

# Intellectual Property Today™

## The Written Description Requirement

### ENZO BIOCHEM v. GEN-PROBE REHEARD AND RECONSIDERED

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On April 2, 2002, the Federal Circuit decided *Enzo Biochem v. Gen-Probe*<sup>1</sup> (*Enzo I*), affirming a decision of the United States District Court for the Southern District of New York.<sup>2</sup> The district court had granted a motion for summary judgment by Gen-Probe et al. (the defendants) that claims 1-6 of U. S. patent 4,900,659 are invalid for failure to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.<sup>3</sup>

In *Enzo I*, the Federal Circuit continued a trend it started in *University of California v. Eli Lilly*<sup>4</sup> toward increasing the burden of satisfying the written description requirement, especially for biotechnology inventions. This more rigorous written description requirement has led to a re-evaluation of how patent applications should be drafted in order to satisfy § 112, ¶1. See, for example, the article by Hoffenberg in the June, 2002 issue of this journal.<sup>5</sup> The present author has

also previously commented on *Enzo I*. See the article in the August, 2002 issue of this journal.<sup>6</sup>

In a stunning reversal, the Federal Circuit on July, 15, 2002 granted Enzo's request for rehearing, stated that genuine issues of material fact exist, and remanded the case back to the district court for resolution. *Enzo Biochem v. Gen-Probe (Enzo II)*.<sup>7</sup>

We will now compare *Enzo I* with *Enzo II*. As will be seen, the rehearing in *Enzo II* will have a significant effect on the parties involved.

In this article, however, we are interested in the broader effect of the *Enzo II* rehearing on the changes in the law relating to the written description requirement wrought by *Enzo I*. As we will see, the effect on the law will be more modest than the effect on the parties involved. While less extreme than *Enzo I*, *Enzo II*, in combination with the *Eli Lilly* decision (see above), significantly increases the written description requirement of §112, ¶1.

The Enzo patent is directed to nucleic acid probes that are capable of distinguishing the various bacterial strains of *N. gonorrhoeae* from the closely related and highly homologous strains of *N. meningitides*. The invention is based on nucleic acid probes that bind to the DNA of *N. gonorrhoeae* with an affinity at least five times higher than the affinity with which they bind to the DNA of *N. meningitides*. Claim 1 of the Enzo patent is directed to the probes generically.

Enzo had isolated three such DNA probes, inserted them into an *E. coli* bacterial host, and deposited the *E. coli* in an approved depository, the ATCC. Also deposited were six strains of *N. gonorrhoeae* and six strains of *N. meningitides*.<sup>8</sup> The three deposited probes, along with certain mutated variants, were recited in claims 4 and 6 of the Enzo patent. At the time the Enzo patent application was filed, the nucleic acid sequence of neither the probes nor the *N. gonorrhoeae* and *N. meningitides* bacteria was known.<sup>9</sup>

In his previous article, the present author identified the following four holdings in *Enzo I*:

1. A deposit of biological materials can never satisfy the written description requirement in a patent application.<sup>10</sup>
2. A description of a function of a molecule can never satisfy the written description requirement for the molecule in the absence of a description of the structure of the molecule.<sup>11</sup> This holding applies especially to a nucleic acid molecule, where the Federal Circuit has taken the position, *de facto*, that a nucleic acid molecule cannot be adequately described in the absence of a nucleotide sequence.<sup>12</sup>

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3. The written description requirement is not necessarily met for a claim, even if the claim language appears *in ipsius verbis* in the specification, or if the claim at issue appeared in the application as originally filed.<sup>13</sup>
4. “Possession of the invention” by, for example, reducing the invention to practice, without more, is not sufficient to satisfy the written description requirement.<sup>14</sup>

Each of these holdings of *Enzo I* were revisited by the Federal Circuit on rehearing in *Enzo II*. We will now see how each of the holdings fared.

