

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

By Chandra Garry

In *Enzo Biochem, Inc. v. Gen-Probe, Inc.*,<sup>1</sup> (hereinafter “*Enzo*”) the Federal Circuit concluded, as a matter of first impression, that the written description requirement for genetic material may be satisfied by reference to a deposited nucleotide sequence.<sup>2</sup> Prior to *Enzo*, the written description requirement for biotechnology inventions was satisfied solely by a description of a DNA molecule’s nucleotide sequence. The *Enzo* decision appears to relax the separate heightened written description requirement for biotechnological inventions.<sup>3</sup> However, by essentially redefining the written description standard *Enzo* creates an obscure standard specific to genus claims that will be difficult to interpret. Adding to the confusion is the possibility that the court intended to limit *Enzo* to its facts. If not limited to its facts, *Enzo* will have important consequences for written description satisfaction of all biotechnological patents having genus claims.

### I. BACKGROUND

#### A. Judicial Interpretation of the Statutory Written Description Requirement

In the United States, the patent law system promotes advances in science and technology by providing a limited monopoly to inventors in exchange for the disclosure of the invention.<sup>4</sup> 35 U.S.C. § 112 sets the standards for disclosure, including the written description requirement:

The specification shall contain a written description of the invention, and 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

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1. 296 F.3d 1316 (Fed. Cir. 2002).

2. *Id.* at 1330.

3. Many sources state that a heightened written description requirement exists for biotechnological inventions. *See, e.g.*, Robert Schulman, *Better to Describe than Provide: Fed. Cir. Adopts One-Size-Fits-All Approach to Genetic Inventions*, 3 No. Pat. Strategy & Mgmt. 1 (2002); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998).

4. U.S. CONST. ART. I, § 8, cl. 8.

the best mode contemplated by the inventor of carrying out his invention.<sup>5</sup>

Courts interpret § 112 as involving three discreet requirements: (1) written description, (2) enablement, and (3) best mode.<sup>6</sup>

The 1991 opinion in *Vas-Cath Inc. v. Mahurkar* (“*Vas-Cath*”) provides a leading authority on the written description requirement.<sup>7</sup> The court clarified that, while the invention is by necessity the subject matter defined by the patent claims, the separate written description requirement serves to put the public in possession of the invention by providing a truthful representation as to the scope the claimed invention.<sup>8</sup>

The court in *Vas-Cath* declared that the purpose of the written description requirement “is broader than to merely explain how to ‘make and use’; the applicant must also convey . . . that, as of the filing date sought, he or she was in possession of the invention.”<sup>9</sup> The court explained that possession was shown if the disclosure reasonably conveyed to a person of ordinary skill in the art that the applicant *possessed* the claimed invention when the patent application was filed.<sup>10</sup> The court in *Vas-Cath* thus established the “possession” test as a means to secure the priority date of the invention.<sup>11</sup>

## **B. Evolution of a Heightened Written Description Requirement and Written Description Review of Originally Filed Claims for Biotechnology Patents**

The Federal Circuit developed a heightened written description standard for biotechnology patents in cases such as *Amgen Inc., v. Chugai Pharmaceutical Co.* (“*Amgen*”) in 1991,<sup>12</sup> *Fiers v. Revel* (“*Fiers*”) in

5. 35 U.S.C. § 112 (2000).

6. *In re Rushig*, 379 F.2d 990 (C.C.P.A. 1967) (separating the written description requirement from the enablement requirement for the first time); see 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (2001).

7. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991) (providing a well-reasoned standard to be applied after reviewing the courts’ previous decisions on the written description and responding to the district court’s comment that “[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is”).

8. *Id.* at 1560-61.

9. *Id.* at 1563-64.

10. *Id.* at 1563; see also Limin Zheng, Note, *Purdue Pharma v. Faulding*, 17 BERKELEY TECH. L.J. 95, at 106-07 (2002) (“What is required to show possession is worded broadly, and the court has administered this test flexibly stating that the Federal Circuit has yet to clearly define what ‘in possession’ means.”).

