029 (1997).

wording of the court, “An 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.”<sup>58</sup> This wording essentially narrows the options to disclosing the nucleotide sequence, because DNA has no distinctive structure, formula, chemical name, or physical properties other than its nucleotide sequence.<sup>59</sup> DNA is a molecule comprised of a double helix structure formed by complementary base pairs of nucleotides.<sup>60</sup> What distinguishes one DNA from another is the pattern of the nucleic acids that form the complementary base pairs of the double helix structure.<sup>61</sup> As a result, any request for a description of DNA sufficient to distinguish it from other DNA, without relying on function, is almost ipso facto asking for the nucleotide sequence.<sup>62</sup>

#### IV. ENZO BIOCHEM, INC. V. GEN-PROBE INC.

In *Enzo Biochem, Inc. v. Gen-Probe Inc.*,<sup>63</sup> Enzo Biochem sued the defendants, Gen-Probe, Chugai Pharmaceutical, Biomerieux, and Becton Dickinson, for violation of Enzo’s patent, which claimed nucleic acid probes that selectively hybridize to *Neisseria gonorrhoeae*, the genetic material of the bacteria that causes gonorrhea, over *Neisseria meningitidis*.<sup>64</sup> Detection of *gonorrhoeae* is difficult because *N. gonorrhoeae* has between eighty and ninety-three percent homology

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58. *Eli Lilly*, 119 F.3d at 1566 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

59. OFFICE OF HEALTH & ENVTL. RESEARCH, *supra* note 33, at 6.

60. J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953).

61. DONALD VOET & JUDITH G. VOET, BIOCHEMISTRY 793–804 (1990). Although there are levels of complexity to the structure of DNA that extend beyond the basic double helix structure, those elements are related to the storage and regulation of DNA within the cell. J.R. Pollack & V.R. Iyer, *Characterizing the Physical Genome*, 32 NATURE GENETICS 515, 515–21 (2002). It is unlikely that those portions of the DNA will be used for patentable subject matter.

62. One suggested alternative is to describe a DNA sequence by its number of bases coupled with a detailed restriction map. See Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After Regents of the University of California v. Eli Lilly & Co.*, 32 IND. L. REV. 537, 555 (1999). However, this method provides very little descriptive information concerning the DNA and will probably not suffice to fulfill the written description requirement. See *Ex parte Maizel*, 27 U.S.P.Q.2d (BNA) 1662, 1664–65 (Bd. Pat. App. & Interf. 1992) (discussing certain descriptive terms which were found to be inadequate).

63. 285 F.3d 1013 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002).

64. *Id.* at 1015–16.

with *Neisseria meningitidis*; as a result, any probe capable of detecting *N. gonorrhoeae* might also show a positive result when only *N. meningitidis* is present.<sup>65</sup> Enzo believed that because its probes exhibited a selective hybridization ratio of greater than fifty, they would “hybridize to virtually all strains of *Neisseria gonorrhoeae* and to no strain of *Neisseria meningitidis*.”<sup>66</sup> Enzo had deposited these “probes in the form of a recombinant DNA molecule within an *E. coli* bacterial host at the American Type Culture Collection.”<sup>67</sup> The Enzo patent claimed the three deposited sequences and all sequences with a preferential hybridization ratio of *Neisseria gonorrhoeae* over *Neisseria meningitidis* greater than five to one.<sup>68</sup> The Enzo specification described the invention only by reference to the deposited sequences and by their preferential-hybridization ratio.<sup>69</sup> The defendants moved for summary judgment, arguing that Enzo’s patent failed to meet the 35 U.S.C. § 112 written description requirement as a matter of law.<sup>70</sup>

#### A. The First Enzo Decision

In its original holding, the Court of Appeals for the Federal Circuit clearly articulated the position that an invention may not be described by its function in order to fulfill § 112’s written description requirement.<sup>71</sup> Basing its decision largely on *Eli Lilly*, the court held that “[a] description of what the genetic material does, rather than of what it is, does not suffice.”<sup>72</sup> The court further stated 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.’”<sup>73</sup> The court did not see a distinction between describing a DNA by protein expression and describing a DNA by hybridization, as both were descriptions by function.<sup>74</sup> As a result, the court held that the Enzo claims were insufficiently described as a matter of law.<sup>75</sup> In continuing

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65. *Id.* at 1015.