## 1. DEPOSIT OF BIOLOGICAL MATERIALS

In *Enzo I*, the patentee, Enzo, argued “...that biological deposits necessarily satisfy the written description requirement.” The Federal Circuit in *Enzo I* disagreed.<sup>15</sup>

Citing *In re Lundak*,<sup>16</sup> the Federal Circuit first noted that the system of depositing biological materials was developed by the PTO<sup>17</sup> for the purpose of providing a means to satisfy the enablement requirement of §112, ¶1. A deposit of biological materials was, however, held not to satisfy the written description requirement.<sup>18</sup>

Therefore, the court in *Enzo I* rejected Enzo’s argument, and held that the deposit of the *E. coli* host cells, from which the claimed probes could be obtained and their nucleotide sequences deduced, was insufficient to satisfy 35 U.S.C. 112. Citing the PTO’s written description guidelines,<sup>19</sup> the court held that the written description had to be in the specification. In explaining its *Enzo I* decision, the court stated: “The written description requirement is not satisfied by what could have been disclosed, but was not.”<sup>20</sup>

On rehearing in *Enzo II*, the Federal Circuit reconsidered whether Enzo’s deposits of the claimed nucleotide sequences of claims 4 and 6 constituted an adequate description of those sequences. According to the court, “...we have determined that our prior decision that a deposit may not satisfy the written description requirement (*i.e.*, *Enzo I*) was incorrect.”<sup>21</sup>

Therefore, in a dramatic departure from its decision in *Enzo I*, the court in *Enzo II* now agreed with Enzo, stating:<sup>22</sup>

...we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of section 112, paragraph 1.

The court noted, however, that in addition to reciting just the sequences of the deposited probes, claims 4 and 6 also recite certain mutant variants. Therefore, the court remanded the case back to the district court to decide whether the mutant variants that are also covered by claims 4 and 6 are likewise adequately described.<sup>23</sup>

## 2. FUNCTIONAL DESCRIPTION OF A MOLECULE

In *Enzo I*, the Federal Circuit adopted the holding from its earlier *Eli Lilly* decision (see above) that:<sup>24</sup>

... 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.’

The court in *Enzo I* found Enzo’s claims to suffer from the “fatal flaw” of relying solely on a definition of nucleic acid molecules by activity and function, and not by “inherent structure.”<sup>25</sup>

In *Enzo II*, the Federal Circuit addressed Enzo’s additional argument that the structures of its probes are described “...by means of the disclosed correlation of the function of hybridization (of the claimed probes) with the bacterial DNA.” As asserted by Enzo:<sup>26</sup>

... the description and claiming of biological materials by their affinity to other materials that are clearly identified in the specification and claims (the particular deposited strains of *N. gonorrhoeae* and *N.*

*meningitides*) inherently specifies structure, and is routine in this field.

The Federal Circuit noted that the nucleotide sequences of *N. gonorrhoeae* and *N. meningitides* were not known at the time the Enzo application was filed. The court also noted, however, that Enzo had made six strains of each available to the public by means of the ATCC deposit. Therefore, in accordance with its revised decision in *Enzo II* that a deposit of biological materials constitutes an adequate written description of the structure of the biological materials deposited, (see holding 1 above), the deposits of the *N. gonorrhoeae* and *N. meningitides* strains were held to constitute an adequate written description of the sequence of each strain.<sup>27</sup>

The court further reasoned that some information about the sequence of the probes could be deduced from their known selective hybridization to segments of the deposited *N. gonorrhoeae* strains, and of the complementary relationship between the probes and the sequences of these segments. Since the specific segments to which the probes hybridized were not known, the sequence of the probes could not be directly deduced. Nevertheless, the court stated that Enzo had “...at least raised a genuine issue of material fact as to whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public.”<sup>28</sup>

Of course, a “reasonable fact-finder” would know that the probes were also deposited. In accordance with holding 1 described above, therefore, a reasonable fact-finder would conclude that the exercise of attempting to deduce information about the probes’ sequences from the probes’ ability to hybridize to publicly available bacterial sequences was unnecessary. The Court had already held that the sequences of the probes were adequately described in view of their having been deposited. Therefore, holding 2 of *Enzo II* could be considered *dicta*.

Nevertheless, holding 2 has an intriguing aspect to it. As pointed out in his previous article (see above), the present author is unaware of the Federal Circuit's approval of a description of a nucleic acid molecule other than by its sequence.

In holding 2, the Federal Circuit ruled that knowledge about the selective hybridization of a nucleic acid probe to bacterial strains with known or available nucleotide sequences, even in the absence of knowledge about the location of the hybridization, at least raised a genuine issue of material fact sufficient to defeat a motion for summary judgment that the written description of the probes does not satisfy 35 U.S.C. 112. Therefore, holding 2 raises some interesting questions.

For example, did the court mean to imply that a nucleotide sequence was not always necessary for an adequate written description of a nucleic acid molecule? Is this the first crack in the Federal Circuit's armor regarding this previous *de facto* requirement? Or did the Federal Circuit mean that, under the circumstances, there may have been sufficient information to deduce the sequences of the probes from their known selective hybridization to the DNA of various strains of *N. gonorrhoeae* in the presence of *N. meningitides*. The only certainty is that this issue will be before the Federal Circuit again.