11. *Vas-Cath*, *supra* note 7, at 1562-64.

12. 927 F.2d 1200 (Fed. Cir. 1991).

1993,<sup>13</sup> and *The Regents of the University of California v. Eli Lilly and Company* (“*Lilly*”) in 1997.<sup>14</sup> These cases held that for patents involving DNA, a patentee cannot support a claim to a gene by only disclosing a method of its isolation.

In *Amgen*, a case that did not turn on satisfaction of the written description requirement, the court held that proof of conception required provision of a gene sequence.<sup>15</sup> In *Fiers*, the court imported the *Amgen* standard for conception into the written description requirement, reasoning that since “a conception of a DNA requires a precise definition . . . then a [written] description also requires that degree of specificity.”<sup>16</sup> After all, one cannot describe what one has not yet conceived, and if one needs the actual nucleotide sequence to establish conception, then presumably, one also needs it to fulfill the written description requirement.<sup>17</sup> As a result, the court in *Fiers* established a DNA-specific standard for satisfaction of the written description requirement but left open other ways to claim DNA.<sup>18</sup>

In *Lilly*, the court affirmed the earlier decisions, stating that “an adequate written description of a DNA”<sup>19</sup> 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>20</sup> While *Lilly* has been interpreted by the biotechnology community to mean that *only* a nucleotide sequence for claimed DNA would satisfy written description, the court also stated that a precise written description could be provided by “structure, formula, chemical name, or physical properties.”<sup>21</sup>

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13. 984 F.2d 1164 (Fed. Cir. 1993).

14. 119 F.3d 1559, 1568 (Fed. Cir. 1997).

15. *Amgen*, 927 F.2d at 1206 (stating that conception is the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice”).

16. *Fiers*, 984 F.2d at 1171.

17. Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC’Y 209, 223 (1998) (criticizing *Fiers* for wrongly importing the conception analysis under 35 U.S.C. § 102(g), which serves a different purpose, into the written description analysis under 35 U.S.C. § 112).

18. *Fiers*, 984 F.2d at 1169-70; *Mueller*, *supra* note 3, at 624 (“Prior to *Lilly*, 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 as of the application filing date.”).

19. *Lilly*, 119 F.3d at 1566.

20. *Id.* at 1566-67 (quoting *Fiers*, 984 F.2d at 1170).

21. *Id.* at 1566. *Cf. id.* at 1569 (supporting the narrow reading by the biotechnology community because the court states that a cDNA, requires the kind of “specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA”).

The court, in *Lilly*, also broadens the heightened written description for biotechnological inventions by using the DNA-specific standard of *Fiers* to invalidate, not species, but genus claims filed as part of the original patent application. The court reviewed originally filed claims, even though these claims are typically subject to a strong presumption that an adequate written description was present when the application was filed.<sup>22</sup> Written description analysis is traditionally limited to review of the specification and later amended claims for the purpose of verifying the invention's priority date.

In cases involving emerging technologies that are difficult to describe, the patentee may enjoy greater opportunity to satisfy the written description due to the more extensive review of patent materials that include originally filed claims.<sup>23</sup> However, many commentators have criticized the *Lilly* decision as unduly replacing the traditional written description standard, as a test of an invention's priority date, with a less discreet standard that instead looks to the invention as a whole.<sup>24</sup>

### C. The Patent and Trademark Office Guidelines Provide a Universal Written Description Standard

The court in *Enzo* directs the Federal Circuit to follow the U.S. Patent and Trademark Office's ("PTO") Guidelines for Examination of Patent Applications ("*Guidelines*"), in the future.<sup>25</sup> The PTO created the *Guidelines* for § 112 in response to concerns raised by *Lilly* in an attempt to resolve uncertainty about written description satisfaction in the patent community.<sup>26</sup> While the *Guidelines* do not carry the force of law, they do represent the PTO's current understanding of the statutory requirements of

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22. *Id.* at 1566-68; see Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099, 1105, available at <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.htm> (Jan. 5, 2001) [hereinafter *Guidelines*].

