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The Written Description Requirement for Biotechnology Inventions in the Federal Circuit

THE LONG ROAD FROM VAS-CATH TO ENZO VIA ELI LILLY



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The written description requirement is set forth in 35 U.S.C. §112 with admirable simplicity: “The specification shall contain a written description of the invention...” Two recent decisions of the Federal Circuit regarding application of the written description requirement to biotechnology inventions are causing considerable concern and controversy, *University of California v. Eli Lilly*¹ and *Enzo Biochem v. Gen-Probe*.²

In this article, we will discuss these decisions, and their impact on biotechnology patent applications. First, we will review the most authoritative decision of the Federal Circuit relating generally to the written description requirement, namely, *Vas-Cath v. Mahurkar*.³

VAS-CATH v. MAHURKAR

The *Vas-Cath* decision, above, involved two U.S. utility patents of Mahurkar, both entitled “Double Lumen Catheter.”⁴ The utility applications that matured into the two patents had been designated continuations of a design application. The design application and the two utility applications contained the same drawings of the catheters.⁵

A related design application with the same drawings had also been filed in Canada. The Canadian design application issued as Canadian industrial design 50,089 (Canadian ‘089) more than one year before the filing date of the two utility patents in the United States.⁶

Mahurkar attempted to enforce its patents against Vas-Cath in the District Court for the Northern District of Illinois. Vas-Cath sought summary judgment that Mahurkar’s two utility patents were invalid under 35 U.S.C. §102(b) over Canadian ‘089.⁷

The district court agreed with Vas-Cath that Mahurkar’s utility patents were not enti-

tled to the filing date of the U.S. design application under 35 U.S.C. §120. According to the district court, the drawings in the design application did not provide an adequate written description of the claimed catheter as required by 35 U.S.C. §112, first paragraph.⁸

The district court further agreed with Vas-Cath that no genuine issues of material fact were in dispute.⁹ Therefore, the district court granted Vas-Cath’s motion for summary judgment that the utility patents are invalid.¹⁰

On appeal to the Federal Circuit, both parties conceded that the claims were enabled.¹¹ Therefore, the sole issue before the Federal Circuit was whether the figures in the U.S. design application provided an adequate written description of the catheters claimed in the utility applications in satisfaction of the requirement of §112, first paragraph. If so, Mahurkar’s utility patents are entitled to the filing date of the design patent, antedating thereby Canadian ‘089.¹²

In view of some earlier internally inconsistent decisions, the Federal Circuit panel that heard the *Vas-Cath* case, which included Judges Rich, Michel, and Plager., provided a thorough history of the written description requirement in the Federal Circuit and its predecessor courts.¹³ The decision, which was written by Judge Rich, is generally con-

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sidered to be the leading authority on the law of the written description requirement in the Federal Circuit.

Judge Rich first pointed out that, at least as of the time he wrote the *Vas-Cath* opinion, *i.e.*, 1991, the written description requirement was generally at issue under two circumstances. The first circumstance occurs when pending claims in a patent application were not presented in the application as filed. The second circumstance occurs when pending claims in a patent application were not presented in an earlier-filed foreign or U.S. application, the benefit of the filing date of which is sought under 35 U.S.C. §119 or §120, respectively. Judge Rich further noted that the question raised by such situations is most often phrased as whether the application provides adequate support for the claims at issue, or, alternatively, as whether the application contains new matter.¹⁴

The Court then addressed what Judge Rich referred to as “...some confusion in our decisions concerning the extent to which the ‘written description requirement’ is separate and distinct from the enablement requirement.”¹⁵ According to Judge Rich, the precedential opinion of the Federal Circuit regarding this issue is found in *In re Wilder*¹⁶:

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby re-affirm, that 35 USC §112, first paragraph, requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement.¹⁷

The Federal Circuit then addressed the purpose of the written description requirement. According to Judge Rich, in addition to an enabling disclosure:

... 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. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*. (original emphasis).¹⁸

According to Judge Rich in *Vas-Cath*, what is necessary to establish “possession of an invention” is a written description that con-

veys with reasonable clarity to those of ordinary skill that the inventor had in fact invented the subject matter claimed.¹⁹

Inventors have traditionally been considered to be in possession of their inventions if they could demonstrate that they intended to claim the invention in a patent application. For example, if a patent application as originally filed claimed certain subject matter, the applicant was considered to be in possession of that subject matter. Nothing in the exhaustive discussion in *Vas-Cath* of the law of the written description requirement in the Federal Circuit, and its history, suggests that this so-called “original claim” doctrine was in any way disfavored, although it was not addressed directly.²⁰