### 3. SUFFICIENCY OF DESCRIPTION OF THE INVENTION IN *ipsis verbis* IN THE SPECIFICATION OR IN AN ORIGINAL CLAIM IN THE APPLICATION AS FILED

The Federal Circuit in *Enzo I* "also concluded that Enzo's claims do not meet the written description requirement simply because they are *in ipsis verbis* supported by the specification."<sup>29</sup> Citing *Eli Lilly*, the court explained that:<sup>30</sup>

If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.

The court reconsidered the issue during the rehearing in *Enzo II*, but did not deviate from the opinion it expressed in *Enzo I*. The above quote from *Enzo I* appears *in ipsis verbis*, in *Enzo II*.<sup>31</sup>

### 4. SUFFICIENCY OF "POSSESSION OF THE INVENTION"

In *Enzo I*, Enzo made the novel argument<sup>32</sup> that it had complied with the so-called "possession of the invention" test of *Vas-Cath v. Mahurkar*<sup>33</sup> by reducing its three probes to practice. "Possession of the invention" had been considered both necessary and sufficient for satisfying the written description requirement prior to *Enzo I*.<sup>34</sup>

The Federal Circuit, in *Enzo I*, did not accept Enzo's argument. According to the court, showing that an applicant had possession of the invention as of the desired filing date is only one purpose of the written description requirement.<sup>35</sup>

The Federal Circuit reconsidered this issue during the rehearing in *Enzo II*. The court, once again, did not deviate from the original opinion it expressed in *Enzo I*. The Court reiterated in *Enzo II*:<sup>36</sup>

... that proof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of §112, ¶1. As with 'possession,' proof of a reduction to practice may show priority of invention or allow one to ante-date a reference, but it does not by itself provide a written description *in the patent specification*. (Original emphasis.)

### CONCLUSION

In *Enzo II*, the Federal Circuit reversed its original opinion in *Enzo I* by holding that:

For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material...<sup>37</sup>

See holding 1, above.

This decision will no doubt have an important impact on the final disposition of the litigation, and on the litigants. Its impact on the law relating to the written description requirement of §112, ¶1 will, however, be modest.

Thus, the circumstances under which "providing a description in written form is not practicable" were more prevalent in 1986, when the application that matured into the Enzo patent<sup>38</sup> was filed, than they are today. The technological advances in sequencing nucleic acid and amino acid sequences have made providing adequate written descriptions easier, and depositing biological materials correspondingly less important, than they were in 1986.<sup>39</sup>

The remainder of the *Enzo II* decision left the more stringent view of the written description requirement expressed in *Enzo I* and *Eli Lilly* largely in place. See above.

It is true that the Federal Circuit in *Enzo II* ameliorated its apparently absolute refusal in *Enzo I* and *Eli Lilly* to consider any role for function in satisfying the requirement for a written description of nucleic acid molecules. See holding 2, above. Thus, the court in *Enzo II*, quoting with approval the PTO guidelines regarding the written description requirement, stated:<sup>40</sup>

...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. ... *functional characteristics when coupled with a known or disclosed correlation between function and structure* or some combination of such characteristics." (Original emphasis.)

Nevertheless, a description of the structure itself, even according to this somewhat more liberal formulation, is still a necessary condition of §112, ¶1. Potentially more significant is that the court may have suggested for the first time that the structure of a nucleic acid molecule may be shown by something less than a full nucleic acid sequence. See above. Future Federal Circuit decisions will be required to clarify this issue.

In addition, the court again rejected the argument, as it had earlier in *Eli Lilly* and *Enzo I*, above, that the written description requirement is necessarily met if the claim language appears *in ipsius verbis* in the specification, or if the claim at issue appeared in the application as originally filed. See holding 3, above.

Similarly, the court again rejected the proposition, as it had for the first time in *Enzo I*, that possession of the invention was sufficient to satisfy the written description requirement. See holding 4, above.

The holdings in *Enzo I* discussed above have generally raised the legal standard applicants must meet in order to satisfy the written description requirement. These holdings may also have other, unintended, consequences.

A, discussed above, for example, the Federal Circuit in *Enzo II* repeated the rule of *Eli Lilly* and *Enzo I* that the written description of a nucleic acid molecule requires disclosure of its structural characteristics. As stated in *Eli Lilly*,<sup>41</sup> and approved in *Enzo I*:<sup>42</sup>

...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.'

