Written Description and Enablement Requirements for Pharmaceutical, Chemical, and Biotechnology Inventions

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This is the first part of a two-part series. The case law applying to the enablement requirement will appear in the June/July issue of IP Litigator.

There have been some recent cases ruling on written description and the US Patent Office published Guidelines for Examination of Patent Applications under 35 U.S.C. section 112, paragraph 1. Specifically, they deal with how these guidelines apply to inventions in the areas of pharmaceuticals, chemicals, and biotechnologies. No attempt is made to survey all cases pertaining to these issues, instead the intention is to provide a sampling of the current flavor of statutory and regulatory interpretation.[1]

Paragraph one of 35 U.S.C. section 112 reads as follows:

> 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 closely connected, *to make and use the same,* and shall set forth the best mode contemplated by the inventor of carrying out his invention.
> (emphasis added).

These seemingly straightforward requirements to (1) provide a written description (the "written description" requirement) and (2) describe how to make and use the invention in such full, clear, concise, and exact terms as to enable a person skilled in the art to carry out the invention (the "enablement" requirement) have fostered extensive debate when applied to the last decade's explosive developments in pharmaceutical and biotech inventions.

Written Description

An analysis of whether a specification provides an adequate written description of a claimed invention requires a reading of the complete specification to determine whether the text as a whole conveys the invention. The primary consideration in a written description case is factual and "depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure."[2] The case law makes clear that patent disclosures are addressed to persons skilled in the art and that there is no magic formula or requirement of strict literalism imposed by the statute.[3]

The specification does not have to describe the invention using the same words as those used in the claims, as long as the skilled reader understands that the text, taken as a whole, conveys the same meaning. As commonly quoted, an applicant's "specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement."[4]

PTO Guidelines

On January 5, 2001, the US Patent and Trademark Office (PTO) issued the final version of its "Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1 Written Description Requirement" (Guidelines).[5] The Guidelines are used by PTO personnel as they review patent applications for compliance with the written description requirement. Because the Guidelines do not constitute substantive rulemaking, any perceived failure by PTO personnel to follow these Guidelines is neither appealable nor petitionable.[6] The Guidelines are useful, however, in providing insight into how the PTO will apply recent case law from the Court of Appeals for the Federal Circuit on this subject. Again, no attempt is being made to summarize the entire scope of the Guidelines, but merely to point out certain areas of interest.

First, the Guidelines address the issue of whether claims as originally filed meet the written description requirement as a matter of law, because they are considered part of the original specification (the Original Claim Doctrine). The Guidelines state that even though there is a strong presumption that originally filed

3. *See, e.g.,* In re Alton, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996) (emphasis added, citations omitted):

   > The adequate written description requirement, which is distinct from the enablement and best mode requirements, serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; *how the specification accomplishes this is not material.*" In order to meet the adequate written description requirement, the applicant *does not have to utilize any particular form of disclosure* to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