66. *Id.* at 1016.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* at 1018.

72. *Id.* (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

73. *Id.* (quoting *Eli Lilly*, 119 F.3d at 1568) (internal quotation marks omitted).

74. *Id.* at 1018–19.

75. *Id.* at 1018. In contrast to the holding of the court, the dissenting opinion by Dyk argued that the real issue was not whether a nucleotide sequence could be described by its function, but rather whether “one skilled in the art at the time the application was

with the rule that a DNA patent can not be described by its function, the court was in accord with its previous holdings in *Fiers*<sup>76</sup> and *Eli Lilly*.<sup>77</sup>

Enzo argued that it had complied with the written description requirement because the company had actually reduced the invention to practice and had deposited the resulting sequence<sup>78</sup> in a public repository.<sup>79</sup> This would seem a plausible argument in light of *Amgen, Inc. v. Chugai Pharmaceutical Co.*<sup>80</sup> because deposit in a repository would necessitate isolation of the claimed gene. In *Amgen*, as discussed above, the court had allowed two methods of establishing conception: (1) actual knowledge of the nucleotide sequence sufficient to distinguish it from others plus a method for obtaining it, or (2) actual reduction of the nucleotide sequence to practice, which in that case would have entailed isolation of the gene.<sup>81</sup> The language in *Amgen* was imported to the written description requirement in *Fiers*<sup>82</sup> and later echoed in *Eli Lilly*.<sup>83</sup> Surprisingly, the court admitted that reduction to practice may

filed would understand the nature of the claimed invention from the written description.” *Id.* at 1024. The author of the dissenting opinion felt that, although the invention was described by its function, it identified a structural difference between the DNA of *N. gonorrhoeae* and *N. meningitidis*. *Id.* at 1026. Furthermore, this was sufficient information about the structure that it might have been “at least somewhat known to those of skill in the art.” *Id.* Because a patent is presumed valid, the dissenter felt that this was sufficient to raise an issue of fact and overcome summary judgment. *Id.*

76. *Fiers v. Revel*, 984 F.2d 1164, 1172 (Fed. Cir. 1993).

77. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575; *see also Ex parte Maizel*, 27 U.S.P.Q.2d (BNA) 1662, 1667 (Bd. Pat. App. & Interf. 1992) (“As we view it, appellants’ description of the protein solely in terms of its biological function . . . is insufficient to . . . place appellants in ‘possession’ [of the DNA sequence].”).

78. “A deposit is a sample of biological material, needed to practice an invention, that is given to a recognized depository so that after the patent issues anyone who wishes to practice the invention will have access to the material.” Heidi L. Kraus, Article, *A Different New Matter Standard for Biotechnology Patent Applications Accompanied by a Deposit*, 25 AIPLA Q.J. 101, 112 (1997).

79. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013, 1020 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002).

80. 927 F.2d 1200 (Fed. Cir. 1991).

81. *Id.* at 1206.

82. The *Fiers* court took the language from *Amgen* that referred to when an invention had been conceived and applied it directly to the written description requirement, holding, “As we stated in *Amgen* and reaffirmed above . . . [i]f a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity.” *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

83. *Eli Lilly* quoted the same phrase that *Fiers* attributed to *Amgen*, holding, “An adequate description of a DNA . . . ‘requires a precise definition, such as by structure, formula, chemical name, or physical properties’ . . .” *Regents of the Univ. of Cal. v.*

establish possession,<sup>84</sup> yet found that a showing of possession was not enough.<sup>85</sup> The court held that, in addition to showing possession, the written description must adequately describe the claimed invention so that a person skilled in the art could “visualize or recognize the identity of the claimed subject matter.”<sup>86</sup> This holding is unusual and without precedent in the case law, and it is apparently founded on a novel interpretation of the statute alone. In regard to the deposit, the court held that “to require the public to go to a public depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one’s invention in the specification . . . . ‘[A] deposit is not a substitute for a written description of the claimed invention.’”<sup>87</sup>

By continuing to disallow describing a DNA patent by its function, and by disallowing a description by reference to a deposit, the original *Enzo* holding met the expectations of those who had understood the previous rulings in *Fiers* and *Eli Lilly* to require disclosure of the nucleotide sequence of the claimed DNA.<sup>88</sup>

### B. *The Second Enzo Decision*

Subsequent to its first review of the case, the Court of Appeals for the Federal Circuit allowed a rehearing and came to some very different conclusions.<sup>89</sup> The court overruled its previous holding in two key areas. First, the court held that a patent may be described by its function if a known correlation between function and structure exists.<sup>90</sup> Second, the court ruled that the written description requirement may be satisfied by

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Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) (quoting *Fiers*, 984 F.2d at 1171).