23. *Lilly*, 119 F.3d at 1568 (noting that the written description requirement was still not satisfied).

24. See generally Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1064-5 (2000) ("Since the addition of *Lilly* to the *Fiers v. Revel* decision, scholars and commentators alike have argued that the rulings are a radical departure from traditional description requirement jurisprudence.").

25. *Enzo*, 296 F.3d at 1324-25, 1328; see *Guidelines*, *supra*, note 22.

26. See *Guidelines*, *supra* note 22 "While the *Guidelines* are meant to be technology neutral, thirteen of the eighteen examples pertain to biotechnology inventions. This reflects the PTO's recognition of the particular concerns and uncertainties faced by those seeking to patent genetic material." *Id.*

the written description, and are believed “to be fully consistent with binding precedent.”<sup>27</sup>

In the *Guidelines*, the PTO attempts to close the gap between the traditional written description requirement announced in *Vas-Cath* and the heightened written description requirement for biotechnological inventions seen in *Lilly*. For example, the *Guidelines* distinguish between mature and emerging technologies, declaring that review of original claims should not be necessary for the former, but supporting *Lilly*'s review of original claims for the latter.<sup>28</sup> Using *Vas-Cath* as a framework, the PTO has carefully incorporated precedent set by several biotechnology cases to arrive at the current version of *Guidelines*.

The court in *Enzo* made over twenty references to the PTO's *Guidelines*, each time drawing upon its support for their reasoning.<sup>29</sup> This repeated reference to the *Guidelines* to address novel issues of law may indicate their future importance for resolution of emerging biotechnology patentability concerns.<sup>30</sup>

## II. CASE SUMMARY: ENZO BIOCHEM V. GEN-PROBE

### A. Facts

Enzo Biochem, Inc. (“Enzo”) was the assignee of U.S. Patent No. 4,900,659 (“the ‘659 patent”).<sup>31</sup> The ‘659 patent involved nucleic acid probes that preferentially hybridized to, and differentiated, the genetic material of the bacteria that causes gonorrhea—*N. gonorrhoeae*—from that of a closely related bacteria—*N. meningitides*.<sup>32</sup> The claimed nucleic acid probes comprised three sequences that preferentially hybridized to six common strains of *N. gonorrhoeae* over six common strains of *N. meningitides*.<sup>33</sup> These sequences had a “preferential hybridization ratio” of greater than fifty.<sup>34</sup> *Enzo* deposited these sequences in the form of recom-

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27. *Id.* at 1104-06.

28. *Id.* at 1106; see *Lilly*, 119 F.3d at 1568 (drawing reference to the appropriateness of a distinct written description for emerging technologies, stating that “where there is unpredictability . . . one skilled in the art may be found not to have been placed in possession of a genus.”).

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

30. See *id.*

31. U.S. Patent No. 4,900,659 (issued Feb. 13, 1990) [hereinafter “the ‘659 patent’”].

32. *Enzo*, 296 F.3d at 1321.

33. *Id.*

34. In reference to the ‘659 patent, col. 12, ll. 60-65, a “preferential hybridization ratio” refers to the rate at which the probe deployed in the presence of both *N. gonorrhoeae* and *N. meningitides* will bind more readily to *N. gonorrhoeae*.

binant DNA molecules within *E. coli* bacterial hosts with the American Type Culture Collection ("ATCC").<sup>35</sup>

## B. The District Court

Enzo brought suit against Gen-Probe Inc., Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., Biomerieux, Inc., and Becton Dickinson and Company (collectively "Gen-Probe") in the Southern District of New York, alleging infringement of the '659 patent.<sup>36</sup> The district court granted Gen-Probe's motion for summary judgment on the basis that claims one through six were invalid for failure to meet the written description requirement.