Another important point made by the Federal Circuit in *Vas-Cath* is the fact-specificity of the written description requirement. Judge Rich stressed that each case must be decided on its own fact.²¹

With regard to the specific facts in *Vas-Cath*, Judge Rich found ample precedent for the proposition that a utility patent can claim priority under 35 U.S.C. §120 of a disclosure in a design application.²² Judge Rich also agreed with the district court that, under proper circumstances, drawings alone may provide a written description of an invention as required by §112.²³

Unlike the district court, however, the Federal Circuit in *Vas-Cath* found that a declaration by Mahurkar’s expert could not be ignored. The declaration addressed the issue that certain ratios claimed in the utility patents were not explicitly disclosed by the figures in the design application. According to the expert, a person having ordinary skill would appreciate these ratios implicitly from the figures. The declaration was not refuted by *Vas-Cath*. The Federal Circuit held that the declaration gave rise to a genuine issue of material fact regarding whether the drawings in the U.S. design application satisfied the written description requirement for the claims in the two utility patents. Therefore, the court reversed the district court’s summary judgment of invalidity.²⁴

UNIVERSITY OF CALIFORNIA v. ELI LILLY

In 1997, the Federal Circuit addressed the written description requirement for biotechnology inventions in *University of California v. Eli Lilly*, above. In the *Eli Lilly* decision, a U.S. patent of the University of California (UC) disclosed the actual isolation and sequencing of the rat insulin gene. The UC patent proposed a method for isolating the human insulin gene, but not the actual isolation of it.²⁵

The UC patent as originally filed claimed both the rat and human genes.²⁶ In accordance with the “original claim” doctrine discussed above, the inventors were “in possession” of the human gene. Moreover, the Federal Circuit conceded that the UC patent disclosed a method for isolating the human gene.²⁷ Therefore, the claim to the human gene appeared to satisfy both the written description and enablement requirements of §112 under the case law existing at the time of the *Eli Lilly* decision.

Nevertheless, the Federal Circuit held the UC patent to be invalid. In doing so, the Federal Circuit added a new barrier to satisfying the written description requirement.

The Federal Circuit in *Eli Lilly* began its analysis by agreeing with its previous *Vas-Cath* decision that the written description must be in sufficient detail “...that one skilled in the art can clearly conclude that the inventor invented the claimed invention.”²⁸

A statement of the function of a gene (*i.e.* expression of insulin), and a description of a method for obtaining it, were, however, said to be insufficient. Rather, the court held 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.” (Emphasis added).²⁹

The Federal Circuit further explained that the written description must provide “... distinguishing information concerning its identity.” The UC patent failed to provide adequate distinguishing information, according to the court, because there was no disclosure of a nucleotide sequence.³⁰

ENZO BIOCHEM v. GEN-PROBE ET AL.

In its very recent decision in *Enzo Biochem v. Gen-Probe et al.*, above, the Federal Circuit considered the written description requirement of a patent assigned to Enzo Biochem. The Enzo patent is directed to nucleic acid probes that can distinguish the bacteria responsible for gonorrhea, *N. gonorrhoeae*, over the closely related and highly homologous bacteria responsible for one form of meningitis, *N. meningitidis*. The invention was based on the discovery by Enzo of three nucleic acid sequences that hybridize to *N. gonorrhoeae* with an affinity at least five times greater than that to *N. meningitidis*.³¹

Of particular interest here was dependent claim 4, which limited the probes of generic claim 1 to the three specific sequences and certain variations thereof. These probes were inserted into *E. coli* hosts, which were deposited in the ATCC.³²

Enzo attempted to enforce its patent against the defendants. The Federal District Court for the Southern District of New York granted summary judgment of invalidity of all claims in the Enzo patent for failure to provide an adequate written description. Even claim 4, which was directed to the deposited probes, was declared to be invalid.³³

On appeal, the Federal Circuit affirmed the grant of summary judgment.³⁴ In doing so, the Federal Circuit appears to have added an additional hurdle to overcome in satisfying the written description requirement.

The Federal Circuit noted that Enzo had reduced to practice at least the three probes it deposited. The court conceded, therefore, that "...Enzo apparently has achieved more than a 'wish or a plan' for obtaining the genetic material,"³⁵ thereby distinguishing the facts from those in *Eli Lilly*. See above.