84. *Enzo*, 285 F.3d at 1023. “Although an actual reduction to practice, assuming one exists here, may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is.” *Id.*

85. *Id.* at 1020–21.

86. *Id.* at 1021.

87. *Id.* at 1021–22 (quoting Guidelines for Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 11007–08 n.6 (Jan. 5, 2001)); see also Deposit of Biological Materials for Patent Purposes, 54 Fed. Reg. 34,864 (Aug. 22, 1989) (to be codified at 37 C.F.R. pt. 1) (“Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible or repeatable manner, access to the biological material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112.”).

88. See *supra* note 52.

89. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1320 (Fed. Cir. 2002).

90. The court adopted the position of the PTO that the written description requirement can be met by “functional characteristics when coupled with a known or disclosed correlation between function and structure . . . .” *Id.* at 1324 (quoting Guidelines for Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. at 1106).

reference in the specification to a deposit of the genetic material in a public depository when the practical difficulties of describing the genetic material make a written description unavailable.<sup>91</sup> In keeping with their first decision, the court continued to hold that compliance with the written description requirement is not fulfilled simply by disclosing enough descriptive information to allow a person reasonably skilled in the art to know that the inventor was in possession of the claimed invention at the time of application.<sup>92</sup> In addition, the applicant must also disclose enough descriptive information to adequately describe or identify the invention.<sup>93</sup>

### 1. Analysis of the Second Enzo Decision

#### a. Description by Function

In its second review of *Enzo Biochem v. Gen-Probe Inc.*, the court acknowledged the prior precedent of *Eli Lilly* in finding that when gene material “has been defined only by a statement of function or result . . . such a statement alone did not adequately describe the claimed invention.”<sup>94</sup> The court also acknowledged *Fiers v. Revel*, which it quoted for the rule that an adequate written description “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.<sup>95</sup> However, unlike its previous holding, the court did not find that these cases amounted to a rule that a nucleotide sequence may not be defined by its function; rather the court oppositely concluded: “It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement.”<sup>96</sup> It is difficult to imagine a more contrary rule that could have been constructed based on the cited precedent. Rather, the court seems to have based its conclusion not on those prior holdings, but purely on the

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91. *Id.* at 1325. “[W]e hold that reference in the specification to a deposit in a public depository . . . when it is not otherwise available in written form, constitutes an adequate description . . .” *Id.*

92. *Id.* at 1329.

93. *Id.* at 1330.

94. *Id.* at 1324 (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

95. *Id.* (quoting *Eli Lilly*, 119 F.3d at 1566 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993))).

96. *Id.*

persuasive authority of the PTO Written Description Guidelines.<sup>97</sup> Legal inconsistencies notwithstanding, the court held:

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.” . . . 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.*<sup>98</sup>

Outside the Guidelines, the court cited no authority for this change of position.<sup>99</sup> According to the explicit phrasing given by the court, the written description requirement can be met with a description by function when there is a known correlation between function and structure.<sup>100</sup> At first blush, this holding merely appears to be a simple exception to the rule set forth in cases disallowing descriptions of DNA by function; however, the court does not clarify exactly how exact the correlation between the function and structure must be or how much descriptive information that known correlation must yield.<sup>101</sup> Because the structure of DNA is entirely concerned with storage, transmission, and transfer of genetic information,<sup>102</sup> and because it is generally known how the structure of DNA relates to its function,<sup>103</sup> it could be argued that there is always some known correlation between function and structure although that known correlation might be extremely vague. This leaves the holding open to an overly broad interpretation. It might be a different matter had the court narrowly tailored the exception to situations in which the specification describes stringent hybridization ratios to a disclosed substrate, but the court did not adopt that

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97. *Id.* at 1325.

98. *Id.* at 1324–25 (final emphasis added) (citations omitted) (internal quotation alterations in original).