## C. The First Federal Circuit *Enzo* Decision

On first review, the Federal Circuit affirmed the district court decision.<sup>37</sup> It followed the district court's reasoning, stating that the '659 patent claims described the functional ability of the probes to hybridize to the bacterial DNA, but did not provide the DNA's nucleotide sequence.<sup>38</sup> These functional claims for DNA, without description of the nucleotide sequence, did not satisfy the written description requirement; and deposit alone did not provide the notice required for written description.<sup>39</sup> The court reviewed the originally filed claims, and decreased the importance of the traditional possession test of *Vas-Cath* by declaring that merely showing possession of the invention at the time of filing a patent did not, by itself, satisfy written description.<sup>40</sup>

## D. Federal Circuit Review and Reversal on Rehearing

On grant of petition for rehearing, the Federal Circuit reversed and remanded its earlier decision.<sup>41</sup> The court held that reference in a patent to a deposit in a public depository could satisfy the written description requirement as a matter of law.<sup>42</sup> The court emphasized that the access pro-

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35. *Enzo*, 296 F.3d at 1321.

36. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, No. 99 Civ. 4548 (S.D.N.Y. Apr. 4, 2001).

37. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 285 F.3d 1013 (Fed. Cir. 2002).

38. *Id.* at 1018.

39. The notice function serves to make public the invention so as to ascertain if the patentee claims any thing that is in common use, or is already known. *Id.* at 1023.

40. *Id.* at 1020 ("The appearance of the words of the claim in the specification or as an original claim does not necessarily satisfy that requirement.")

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

42. *Id.* at 1320 ("[U]nder the *Guidelines*, the written description requirement would be met for all of the claims . . . if the functional characteristic of preferential [hybridiza-

vided to the public by the deposit was critical to the reversal of its earlier decision, particularly because the invention was not otherwise available in written form.<sup>43</sup> Similar to its earlier decision, however, the court reviewed originally filed claims for satisfaction of written description and held that a showing of possession was not central to written description satisfaction.<sup>44</sup>

In addition, the court in *Enzo* differentiated broader and narrower genus claims and made suggestions as to how the court may resolve genus claim disputes in the future. For the narrower genus claims which incorporate reference to the ATCC deposits, the court declared that a showing of possession is still required for written description satisfaction.<sup>45</sup> For the broader genus claims, however, the court declared that a showing of possession is not central for determination of satisfaction of the written description requirement.<sup>46</sup> Instead, for these broader genus claims, the court declared that a written description indicating that the patentee "has invented species sufficient to constitute the genera" is of paramount importance.<sup>47</sup> Ultimately, the court directed future decisions involving each of these disputed genus claims to be made in accordance with the precedent set by both the court and the PTO's *Guidelines*.<sup>48</sup>

### III. DISCUSSION

*Enzo* is the first Federal Circuit decision to hold that reference to a biological deposit may satisfy the written description requirement, even when a nucleotide sequence is not specified for the claimed genetic invention.<sup>49</sup> Prior to *Enzo*, a written description for a genetic invention could not be satisfied without provision of a detailed nucleotide sequence. The court recognized that the decision changed precedent when it commented that the district court "clearly understood and correctly applied this courts ex-

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tion] . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.").

43. *Id.* at 1325.

44. *Id.* at 1328, 1330.

45. *Id.* at 1327 (regarding "claims 4 and 6 . . . on remand, the court should determine whether a person of skill in the art would glean from the written description, including information . . . sufficient to demonstrate possession of the generic scope of the claims").

46. *Enzo*, 296 F.3d at 1329 (referring to claims 1-3, and 5).

47. *Id.* at 1327.

48. *Id.* at 1327-28.

49. *Id.*

isting precedent.”<sup>50</sup> In the course of its departure from precedent, the court effectively redefines what is necessary for satisfaction of the written description.

