



AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

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December 14, 1998

The Honorable Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
United States Department of Commerce
P. O. Box 4
Washington, D.C. 20231

Attention: **Box 8 - Solicitor**
Scott A. Chambers

Box Comments - Patents
Linda S. Therkorn

Re: AIPLA Comments on the Interim Guidelines for Examination
of Patent Applications Under the 35 U.S.C. 112 paragraph 1,
"Written Description" Requirement -
63 Fed. Reg. 32639 (June 15, 1998)

Dear Commissioner Lehman:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to present its views on the Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 paragraph 1 "Written Description" Requirement published in the *Federal Register* on June 15, 1998.

The AIPLA is a national bar association of more than 10,000 members engaged in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property.

GENERAL COMMENT

AIPLA fully supports and appreciates the PTO's efforts and enthusiasm for providing training of its Examiners, particularly in the biotechnology arts, and for attempting to clarify how recent case law is to be applied to the examination of patent applications.

A general theme of the Interim Guidelines appears to be an attempt to interpret and demonstrate by example an "in possession of the invention" test for compliance with the statutory written description requirement. However, that test does not appear in the statute itself, and its

definition and application are not clearly stated in the Federal Circuit cases to date. Rather, it appears to be a shorthand label for the statutory written description requirement which applicability and meaning are still emerging in the Federal Circuit jurisprudence. We note that *Vas-Cath, Inc. v. Mahurkar*, 935 F.3d 1555, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991) and its predecessors and progeny which mention the "possession" test typically involve fact situations in which "new matter" (per 35 U.S.C. §132) or adequate support in a parent application for claims in a continuation-in-part application (i.e. the question of new matter first disclosed and claimed in the latter application) were key facts.¹ AIPLA submits that if an "in possession of the invention" test is to be a doctrinal foundation for the Interim Guidelines, the test must be consistent with the statute and controlling precedents, and be sufficiently clearly defined and understood, and consistently and evenhandedly applied by the Examining Corps, to embody and practice the substance and spirit of the statute.

In that regard, AIPLA notes that the U.S. Supreme Court in *Pfaff v. Wells Electronics, Inc.*, ___ U.S. ___ (November 10, 1998) in affirming a 35 U.S.C. §102(b) "on sale" bar, focused upon a complete provable, and enabling conception as essential evidence of "invention" in U.S. law. The Supreme Court said "the word 'invention' must refer to a concept that is complete..." *Pfaff v. Wells Electronics, Inc.*, slip. op. at 10. And, "one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice." *Id.* at 11. "That condition may be satisfied . . . by proof that prior to the critical date the inventor had prepared drawings or descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id.* at 12. If such complete, provable, enabling conception evidences an invention ready for patenting, presumably a written description of that subject matter satisfies the written description requirement of §112, paragraph 1. Any shorthand "in possession of the invention" analysis should be consistent with the statute and the Supreme Court's statements in *Pfaff v. Wells Electronics*.

Furthermore, the proposed Interim Guidelines also include several new terms and phrases that are not well defined, such as "safe harbors," "level of predictability," and predictability of structure," none of which appear in the statute itself. AIPLA again suggests that the proposed Interim Guidelines be revised with care to ensure that they do not introduce unnecessary new terms, procedures, or requirements, and that they are consistent with the statute and controlling precedents.

¹ See, for example, *Tronzo v. Biomet*, 47 U.S.P.Q. 2d 1829 (Fed. Cir. 1998); *Lockwood v. American Airlines, Inc.*, 41 U.S.P.Q. 2d 1961 (Fed. Cir. 1997); *Fiers v. Revel*, 25 U.S.P.Q. 2d 1601 (Fed. Cir. 1993); *Ralston Purina Company v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1572, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985); *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983); *In re Herschler*, 591 F.2d 693, 200 U.S.P.Q. 711, 717 (CCPA 1979); *In re Edwards*, 558 F.2d 1349, 196 U.S.P.Q. 465 (CCPA 1978); *In re Smythe*, 480 F.2d 1376, 1383, 178 U.S.P.Q. 279, 284, 285 (CCPA 1973) and *In re Smith*, 481 F.2d 910, 178 U.S.P.Q. 620, 623 (CCPA 1973).