99. The court’s understanding of the Guidelines here sharply contrasts with that of its prior decision. In the first hearing, Enzo had argued that the binding affinity of their sequences was a sufficient description under the Guidelines. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013, 1019 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002). In response, the court pointed out that the Guidelines were not binding and stated, “The Guidelines do not provide that a nucleotide sequence may be defined only by its function.” *Id.*

100. *Enzo*, 296 F.3d at 1324–25.

101. *Id.*

102. VOET & VOET, *supra* note 61, at 791–93.

103. *Id.*

approach.<sup>104</sup> Under the current phrasing of the *Enzo* decision, there is a risk that the new exception will swallow the old rule that a description by function does not suffice.

Allowing a description by function when the known correlation between function and structure is vague will undoubtedly prove to be unworkable. Whether the function is protein expression or hybridization, patents that describe the subject matter by function will always be open to the criticism that they are nothing more than a wish<sup>105</sup> or an attempt to preempt the future<sup>106</sup> and patents that offer a description by function with a known correlation to the structure of the DNA where that correlation is vague will be open to the same criticism. As a result, it is unlikely that courts will allow description by function unless the correlation is very specific, such as when the claimed sequence demonstrates a strict hybridization ratio to a known sequence. Courts will likely distinguish *Enzo* on its facts and understand *Enzo*'s statement that a description by function will suffice when there is a known correlation to structure to be mere dicta and not a statement essential to the holding. Based on the facts of the case and the relevant portions of the Guidelines upon which the court relied,<sup>107</sup> the courts should understand *Enzo* to mean that description by function can contribute to the description of a DNA molecule when combined with other relevant information such as a reference to a deposit, partial structure, or physical properties, which would allow a person skilled in the art to know that the inventor had been in possession of the claimed invention. Of course, any description by function will be complicated by the curious addition, beyond a showing of possession, that the *Enzo* court added to the written description.<sup>108</sup>

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104. *Enzo*, 296 F.3d at 1327–28.

105. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). “[A]n 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.” *Id.* (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

106. *See Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (“Claiming . . . a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.”).

107. *Enzo*, 296 F.3d at 1324 (citing Guidelines for Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)).

108. *Id.* at 1330.



*b. A Demonstration of Possession Is Insufficient for the Written Description Requirement*

In the second *Enzo* decision, the court continued with its holding from the original *Enzo* decision that a demonstration of possession was not sufficient to meet the written description requirement.<sup>109</sup> The court's ruling in this matter is problematic. To begin with, the holding was based upon an erroneous reading of *Lockwood v. American Airlines, Inc.*<sup>110</sup> The *Enzo* court falsely stated that the *Lockwood* court had rejected the rule that "all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention."<sup>111</sup> In fact, *Lockwood* had upheld this rule.<sup>112</sup> The *Enzo* court misinterpreted *Lockwood* as requiring, in addition to a showing of possession, a "disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'"<sup>113</sup> A correct reading of *Lockwood* is that possession is demonstrated by the disclosure of sufficiently descriptive words, not that the descriptive words are a requirement in addition to showing possession.<sup>114</sup>

Additionally, the notion that something beyond a showing of possession is necessary to meet the written description requirement is not consistent with the court's prior decisions.<sup>115</sup> It has been understood by both the Court of Appeals for the Federal Circuit and the Patent and Trademark Office that the written description requirement for genetic and biotechnology patents demanded greater specificity to demonstrate possession than other arts;<sup>116</sup> however, it has been understood as a

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109. The first decision held that a showing of possession was insufficient. *Enzo Biochem v. Gen-Probe Inc.*, 285 F.3d 1013, 1020–21 (Fed. Cir.), *vacated by* 296 F.3d 1316 (Fed. Cir. 2002). The vacating decision took an identical position, holding, "Application of the written description requirement, however, is not subsumed by the 'possession' inquiry." *Enzo*, 296 F.3d at 1330.

110. 107 F.3d 1565, 1572 (Fed. Cir. 1997).

111. *Enzo*, 285 F.3d at 1020–21 (quoting *Lockwood*, 107 F.3d at 1572).

112. The court noted, "Lockwood argues that all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention. Lockwood accurately states the test . . ." *Lockwood*, 107 F.3d at 1572 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991)).

