

Comment 48

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March 21, 2000

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
United States Department of Commerce
P.O. Box 8
Washington, D.C. 20231

Attention: **Box 8**

Box Comments

Stephen Walsh

Linda S. Therkorn

Re: AIPLA Comments on the Revised Interim Guidelines for Examination of
Patent Applications Under the 35 U.S.C. 112 ¶ 1, Written Description
64 Fed. Reg. 71427 (December 21, 1999)

Dear Commissioner Dickinson:

Pursuant to your request, I wish to present my comments on the Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1 Written Description Requirement published in the *Federal Register* on December 21, 1999.³⁹

I am a founding partner of Schwegman, Lundberg, Woessner & Kluth. My practice focuses on chemical patent law, including biotechnology, pharmaceuticals, vaccines, medical treatments, diagnostics, and agricultural and food chemistry, including related opinion and licensing matters. I co-founded the Biotechnology Committee of the Minnesota Intellectual Property Law Association. I was the 1993-1995 chair of the Chemical Practice Committee of the American Intellectual Property Law Association, and am currently an ABA representative to the PTO Biotechnology Customer Partnership, and a member of the Board of Directors of MNBIO.

³⁹ 64 Fed. Reg., 71427-40 (December 21, 1999) (hereinafter “guidelines”)

Comments:

The guidelines are much improved over the 1998 draft. For example, as set forth in the “Overview of Comments”: “The Revised Interim Guidelines distinguish between novel and old elements in a claim to clarify that the amount of written support needed in an application can vary depending on the general knowledge that was readily available in a particular art.”⁴⁰ In fact, the guidelines are more explicit in stating that “old” claim elements need not be described in detail, i.e., by representative species: “The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112, ¶ 1, for lack of adequate written description.”⁴¹ This should prevent rejections on the basis that “old” claim elements are inadequately described in the specification.⁴²

Rather, it is the analytical framework of the guidelines that could be presented in a more organized fashion. The “General Principles” section sets forth ways in which a patent specification can satisfy the written description requirement, and demonstrate (legal) possession of the claimed invention: (a) show actual reduction to practice or (b) show that the invention was “ready for patenting,” such as by the disclosure of drawings or other descriptions of the invention that would enable the art worker to practice the invention.⁴³ However, by Section II (“Methodology”), this two-pronged test has become three-pronged. The applicant can (a) show actual reduction to practice, (b) provide “a clear depiction of the invention in detailed drawings” or (c) provide a description of “sufficient relevant identifying characteristics” of the invention.⁴⁴ Since it is difficult to envision how part (c) could be satisfied without physical possession of a species of the invention, part (c) should logically follow as a further explication of part (a), actual reduction to practice. In other words, Col. 3, full paragraph 1 of 64 Fed. Reg. 71435, which explicates the “sufficiently detailed relevant identifying characteristics” test should be moved to follow Col. 2, full paragraph 3, where it is stated that actual reduction to practice of a biological material can be shown by specifically describing a deposit.

The part 2 test of disclosure of “sufficiently detailed drawings” in the paragraph bridging Cols. 2-3 of page 71435 now clearly sets forth a test that does not require actual reduction to practice. This standard is recognized in University of California v. Eli Lilly, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) wherein the Federal Circuit stated:

⁴⁰ Id. at 71430.

⁴¹ Id. at 71435.

⁴² Without recourse to extrinsic evidence that the element is, in fact, well-known to the art, such rejections cannot be rebutted. The use of such extrinsic evidence was recently endorsed in In re Alton, 37 USPQ2d 78 (Fed. Cir. 1996).

⁴³ Citing Pfaff v. Wells Electronics, 48 USPQ2d 641 (1998).

⁴⁴ Citing Pfaff, and Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991).

[I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed invention.

Therefore, the guidelines should specifically point out that the test for “detailed drawings” can be met by structural claiming of chemical entities.

In conclusion, the analytical clarity of the revised written description guidelines could be improved by: (a) reorganizing them so that the “sufficient identifying characteristics” test is a subsection of actual reduction to practice and (b) expanding the “detailed drawings” test in accord with the guidance of Lilly to indicate that generic formulae can adequately describe a chem/biotech invention.

Thank you for your consideration, and for the “obvious” effort that went into these extensive revisions.

Respectfully submitted,

Warren D. Woessner, Ph.D.

WDW/sjz