   Accord In re Hayes Microcomputer Prod. Inc., 982 F.2d 1527, 1533-1535, 25 U.S.P.Q.2d 1241, 1245-1246 (Fed. Cir. 1992). *See also* Purdue Pharma L.P. v. Fauling Inc., 230 F.3d 1320, 1322, 56 U.S.P.Q.2d 1481 (Fed. Cir. 2000) (holding that in order to satisfy the written description requirement, "one skilled in the art, after reading the original disclosure, must immediately discern the limitation at issue in the claims").
4. *Ex parte* Sorenson, 3 U.S.P.Q.2d 1462, 1463 (Bd. Pat. App. & Interf. 1987) (reversal of 35 U.S.C. § 112, ¶ 1 rejection of claims because one skilled in the art would have understood "imines" to have been intended for "amines" even though specification did not say so), *citing* In re Edwards, 568 F.2d 1349, 196 U.S.P.Q. 465 (C.C.P.A. 1978) (reversal of rejection of claims for polyol under 35 U.S.C. § 112, ¶ 1, because application entitled to filing date of parent application even though parent does not name the compound in *ipsis verbis,* because the "parent application provides adequate direction which reasonably leads persons skilled in the art to the later claimed compound." 568 F.2d at 1352, 196 U.S.P.Q. at 467); *see also* Application of Eickmeyer, 602 F.2d 974, 982, 202 U.S.P.Q. 655, 663 (C.C.P.A 1979) (reversal of 35 U.S.C. § 112, ¶ 1 rejection on the basis that limitation "at an elevated temperature of at least about 56° C" is "fully described" in the specification and its parent applications).
5. 66 Fed. Reg. 1099.
6. *Id.* at 1104.
7. *Id.* at 1105.
8. *Id.*
9. *Id.* at 1100.
10. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d. 1559, 43 U.S.P.Q. 2d. 1398 (Fed. Cir. 1997).
11. Response to Comment 9 to the Written Description Guidelines; 66 Fed. Reg. at 1101.
12. 66 Fed. Reg. No. 4 at 1104.
13. In re Edwards, 568 F.2d at 1351, 196 U.S.P.Q.2d at 468.
14. *See* In re Nathan, 328 F.2d 1005, 140 U.S.P.Q. 601 (C.C.P.A. 1964).
15. In re Magerlein, 346 F.2d 609, 145 U.S.P.Q. 683 (C.C.P.A. 1965).
16. Spero v. Reingold, 377 F.2d 652, 153 U.S.P.Q. 726 (C.C.P.A. 1967).
17. Petisi v. Rennhard, 363 F.2d 903, 907, 150 U.S.P.Q. 669, 672 (C.C.P.A. 1966).
18. *Spero,* 377 F.2d at 656, 153 U.S.P.Q. at 728-729 (emphasis in original).
19. *Magerlein,* 346 F.2d 609, 145 U.S.P.Q. 683.
20. *Spero,* 377 F.2d at 658, 153 U.S.P.Q. at 730.
21. To the same effect, *see* In re Nathan, 328 F.2d at 1008-1009, 140 U.S.P.Q. at 604 ("alpha orientation" need not be specifically disclosed in order to have a "written description" because it was an inherent characteristic of product).
22. Emory Univ. v. GlaxoWellcome, Inc. and Biochem Pharma, Inc., No. 1:96-CV-1868-GET, 1997 WL 817342 (N.D. Ga. July 14, 1997).
23. *Id.* at *3.
24. *Id.* at *6.
25. In re Ruschig, 54 CCPA 1551, 1557, 154 USPQ 118, 122 (CCPA 1967).
26. Wako, WL at 95789.
27. Fiers v. Revel, 984 F.2d 1164, 1171, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993).
28. *Id.*, 984 F.2d at 1170, 25 U.S.P.Q. at 1606.
29. The University also sued Eli Lilly for infringement of US Patent No. 4,431,740. The Federal Circuit held that the US District Court for the Southern District of Indiana did not err in finding that Eli Lilly did not infringe the claims of the '740 patent under the doctrine of file wrapper estoppel.
30. *Eli Lilly,* 119 F.3d at 1567, 43 U.S.P.Q.2d at 1405.
31. *Id.*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406.
32. Response to Comment 29 of the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement issued on January 5, 2001 confirm that these training materials reflect the manner in which the Patent Office currently interprets the Written Description Guidelines.
33. Example 7 refers to an "EST" or expressed sequence tag, which is a gene fragment that may not have a known utility other than as a probe or hybridizing agent. The Response to Comment 27 to the Written Description Guidelines confirms that a claim reciting a nucleic acid comprising SEQ ID No:1 may be subject to a rejection for lack of an adequate written description when particular indentifiable species within the scope of the claim lack an adequate written description. *See also* the Comments of Eli Lilly & Co. on the Revised Interim Written Description Guidelines (*www.uspto.gov/web/offices/com/sol/comments/utilit/ywd/elillyco.pdf*) criticizing the patenting of an EST with comprising language on the basis that if the claim is deemed to lack written description because no complete gene sequence is disclosed that contains the claimed EST sequence, the problem cannot be remedied merely by the disclosure of a single cDNA species, because the open-ended claim could encompass many different DNA sequences that are not described.
34. Response to Comment 14 to the Written Description Guidelines confirms that if an amino acid sequence for a polypeptide whose utility has been identified is described, there is adequate written support for a class of nucleotides encoding that polypeptide using the understanding of the genetic code, however, this does not mean that the applicant was in possession of any particular species of the broad species of encoding nucleotides.
35. *See* the Comments of Eli Lilly & Co. on the Revised Interim Written Description Guidelines (*www.uspto.gov/web/offices/com/sol/comments/utilit/ywd/elillyco.pdf*) that provide numerous criticisms of this Example. Eli Lilly writes that:

    > Under the Training Materials as currently drafted, a generic claim similar to Example 14 would be adequately described under Section 112, ¶ 1, because (1) "[t]he single species disclosed is *representative of the genus* because all members have at least 95 percent structural identity with the reference compound," and (2) because of the limitation requiring the stated compounds to catalyze the reaction of AÕB. *See* Training Materials at 54. (Emphasis added). In Lilly's view, the PTO's proposed approach merely substitutes one linguistic formulation ("percent identity," "similarity," or "homology" coupled with a required biochemical property) for another linguistic formulation (encoding a particular class of proteins) found insufficient to satisfy the requirement of an adequate written description under the Federal Circuit's decision in the *Lilly* case. While different sets of words have been used, the fact remains that no generic invention has been made, disclosed, or described.
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    > In *Lilly*, the Federal Circuit held invalid claims directed to "vertebrate insulin cDNA" and "mammalian insulin cDNA" because neither genus was adequately described by the disclosure of the single species, rat insulin cDNA, in the patent specification. However, contrary to the reasoning set forth in *Lilly*, the Training Materials suggest that claims to analogous proteins could be adequately supported by the disclosure of a single species by a mere change of claim wording from "mammalian insulin" to "protein variants at least 95 percent identical to insulin." This change, however, is little more than a different linguistic construct fashioned over the same inadequate description. In the *Lilly* case, there was no manner in which a person skilled in the art could identify the things—the chemical structures—that were "mammalian proinsulin cDNAs." No structures, no described genus. Example 14 embodies a fully analogous defect: What are the structures of the 95 percent homologous proteins that have the required catalysis biochemical activity? They are unknown and unknowable from even the closest inspection of a patent specification disclosing only one, or even a few, biochemical species.
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    > A claim to a genus of protein variants *at least 95 percent identical* to a native protein may be, in form, narrower than a claim to *all variants* having the native protein's function. However, the claimed genus in substance still encompasses an enormous number of species with potentially widely diverse properties and describes little in the way of common structural features of the claimed proteins. Indeed, the genus of all variants at least 95 percent identical to a protein of 300 amino acids would encompass every species having between 1 and 15 amino acid changes to any of the 20 naturally occurring amino acids, at any location in the protein chain. Mathematically such a genus would potentially encompass *thousands of trillions* of chemical compounds, even assuming that no gaps, truncations, extensions, or insertions are made to the chain. On the DNA level, even greater numbers of compounds are involved. If only a few hundreds of billions of proteins within this mass of thousands of trillions of compounds are catalytically active, then the structures of the compounds comprehended by the claimed genus are mere needles in a haystack. Finding one needle is no description of the remainder.
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    > Regarding the potentially substantial difference in properties allowed by changes well within the 95 percent cutoff proposed by the PTO, one need look no further than the genetic defect responsible for sickle cell anemia. There, a change in a single nucleotide converts the encoded hemoglobin molecule from one with the natural function to one that carries with it properties associated with debilitating disease and even death. Many other examples can be found in the literature. Indeed, the genome of the chimpanzee is approximately 99 percent homologous to the human genome and yet there are obvious substantial differences between the two species.