113. *Enzo*, 296 F.3d at 1329 (citing *Lockwood*, 107 F.3d at 1572).

114. *See Lockwood*, 107 F.3d at 1572. "The applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention . . ." One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc." *Id.* (citing *Vas-Cath*, 935 F.2d at 1563–64)

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

116. *See, e.g., Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993) (adopting the Patent and Trademark Office Board of Patent Appeals and Interferences argument that "what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed"); Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099,

heightened requirement to demonstrate possession,<sup>117</sup> not as a requirement in addition to a demonstration of possession.<sup>118</sup> Until the first *Enzo* decision,<sup>119</sup> the case law overwhelmingly had indicated that the purpose of the written description requirement was to show possession at the time of application.<sup>120</sup> The Court of Appeals for the Federal Circuit treated this topic in some depth in *Vas-Cath Inc. v. Mahurkar*, in which the court observed:

Since its inception, the Court of Appeals for the Federal Circuit has frequently addressed the “written description” requirement of § 112. A fairly uniform standard for determining compliance with the “written description” requirement has been maintained throughout: “. . . The description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”<sup>121</sup>

The court continued, “[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.”<sup>122</sup>

In acknowledging the understanding of the prior case law as explained in *Vas-Cath*, the *Enzo* court suggested that the “possession” test was “especially meaningful” in cases of later-filed claims.<sup>123</sup> As a result, the implication seemed to be that the possession test had not been the rule in cases that did not involve later-filed claims.<sup>124</sup> The court dared not press this point too hard though, as the possession test had been applied to original claims in *Eli Lilly*.<sup>125</sup> Rather, the court made the point that

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1106 (Jan. 5, 2001) (codifying that “for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession”).

117. *Fiers*, 984 F.2d at 1170–71.

118. *Vas-Cath*, 935 F.2d at 1563–64.

119. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1329 (Fed. Cir. 2002).

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

121. *Id.* at 1562–63 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)) (second alteration in original).

122. *Id.* at 1563 (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)) (internal quotations omitted).

123. *Enzo*, 296 F.3d at 1329.

124. Interestingly, it was the view of many commentators that it was inappropriate to apply the written description analysis to originally filed claim, this view was disappointed by the holding in *Eli Lilly*. *See, e.g., Ren, supra* note 23, at 1312.

125. Although the court in *Eli Lilly* did not specifically say it was applying the possession test, it did. The court articulated the functional equivalent of the “possession” test by stating, “To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that ‘the inventor invented the claimed invention.’” *Regents of the Univ. of*

while the question of showing possession has been viewed as the only test in cases involving later-filed claims, it is not the only test in which original claims are involved.<sup>126</sup> Although this position had never before been articulated, it is true that the vast majority of written description cases have involved later-filed claims.<sup>127</sup> This left open the possibility, or at least the plausible legal fiction, that an additional requirement has quietly existed all along without an opportunity to be explicitly stated.

The idea that the written description requirement may entail something more than a mere showing of possession is neither without some logical basis nor unanticipated, but the particular rationale used by the *Enzo* court for introducing an additional requirement is novel. Esteemed commentators have held the view that the written description requirement not only serves to show possession of the invention, but also serves a second purpose of giving “the public notice of the limits of the patent in order to allow third parties to improve on and invent around the patent without infringing.”<sup>128</sup> This view of the written description, as describing a limit to the scope of the patent, is actually a throwback to the role that the written description requirement filled prior to the Patent Act of 1870.<sup>129</sup> As cases preceding *Enzo* relating to genetic patents<sup>130</sup> began to require what was perceived as a higher degree of precision in describing genetic patents,<sup>131</sup> an enlarged view of the written description requirement seemed to possess an almost subliminal presence in the decisions. Commentators began to see as subtext that the written description requirement was being used to limit the scope of the

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Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). The court further cited to *Lockwood*, which specifically stated the “possession” test. *Id.*; *Lockwood*, 107 F.3d at 1572.

126. *Enzo*, 296 F.3d at 1329.

127. *See, e.g., Vas-Cath*, 935 F.2d at 1560 (“The cases indicate that the ‘written description’ requirement most often comes into play where claims not presented in the application when filed are presented thereafter.”).