ANSWERS TO QUESTIONS

1. Is the methodology in the interim guidelines accurate?

(a) If a "possession test" is to be articulated in the proposed guidelines, it must be well defined and consistent with the statute:

The Federal Circuit in restating the "standard for determining compliance with the 'written description' requirement," said in *Vas-Cath*: "[The description must clearly allow persons of ordinary skill in the art to recognize that [applicant] invented what is claimed." *Id.* 19 USPQ2d at 116. The Court there also said the test is "whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession . . . of the . . . claimed subject matter." *Id.* AIPLA understands that an inventor is "in possession of" an invention when he or she demonstrably has at least a complete, enabling conception thereof, and that the §112, paragraph 1, written description requirement is satisfied when that complete, enabling conception is disclosed in the written description in the inventor's patent specification, claims, and drawings, which written description includes sufficient detail communicating to one skilled in the art what the invention is and how to make and use it. Such a definition or understanding of the "possession test" should be specified in the Interim Guidelines before any such test is sought to be embodied in the guidelines or their hypothetical examples.

The guidelines admittedly have their genesis in the Patent and Trademark Office biotechnology groups in attempting to assist Examiners in evaluating compliance with the written description requirement in view of the Federal Circuit's decision in *University of California v. Eli Lilly*, 199 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and earlier cases. The identified "safe harbors" and suggested need for "determination of level of predictability" and "predictability of structure" were apparently motivated from biotechnology cases wherein completion of conception was held to have occurred simultaneously with reduction to practice of the claimed subject matter. AIPLA suggests that the doctrine of simultaneous conception and reduction to practice historically has been applicable only to a very small number of reported cases, and that frequency of its applicability, even in biotechnology cases, is today seriously challenged by the maturation of the technology and the rapid pace of evolving understanding of the scientific principles which constitute the foundation of such technology. Thus any previously perceived need for proposed guidelines to attempt to provide avenues to assist applicants in complying with the written description requirement because of the perceived applicability of the simultaneous conception and reduction to practice doctrine is rapidly diminishing.

The proposed Interim Guidelines are said to be intended to be equally applicable not only to patent applications describing inventions from the biotechnological arts, but also from all fields of invention. This is appropriate since the understanding of the technology by inventors, those skilled in the art, and patent examiners in the biotechnological fields, has today progressed to the point that those involved in the patent application writing and examination processes should be comfortable in examining such patent applications using the same basic guidelines applicable to

applications in all other fields of invention. AIPLA supports a set of guidelines which is universally applicable regardless of the technical subject matter of a particular patent application.

The use of new terminology and requirements including the above-discussed "possession test," and the asserted need for "determination" of the "level of predictability in the art," and determinations concerning "predictability of structure," appear to be unnecessary to the statutory analysis and may create unnecessary ambiguity and complexity in sound application of the statutory written description requirement. AIPLA recommends that the guidelines be based upon sound foundations consistent with the statutory language and the controlling precedents, and that any unnecessary new terminology or test be avoided. AIPLA's views on the "possession test" have been expressed above herein. While predictability is not a word found in the statute, it is certainly a factor which has been discussed in the Federal Circuit jurisprudence on evaluating enablement, rather than the separate written description requirement. However, AIPLA is presently unaware that any controlling precedents require determinations of specific levels of predictability or "predictability of structure" in conjunction with the separate written description requirement.

2. Do the guidelines list the appropriate relevant factors and descriptive attributes to consider in determining whether the written description requirement of 35 USC 112 (1) is satisfied?

(a) factors and descriptive attributes which have been omitted:

While the proposed guidelines stress that the needed disclosure is inversely proportional to the level of predictability in the art, in practice the Examiner's reliance on prior Federal Circuit cases deciding biotechnology cases based on 1980's or earlier technology does not often afford the applicant the contemporaneous knowledge of one of skill in the art. It is proposed that the guidelines explicitly state that the maturation of the technology will increase the understanding of one skilled in the art, and increase the predictable scope of the claimed invention beyond the exemplified embodiments, as recognized in the applicant's specification. Applicants and Examiners are charged with both the responsibility of understanding the technology at the time of the invention and for according the patentee the full scope of his or her invention.