The last phrase from the above quote ("...not a mere wish or plan for obtaining the claimed chemical invention") suggests that the rule may not be limited to genetic material, but may apply to molecules in general.

For example, in product by process claims, a structure is claimed by describing only, or at least primarily, the process used to obtain it. Such claims are usually directed to chemical compositions that cannot be

described by "...a precise definition, such as by structure, formula, chemical name, or physical properties."<sup>43</sup> In such cases, the chemical compositions can only be described by the processes for obtaining them. If, however, satisfaction of §112, ¶1 for a chemical composition requires a description of the chemical composition *per se*, the validity of product by process claims might be called into question.<sup>44</sup>

*The opinions expressed in this article are the current opinions of the author, and not necessarily those of any other attorney or agent of Hoffmann & Baron, LLP, or of any former, present, or future client of Hoffmann & Baron, LLP*

#### ENDNOTES

1. *Enzo Biochem v. Gen-Probe (Enzo I)* 285 F.3d 1013, 62 USPQ2d 1289 (fed. Cir. 2002).
2. *Enzo I* at 1290.
3. *Enzo I* at 1291.
4. *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), cert. denied 523 U.S. 1089 (1998).
5. Hoffenberg, 9 Intellectual Property Today 6 (June, 2002).
6. Feit, 9 Intellectual Property Today 16-18 (July, 2002).
7. *Enzo Biochem v. Gen-Probe (Enzo II)* \_\_\_ F.3d \_\_\_, 63 USPQ2d 1609 (Fed. Cir. 2002).
8. *Enzo II* at 1610-1611.
9. *Enzo I* at 1290.
10. See *Enzo I* at 1295 and the author's previous article at discussion around endnote 40.
11. See *Enzo I* at 1292 and the author's previous article at discussion around endnotes 29 and 42.
12. See the author's previous article at discussion around endnotes 43 and 44, *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and *Amgen v. Chugai Pharmaceutical* 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).
13. See *Enzo I* at 1294 and the author's previous article at discussion around endnotes 20 and 41.
14. See *Enzo I* at 1294 and the author's previous article at discussion around endnotes 18, 19, 36 and 37.
15. *Enzo I* at 1295.
16. *In re Lundak*, 773 F.2d 1216, 1217, 227 USPQ 90, 92 (Fed. Cir. 1985).

17. 37 CFR 1.801-1.809.
18. *Enzo I* at 1295.
19. 66 Fed. Reg. 1099 (January 5, 2001).
20. *Enzo I* at 1295.
21. *Enzo II* at 1610.
22. *Enzo II* at 1613.
23. *Id.*
24. *Enzo I* at 1292.
25. *Enzo I* at 1293.
26. *Enzo II* at 1615.
27. *Enzo II* at 1616.
28. *Id.*
29. *Enzo I* at 1293.
30. *Enzo I* at 1294.
31. *Enzo II* at 1616.
32. 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).
33. *Vas-Cath*, 935 F.2d at 1563-1564, 19 USPQ2d at 1117. The Federal Circuit stated the "possession" test in *Vas-Cath* as follows: "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."
34. See *Vas-Cath*, above, *Eli Lilly*, above, and the author's previous article in the discussion around endnote 42.
35. *Enzo I* at 1294.
36. *Enzo II* at 1617.
37. *Id.*
38. U.S. 4,900,659
39. The Federal Circuit observed in *Enzo II* that, at the time of *Enzo*'s invention, it would have taken 3,000 scientists one month to sequence the genome of one strain of *N. gonorrhoeae* and one strain of *N. meningitides*. *Enzo II* at 1616. (*Enzo* deposited a total twelve strains, six strains each of *N. gonorrhoeae* and *N. meningitides*.)
40. *Enzo II* at 1613.
41. *Eli Lilly* at 1406.
42. *Enzo I* at 1292.
43. Until 1974, the inability to describe the structure of a claimed molecule was a requirement for being able to claim the molecule by means of a product by process claim. See Faber, Landis on Mechanics of Patent Claim Drafting, Practising Law Institute, §46, page V-4, Fourth Edition, December, 1999.
44. Product by process claims have a very long history in U.S. patent law without having been questioned. Are they now invalid? Perhaps there is a distinction between genetic materials and other types of molecules. Perhaps the distinction is between descriptions of molecules solely by function and solely by process of preparation. If such distinctions exist, it is not clear what the basis for them is.

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