A conservative reading of *Enzo* is supported by the Federal Circuit’s recent suggestion that holdings such as *Enzo*’s and *Lilly*’s, may be strictly limited to novel issues of law where the claims deal with new and unknown biological materials, where ordinarily skilled artisans might easily miscomprehend.<sup>51</sup> Thus, while it may first appear that the Federal Circuit is relaxing the heightened written description requirement for biotechnological inventions,<sup>52</sup> any such relaxation may be strictly limited by both “the time of *Enzo*’s invention,”<sup>53</sup> and the specific facts of the case, as “the written description . . . [inquiry] will necessarily vary depending on the nature of the invention claimed.”<sup>54</sup> Nonetheless, the process used by the court to arrive at the decision in *Enzo* may have significant consequences for satisfaction of the written description for biotechnological inventions.

The court, in *Enzo*, created an obscure standard that will be difficult for subsequent courts to interpret. In *Enzo*, the court held, as a matter of law, that the genus claims to a genetic invention may be adequately described by reference to a deposit. However, the court then distinguished between broader and narrower genus claims, rendering a different standard for satisfaction of each class.<sup>55</sup> The court instructed that the narrower genus claims that include reference to the patentee’s deposits must still demonstrate a showing of possession of the claimed invention. In contrast, broader genus claims, regardless of any showing of possession, must be affirmatively described by an adequate number of species to claim the genus, although the court does not specify a number that would be adequate.<sup>56</sup> The court remands all the claims with the instruction that satisfac-

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50. *Id.* at 1330; see also Harold C. Wegner, *When a Written Description Is Not A “Written Description”*: *When Enzo Says It’s Not*, 12 Fed. Circuit B.J. 271 (2002) (“The panel [in *Enzo*] had no choice: only several months before its original denial of ATCC deposits, the Supreme Court . . . had blessed the patent-eligibility of new seeds under 35 U.S.C. § 101 where the very same method was used to identify the invention.”) (referring to *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 142 (Sup. Ct. 2001)).

51. See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).

52. Many sources state that a heightened written description requirement exists for biotechnological inventions. See e.g., *Mueller, supra*, note 3.

53. *Enzo*, 296 F.3d at 1328.

54. *Id.* at 1324.

55. See *id.* at 1326-28.

56. *Id.* at 1327, 1329.

tion of the written description be determined in agreement with the PTO's *Guidelines*. Ultimately, the Federal Circuit refuses rehearing en banc, leaving many questions unresolved.

**A. Enzo Does Not Relax, but Redefines the Written Description Requirement For Broader Genus Claims**

In *Enzo*, the court redefined the written description requirement for the broader genus claims without giving a clear reason. First, the court, following *Lilly*, reviewed originally filed claims for satisfaction of the written description requirement. Second, the court declared that a showing of possession is not required to prove written description satisfaction.<sup>57</sup> However, the court's redefinition of these two written description criteria may be the direct result of a lack of dispute in *Enzo* over either the invention's priority date, or the fact that the inventor undoubtedly "possessed" the invention.

The court in *Enzo* declared that a showing of possession was not critical for satisfaction of the written description requirement for genus claims.<sup>58</sup> In sharp contrast, the court in *Lilly* demanded a showing of possession, through recitation of a number of nucleotide sequences, for genus claims.<sup>59</sup> Similarly, the *Guidelines* instruct that possession is a factual determination of high importance for finding satisfaction of the written description.<sup>60</sup> There are two possible reasons that may explain why the *Enzo* court deviated from case law.