128. Alison E. Cantor, Article, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 282 (2000).

129. *See Mueller, supra* note 25, at 619–20. “Absent claims as we know them today, the written description provided notice to the public of the scope of exclusive rights asserted by an inventor. Through the written description, the public was to be ‘put in possession’ of the boundaries of a patentee’s asserted monopoly.” *Id.* After the Patent Act of 1870, claims were used to define the limits of a patent and the written description requirement became a historic anachronism until the modern use of the requirement was established in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). *Id.* at 620.

130. *See, e.g., Eli Lilly*, 119 F.3d at 1569; *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993).

131. In general, the standard for fulfillment of the written description requirement for DNA-related patents and biotechnology patents is typically higher than for other technological fields. *See Cynthia M. Lambert, Note, Gentry Gallery and the Written Description Requirement*, 7 B.U. J. SCI. & TECH. L. 109, 122 (2001).

patent.<sup>132</sup> In *Enzo*, limiting the scope of the patent was not in the court's contemplation. The court's view is predicated on the concept that "description is the *quid pro quo* of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time."<sup>133</sup> It appears that, unlike previous conceptualizations of the written description requirement, this new understanding has no utility other than as description for description's sake.<sup>134</sup> Whereas previous requirements required that the invention described show the inventor had actually invented and was in possession of the invention,<sup>135</sup> or describe the limits of the claimed invention,<sup>136</sup> this new requirement only requires that the invention be described.<sup>137</sup> As to what will suffice for an adequate description, it is clear that the court intends to require essentially the same amount of descriptive information as was required to establish possession in *Fiers* and *Eli Lilly*,<sup>138</sup> with two exceptions: the option of showing possession by reduction to practice as indicated in *Amgen*<sup>139</sup> is eliminated as not being descriptive enough,<sup>140</sup> and, in at least some instances, the court will allow a reference in the specification to deposit in a public repository.<sup>141</sup>

*c. The Use of a Deposit to Fulfill the Written  
Description Requirement*

The *Enzo* court's allowance of a deposit to fulfill the written description is interesting, because the court did not allow the written description to be fulfilled by reduction to practice; according to the court, reduction to practice only establishes possession,<sup>142</sup> which is

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132. See, e.g., Cantor, *supra* note 128, at 296–97; Vacchiano, *supra* note 57, at 824–25.

133. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

134. "A showing of 'possession' is ancillary to the statutory mandate that '[t]he 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." *Id.* (alteration in original).

135. See, e.g., *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

136. See, e.g., *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433 (1822).

137. See *Enzo*, 296 F.3d at 1330.

138. See *id.* at 1324 (citing *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).

139. 927 F.2d 1200 (Fed. Cir. 1991).

140. See *Enzo*, 296 F.3d at 1330.

141. See *id.* at 1325.

142. *Id.* at 1329.

insufficient to adequately describe the invention.<sup>143</sup> The court found that a DNA invention can be adequately described in two ways: by a written description of its relevant structure or physical characteristics<sup>144</sup> or, in some instances, the isolated sequence can be deposited in a public repository and a reference to the deposit made in the specification.<sup>145</sup> This holding is slightly incongruous because a deposit is very similar to reduction to practice and is primarily useful for establishing possession, not describing the invention.<sup>146</sup>

The court left open the question as to when a reference to a deposit will be accepted to satisfy the written description requirement.<sup>147</sup> The language of the holding was not precise, and it may be argued that reference to a deposit to meet the written description requirement is not limited to occasions in which the written description is unavailable. The exact phrasing of the court was as follows: “[W]e have concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material.”<sup>148</sup> On its face, that statement does not require that the written description be unavailable. The context of the statement, however, makes it appear that the court intended to limit the use of a reference to a deposit to cases in which the written description is unavailable.<sup>149</sup> In laying out the rule, the court drew an analogy between the use of a deposit for the written description requirement and the use of a deposit to disclose enablement.<sup>150</sup> In the latter situation, a deposit is allowed only when the inventions cannot reasonably be enabled by descriptions in written form.<sup>151</sup> Additionally, the court noted that the structures of the claimed composition “may not have been reasonably obtainable and in any event were not known to Enzo when it filed its application in 1986.”<sup>152</sup> The court also noted that it would have taken an estimated “3,000 scientists one month” to sequence the deposited material, which would make a

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143. *Id.* The court noted that the argument that “all that is necessary to satisfy the description requirement is to show that one is ‘in possession’ of the invention” had been rejected in *Lockwood*. *Id.* (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

144. *Id.* at 1324.