Thus, claim 4 in the *Enzo* case presented the Federal Circuit with an interesting dilemma. On the one hand, the Enzo inventors, like the inventors of the UC patent in the *Eli Lilly* case, claimed a nucleic acid molecule based on a disclosure only of its function (i.e., hybridization to *N. gonorrhoeae*). On the other hand, unlike the UC inventors, the Enzo inventors had reduced to practice the invention of claim 4, as evidenced by the ATCC deposit of the three probes.

As late as 1997, establishing that the inventors invented the claimed subject matter (i.e. had possession of the invention) had been considered the ultimate purpose of the written description requirement.³⁶ An actual reduction to practice of an invention has never been interpreted to be necessary to establish possession. Although not necessary, however, an actual reduction to practice, such as that of claim 4 of the *Enzo* patent, would appear to be sufficient to establish the requisite "possession."³⁷


Nevertheless, the Federal Circuit in *Enzo* held that "...mere possession of three nucleotide sequences that are within the scope of the claims does not provide sufficient distinguishing information about those sequences for purposes of satisfying §112, ¶1." (Emphasis added).³⁷

Citing *In re Lundak*,³⁸ the court explained that depositing genetic material is helpful in satisfying the enablement requirement.³⁹ As mentioned above, however, the written description requirement is independent of the enablement requirement. The court, citing the PTO guidelines relating to satisfying the written description requirement, stated: "A deposit is not a substitute for a written description of the claimed invention."⁴⁰

The Federal Circuit in *Enzo* confirmed its repudiation of the "original claim" doctrine in *Eli Lilly*.⁴¹ In addition, the court concluded that "possession of the invention," which was previously considered decisive in satisfying the written description requirement, is secondary to the requirement for a description of the structure of a molecule.⁴² At least until the present time, no description of the structure of a DNA molecule other than a nucleotide sequence has been found by the Federal Circuit to satisfy the written description requirement of §112.

The *Enzo* decision appears to be consistent with the Federal Circuit's general view of nucleic acid molecules. The Federal Circuit has previously held that, in the absence of a nucleotide sequence, a disclosure in the prior art of the amino acid sequence expressed by a nucleic acid molecule, and of a method for making it, do not render obvious a claim to the nucleic acid molecule.⁴³ In fact, as far as the Federal

Circuit is concerned, such disclosure does not even constitute evidence that the nucleic acid molecules have yet been conceived.⁴⁴

It appears that the Federal Circuit hardly acknowledges any legal significance of a description of a nucleic acid molecule in the absence of a nucleotide sequence. It is interesting to note, however, that this attitude has never been applied to proteins in the absence of an amino acid sequence. 

ENDNOTES

1. *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), cert denied 523 U.S. 1089 (1998).
2. *Enzo Biochem v. Gen-Probe*, 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir., 2002).
3. *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (1991).
4. U.S. patent 4,568,329 and U.S. patent 4,692,141.
5. *Vas-Cath*, above, at 1112.
6. *Id.* at 1112, 1113.
7. *Id.* at 1113.
8. *Id.*
9. *Id.* at 1118.
10. *Id.* at 1113.
11. *Id.*
12. *Id.*
13. *Id.* at 1114 *et seq.*
14. *Id.* at 1114.
15. *Id.* at 1116.
16. *In re Wilder* 736 F.2d, 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), cert denied 469 U.S. 1209 (1985).
17. *Vas-Cath*, above, at 1117.
18. *Id.*
19. *Id.* at 1119.
20. *Id.* at 1114 *et seq.*
21. *Id.* at 1116.
22. *Id.* at 1117.
23. *Id.* at 1117, 1118.
24. *Id.* at 1119.
25. *Eli Lilly*, above, at 1404.
26. *Id.* at 1404, 1405.
27. *Id.* at 1405.
28. *Id.* at 1404.
29. *Id.*
30. *Id.* at 1405.
31. *Enzo*, above, at 1290.
32. *Id.* at 1290.
33. *Id.* at 1291.
34. *Id.* at 1290.
35. *Id.* at 1295.
36. *See Vas-Cath and Eli Lilly*, above.
37. *Enzo*, above, at 1295.
38. *In re Lundak* 773 F.2d 1216, 1217, 227 USPQ 90, 92 (Fed. Cir. 1985).
39. *Enzo*, above, at 1295.
40. *Id.* at 1295.
41. *Id.* at 1294.
42. *Id.* at 1294.
43. *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995).
44. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1501, 1606 (1993).

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