One such reason stems from *Enzo*'s own procedural history. The Federal Circuit's first review of *Enzo*, necessitated the elimination of the traditional possession test in order to hold that the patentee failed to satisfy the written description requirement, because the Enzo patentee's possession of the claimed invention was not disputed. This first holding goes against both case precedent and the *Guidelines*, as these teach that a showing of possession is determinative of written description satisfaction. On second review, the Federal Circuit, though reversing their previous holding, maintained this position from the earlier decision, declaring that *Vas-Cath*, the case that established the possession test for satisfaction of written description, did not explicitly "state that possession alone is always sufficient."<sup>61</sup>

Another explanation, indirectly suggested by the court, was that proof of possession may be irrelevant, or "ancillary," where disputes do not con-

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57. *Id.* at 1330.

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

59. *Lilly*, 119 F.3d at 1568.

60. *Guidelines*, *supra* note 22, at 1105-06.

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

cern the invention's priority date.<sup>62</sup> Such a reading meshes well with *Vas-Cath*, as proof of possession originally served primarily as a test of entitlement of later filed claims to an earlier priority date.<sup>63</sup> While *Enzo* fundamentally changes the written description inquiry by lessening the importance of the possession test, the court does not restrict making ancillary use of the possession test in only those cases not involving priority disputes. As a result, it is more likely that the possession test may be disengaged from its original purpose, as a test of priority, in future disputes.

The court in *Enzo*, in addition to dismissing the importance of the possession test, also followed *Lilly*'s holding by declaring that it may strike down originally filed claims.<sup>64</sup> However, the court in *Enzo* actually built upon *Lilly*, declaring that it may strike down original claims, even when they appear in *ipsis verbis*—identical words appear in the claims and in the specification—when neither the specification nor the claim itself sufficiently describes the claimed invention.<sup>65</sup> Traditionally, even amended claims added during prosecution satisfied written description so long as the claim language appeared in *ipsis verbis*. However, *Enzo*'s written description review of originally filed claims is controversial only in part because previous cases did not allow it.

While the court's written description review of originally filed claims is not blocked by statute, precedent, or even the Guidelines, an additional consideration is urged by many commentators.<sup>66</sup> These commentators argue that it is well-established that allowing judges to scrutinize claims in order to analyze the invention in its entirety is contrary to principles of modern claim construction, because hindsight judicial assessment may be less trustworthy.<sup>67</sup> Despite any such risks, the court's review of originally

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62. *Id.* at 1329-30; see also *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 42 Fed. Appx. 439, 457 (Linn, J., dissenting) (agreeing with the majority that a showing of possession alone, "was not and should not be a test for sufficiency of disclosure, per se").

63. *Vas-Cath*, 935 F.2d at 1563-64.

64. *But see* *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996) (deciding that original claims failed to satisfy written description, more than a year before *Lilly*).

65. *Enzo*, 296 F.3d at 1328.

66. See *Wegner*, *supra* note 50 ("Congress did not explicitly limit the statute to prevent review of originally filed claims."); Zhibin Ren, *Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the University of California & Eli Lilly Company*, 1999 WISC. L. REV. 1297 at 1312-13.

67. See e.g., Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 76-77 (2000) ("The same danger is present when a court is free to dissect a disclosure into those individual components deemed essential and those deemed non-essential.").

filed claims appearing in *ipsis verbis* for written description satisfaction makes such review more likely in the future.

In *Enzo*, the written description standard for broad genus claims is redefined in two critical, though perhaps complementary, ways, as both render the standard ultimately reached by the court harmonious with the fact that neither priority nor possession was actually disputed in *Enzo*. Although the court deviates far from the written description standard established by *Vas-Cath* in making the once central possession test "ancillary," the purpose of showing possession to prove priority was simply not necessary in *Enzo*.<sup>68</sup> This is because originally filed claims were undergoing written description review, and originally filed claims provide presumptive proof as to their own priority.<sup>69</sup> Ultimately, the court in *Enzo* suggested that the redefined the written description requirement for genus claims to DNA be considered in accordance with the *Guidelines*.<sup>70</sup>