145. *Id.* at 1326. “[R]eference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for the purposes of meeting the written description requirement.” *Id.*

146. *In re Argoudelis*, 434 F.2d 1390, 1393 (C.C.P.A. 1970).

147. *See Enzo*, 296 F.3d at 1326–27. The ruling does appear to limit the use of a deposit to instances where the invention “cannot reasonably be enabled by a description in written form.” *Id.* at 1326.

148. *Id.*

149. *Id.*

150. *Id.* at 1325–26.

151. *Id.* at 1326.

152. *Id.*

written description of the composition “unduly burdensome.”<sup>153</sup> Still, the language is not as exact as it could be, and it leaves open the issue as to the exact standards to determine whether providing a written description is unduly burdensome, or whether a written description is unavailable as a practical matter.

## 2. *Reliance on the Guidelines*

Perhaps the most remarkable aspect of the *Enzo* court’s decision was the unprecedented reliance on the Guidelines.<sup>154</sup> Although only time will reveal its full impact, the decision potentially represents a shift in patent law jurisprudence of tectonic proportions. The decision extends well beyond the written description requirement and could affect virtually every area of patent law. Prior to the second *Enzo* decision, the Federal Circuit had never relied upon or even taken judicial notice of the Guidelines.<sup>155</sup> It is true that courts have taken judicial notice of the Manual of Patent Examining Procedure (MPEP) as an official interpretation of regulations on procedural issues.<sup>156</sup> However, taking notice of the MPEP does not adequately compare with taking notice of the Guidelines, as the MPEP and the Guidelines play vastly different roles in patent practice and law.

Patent lawyers and agents frequently use the MPEP in advising applicants and in preparing filings.<sup>157</sup> Patent examiners often cite

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153. *Id.* at 1328.

154. Besides the Guidelines, the court did make reference to “the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials.” *Id.* at 1325. These references are all very general and almost completely amorphous. For example, the history of biological deposits does not suggest anything like the rule formed in the latest *Enzo* decision. As the court pointed out, the previous status of a deposit had been that “[a]n accession number and deposit date add nothing to the written description of the invention.” *Id.* (quoting *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985)) (alteration in original).

155. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013, 1019 (Fed. Cir.), vacated by 296 F.3d 1316 (Fed. Cir. 2002); see also *Enzo*, 296 F.3d at 1324.

156. *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996). “The MPEP does not have the force and effect of law; however, it is entitled to judicial notice as the agency’s official interpretation of statutes or regulations, provided that it is not in conflict with the statutes or regulations.” *Id.*

157. “The Manual is published to provide U.S. Patent and Trademark Office patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the U.S. Patent and Trademark Office.” U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2001 & Rev. 2003), available at <http://www.uspto.gov/web/offices/pac/mpep/mpep.htm>.

provisions of the MPEP in their communications with patent applicants, and the MPEP is understood to be the official interpretation of procedural requirements at the PTO.<sup>158</sup> For these reasons, the courts have held that patent applicants should be able to rely on the MPEP in good faith, and courts have taken judicial notice of it as the official interpretation of procedural regulations.<sup>159</sup> In contrast, the Guidelines are intended to be a restatement of policy as enforced by the courts in assisting Patent Office personnel in their review of patent applications.<sup>160</sup> The Guidelines are drafted for internal use, and are not intended to be actual legal authority that patent attorneys may rely upon for the substantive requirements of a patent.<sup>161</sup> Rarely cited by the courts, the Guidelines have often been in conflict with the decisions of the courts and are periodically modified to conform to recent case law.<sup>162</sup>

For patent applicants to claim that they relied upon the MPEP is a completely different argument than a claim that inventors had relied upon the Guidelines. The *Enzo* court did note that judicial notice of the Guidelines can only be taken “to the extent [the Guidelines] do not conflict with the statute.”<sup>163</sup> However, because the meaning of statutes is left to the interpretation of the judiciary,<sup>164</sup> judicial notice of the

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158. See, e.g., *In re Kaghan*, 387 F.2d 398, 401 (C.C.P.A. 1967).