### B. Future Influence of the PTO Guidelines for Genus Claims

The Guidelines provide direct support for the holding in *Enzo*. The Guidelines explicitly state that description "may be shown by specifically describing a deposit," and declare that there is no basis for a per se rule requiring disclosure of complete DNA sequences, or limiting DNA claims to only the sequence disclosed.<sup>71</sup> The court in *Enzo* orders upcoming decisions to be made in compliance with the *Guidelines*, thus giving them judicial weight in future written description controversies.<sup>72</sup> Due to the fact that the *Guidelines* provide needed scientific expertise, the Federal Circuit will likely reference the *Guidelines* when considering novel issues of law.<sup>73</sup>

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68. See *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 42 Fed. Appx. 439 (Linn, J., dissenting).

69. *Enzo*, 296 F.3d at 1329 (declaring that a claim does not become more descriptive by its repetition or its longevity).

70. *Id.* at 1328.

71. *Guidelines*, *supra* note 22, at 1106 (stating that there is no basis for a per se rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed).

72. *Enzo*, 296 F.3d at 1328 (guiding the future court to consider the Guidelines in order to decide as a matter of law whether the written description supported *Enzo*'s genus claims, 1-3, and 5, which were directed not only to the deposited sequences, but also to mutations of those sequences).

73. *Id.* at 1324.

### C. The Decision in *Enzo* May Be Limited For Biotechnological Inventions

#### 1. *Enzo* Does Not Allow Purely Functional Claims to Substitute for Provision of a DNA Sequence

The court in *Enzo* does not allow purely functional claims to satisfy written description for genetic inventions. While it is true that the court in *Lilly* did not declare that all functional descriptions of genetic material necessarily fail, as a matter of law, to meet the written description requirement, the court did stress the need for “a precise definition, such as by structure.”<sup>74</sup> The court’s position in *Enzo*, which is supported by *Lilly* and the *Guidelines*, is that the written description requirement may be satisfied if one of skill in the art finds the disclosed function *sufficiently correlated* to a particular, known structure.<sup>75</sup>

Thus, the court in *Enzo*, upon review of essentially functional claims, implicitly relied upon the baseline rule in *Lilly* that disclosure of a structure was, though perhaps to a lesser degree, still required for written description satisfaction.<sup>76</sup> Any supposed relaxation of the written description requirement must be considered in light of the fact that *Enzo*’s invention, by inclusion of a reference to an accessible deposit, did not rest on purely functional claims. Instead, it should be recognized that in *Enzo*, the court emphasized the importance of access to the deposits by a person of skill in the art.<sup>77</sup> Consequently, the written description requirement is satisfied by functional claims that include reference deposits; deposits that inherently disclose structures correlated to their function.<sup>78</sup>

#### 2. *Enzo* May Be Strictly Limited To Its Unique Facts

It appears that the Federal Circuit may have relaxed the written description requirement set forth in *Lilly* by taking account the state of the art at the time the application was filed. The *Enzo* decision noted difficulties faced by those “of skill in the art” in 1986 to obtain the nucleotide se-

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74. *Id.*

75. *Id.* at 1324 (emphasis added); see *Guidelines*, *supra* note 21, at 1106 (stating that an invention may be described by “functional characteristics when coupled with a known or disclosed correlation between function and structure”).

76. *Id.* at 1324.

77. *Id.* at 1326 (“[R]eading the accession numbers in the patent specification, [a person of skill in the art] can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences.”).

78. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1177-78 (2002).

quences of claimed DNA. The court recognized that in 1986 “it would take 3,000 scientists one month to sequence the genome of one strain of *N. gonorrhoeae* and one strain of *N. meningitides*.”<sup>79</sup> Because the inventor could not have reasonably obtained the nucleotide sequence, they were more or less excused from doing so to meet the written description requirement.<sup>80</sup> The court states in the case of biological inventions for which providing a description in written form is not practicable, one may nevertheless comply by publicly depositing.<sup>81</sup>

*Enzo* is exceptional because, on the whole, the Federal Circuit continues to appear indifferent to the level of certainty in the art at any particular time, preferring instead a standard based on structural precision that ignores the state of technology.<sup>82</sup> For example, the court in *Lilly* demanded provision of a nucleotide sequence for satisfaction of the written description requirement for claims to DNA for an application filed in 1977.<sup>83</sup> Indeed, it was not until 1977 that the method of sequencing DNA was even published, and even then it was highly unpredictable.<sup>84</sup> The exceptional consideration granted to *Enzo*, and its incongruity with prior Federal Circuit treatment of claims to genetic material, supports a reading that the *Enzo* decision will be strictly limited to its facts.

Even presuming that the Federal Circuit, after *Enzo*, continues to demonstrate sensitivity to the state of the art at the time of the invention, *Enzo* will still be less useful to later applicants, and useless to current applicants wishing to rely on a deposit alone to satisfy the written description requirement. This is because the court’s recognition of the state of the art in 1986 would be updated to the post-1986, and current, skill in the art. Today a patentee can reasonably obtain nucleotide sequences of DNA, making deposit for satisfaction of the written description superfluous. For all the above reasons, the holding in *Enzo* will be not likely affect later issued patents.

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79. *Enzo*, 296 F.3d at 1328.

80. *Id.*

81. *Id.* at 1330.

82. Burk & Lemley, *supra* note 78, at 1194 (“The court has maintained its assumption that biotechnology is an uncertain art long after the industry began to mature.”).

83. *Lilly*, 119 F.3d 1559.

84. *Enzo*, 42 Fed. Appx. at 439 (“In 1977, biotechnology was still in its infancy. In fact, the Maxam and Gilbert method of sequencing DNA was just published in 1977. Cloning in that era was, at a minimum, unpredictable and would have required vast amounts of experimentation.”).

### 3. *Enzo May Be Distinguished On Scientific Basis From Other Biotechnology Written Description Cases*

The functional claims at issue in *Enzo* may be distinguished from those in *Amgen*, *Fiers*, and *Lilly*, because *Enzo*'s claims are to probes. The utility of these probes rests in the inherent hybridization capability of the claimed DNA.<sup>85</sup> One of skill in the art may effectively make full use of probes without knowing their nucleotide sequence. In contrast, each of the other cases dealt with generic claims to proteins encoded by genes. For one of skill in the art to make full and independent assessment of a gene's utility, the disclosure of a nucleotide sequence is required. Thus, the claims at issue in *Amgen*, *Fiers*, and *Lilly* may be differentiated from the claims in *Enzo* by their effective utility.<sup>86</sup> If directly confronted with this issue, the Federal Circuit may make the written description requirement truly fact-specific, treating claims to genes differently than claims to probes.

## IV. CONCLUSION

The Federal Circuit in *Enzo* decided for the first time that the written description requirement may be satisfied by a biological deposit.<sup>87</sup> At first glance, it appears that *Enzo* lowers the written description standard applied by the court in *Lilly*, as deposit seems an easy way to satisfy the written description requirement. Any such lowering of the written description standard, however, is by and large illusory. The decision in *Enzo* will likely be strictly limited to its facts. If not limited to its facts, the court's redefined written description is not sufficiently explained by the court so as to provide an easily workable standard for future decisions.

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85. *Enzo*, 296 F.3d at 1323 (citing an *Enzo* attorney's argument, which raises this point).

86. *Lilly*, 119 F.3d 1559 (claiming recombinant DNA plasmids and microorganisms relating to the production of human insulin); *Fiers*, 984 F.2d 1164 (claiming DNA coding for a protein that promotes viral resistance in human tissue); *Amgen*, 927 F.2d 1200 (claiming DNA sequences encoding purified and isolated human erythropoietin, a glycoprotein which stimulates red blood cell production).

87. *Enzo*, 296 F.3d at 1330.