While the MPEP is primarily published for internal use, it is also made available to patent applicants and their lawyers as well as to the general public through the Superintendent of Documents. We take judicial notice of the fact that the manual is used frequently by patent lawyers and agents in advising applicants and in preparing their various papers for filing in the Patent Office, and also of the fact that examiners frequently cite provisions of the manual in their communications with patent applicants.

*Id.*

159. *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 536 n.7 (D.N.J. 2000).

160. “These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the ‘written description’ requirement of 35 U.S.C. 112, ¶ 1 . . . . These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.” Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1099 (Jan. 5, 2001).

161. *Id.* (“Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking . . . .”).

162. See, e.g., *Atmel Corp. v. Info. Storage Devices*, 198 F.3d 1374, 1380 (Fed. Cir. 1999); *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1356 (Fed. Cir. 1999); *In re Trovato*, 60 F.3d 807, 808 (Fed. Cir. 1995); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 148 F. Supp. 2d 1004, 1011–12 (N.D. Cal. 2001). *But see State St. Bank & Trust Co. v. Signature Fin. Group*, 927 F. Supp. 502, 512 (D. Mass. 1996), *rev’d*, 149 F.3d 1368 (Fed. Cir. 1998). In *Signature*, the federal court for the District of Massachusetts relied upon PTO guidelines stating: “the Guidelines may be persuasive authority.” *Id.* The court was later reversed in *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368, 1377 (Fed. Cir. 1998).

163. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002).

164. See *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461 (2002) (“Our role is to

Guidelines should only be observed to the extent that the Guidelines do not conflict with the courts' understanding of statutes.<sup>165</sup> To use the Guidelines to give a construction to the written description requirement contrary to that previously observed by the courts is to give legislative authority to the PTO and violate the better traditions of *stare decisis*.<sup>166</sup> Because it has always been understood by the courts, until now, that case law controls, future litigants will be less certain of the means by which the Federal Circuit Court of Appeals will remedy the tension between the Guidelines and case law. As a result, future outcomes will be less predictable.

## V. CONCLUSION

The latest *Enzo* decision has clarified some issues, but ultimately leaves the § 112 written description requirement for genetic patents in a continued state of uncertainty. It is clear that a DNA can be described by its function in certain instances, but it is not clear what those instances are, except that stringent hybridization ratios to a disclosed substrate will probably suffice.<sup>167</sup> It is also clear that a reference to a deposit can adequately describe a DNA; however, it is not certain whether that will suffice only when the practical difficulties of describing the genetic material make a written description unavailable, or if it will be allowed on every occasion.<sup>168</sup> The *Enzo* court probably intended to allow a reference to a deposit only in cases in which the written description is unavailable, but the court did not inform the public when the procurement of the written description is so unduly burdensome that the practical difficulties make the written description unavailable.<sup>169</sup> Finally, the court based its holding upon the persuasive

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interpret the language of the statute enacted by Congress.”).

165. *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996).

166. See EDGAR BODENHEIMER, JURISPRUDENCE: THE PHILOSOPHY AND METHOD OF THE LAW (rev. ed. 1974).

*Stare decisis* is the most commonly used term for designating the Anglo-American doctrine of precedent. This term is an abbreviation of the Latin phrase *stare decisis et non quieta movere* (to stand by precedents and not disturb settled points). Stated in a general form, *stare decisis* signifies that when a point of law has been once settled by a judicial decision, it forms a precedent which is not to be departed from afterward. Differently expressed, a prior case, being directly in point, must be followed in a subsequent case.

*Id.* at 425.

167. See *supra* Part IV.B.1.a.

168. See *supra* Part IV.B.1.c.

169. See *supra* text accompanying notes 150–54.



authority of the patent Guidelines and reached a conclusion in striking contrast to legal precedent.<sup>170</sup> This newfound willingness to rely upon the Guidelines leaves future litigants guessing as to whether they should expect either the Guidelines or the previous case law to hold sway in future decisions.<sup>171</sup> In sum, the latest *Enzo* decision has shifted the direction of the development of the written description requirement for DNA patents, but it has also left us with even more uncertainty in the law than before the ruling.

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170. *See supra* Part IV.B.2.

171. *See supra* text accompanying notes 164–67.