As discussed above in paragraph 1(a), AIPLA understands that an inventor is "in possession of" an invention when he or she demonstrably has at least a complete, enabling conception thereof, and that the §112, paragraph 1, written description requirement is satisfied when that complete, enabling conception is disclosed in the written description in the inventor's patent specification, original claims, and drawings, which enabling written description includes sufficient detail communicating to one skilled in the art what the invention is and how to make and use it. Factors and descriptive attributes which provide proof of written description will vary on a case by case basis, and should include evidence typically provided to prove a complete and enabling conception.

The Interim Guidelines call for an affirmative determination of predictability not called for in the statute or case law. Such a determination would be very difficult to accomplish. Further, we

are unaware of any cited precedent for such a required determination of the level of predictability, particularly for a determination of level of "predictability of structure."

(b) examples of analysis which are overinclusive

The examples provided in the Interim Guidelines go to the extremes of the biotechnology spectrum. It would be helpful if examples were provided in the gray areas between the extremes, with suggestions of evidence that might push the analysis in one direction or the other. In addition, non-biotechnology examples would be useful.

(c) changes which would improve the analysis

1. Consideration of the recent Supreme Court decision in *Pfaff v. Wells Electronics, Inc.*, cited above in the general comments, and incorporation of this decision into the written description analysis.

2. Specification and definition of a test for written description such as:

An inventor is "in possession of" an invention when he or she demonstrably has at least a complete, enabling conception thereof. The §112, paragraph 1, written description requirement is satisfied when that complete, enabling conception is disclosed in the written description in the inventor's patent specification, original claims, and drawings, which enabling written description includes sufficient detail communicating to one skilled in the art what the invention is and how to make and use it.

3. Avoid use of unnecessary new terminology or tests.

4. Clarify or remove from the Guidelines the asserted need for "determination" of the "level of predictability" and determination concerning "predictability of structure," consistent with the statutory language and the controlling precedents, including *Pfaff v. Wells*. Elaboration of any asserted test or factors should be made in specific examples demonstrating how the factors are weighed and considered. Such examples should include evidence other than "structure", for example, characteristics suggested in the present examples and also taken from existing precedent helping to show what is required to provide an enabling written description.

5. Insert at page 13, prior to "For each claim to a genus:" a statement relating to the evolving predictability of the technology. For example, consider the following:
Because technology is evolving and maturing, sometimes at a very rapid rate, it is understood that what constitutes an "enabling written description," for example of a nucleic acid sequence, is also evolving and maturing. Each invention must be considered on the basis of what the description provides to one of skill in the art at the effective filing date.

6. Delete on page 12 the sentence: "For example, a broadly drawn claim to a specific gene from ruminant mammals may require a representative species from cattle, buffalo, bison, goat, deer, antelope, camel, giraffe, and llama."

7. At page 17, paragraph III.A.(2), insert a statement that the reasons provided by the Examiner must be more than a general "unpredictability of the art" and should weigh as relevant applicant's evidence of what the description provides to one of skill in the art.

3. Should the scope of these guidelines be limited to certain technologies?

AIPLA believes that Guidelines addressing a basic and fundamental principle of patent law such as application of the requirements of §112, should be equally applicable to all inventions and not restricted to one technology. As stated above, this is appropriate since the understanding of the technology by inventors, those skilled in the art, and patent examiners in the biotechnological fields, has today progressed to the point that those involved in the patent application writing and examination processes should be comfortable in examining such patent applications using the same basic guidelines applicable to applications in all other fields of invention. AIPLA supports a set of guidelines which is universally applicable regardless of the technical subject matter of a particular patent application.

A particular problem in a technology or practice area could be appropriately addressed in examples provided in the Guidelines over a wider range of subject matters.

4. Should the scope of these guidelines encompass all technologies?

Yes. It is clear from recent Patent and Trademark Office Actions and recent Federal Circuit decisions that issues of Written Description are impacting all technology areas. Because we support a clear application of the patent laws, rules, and guidelines across all technologies, AIPLA believes the law of written description should be evenly applied.

5. How should "possession of the invention" be defined for purposes of applying the written description requirement?

As discussed above, AIPLA understands that an inventor is "in possession of" an invention when he or she demonstrably has at least a complete, enabling conception thereof, and that the §112, paragraph 1, written description requirement is satisfied when that complete, enabling conception is disclosed in the written description in the inventor's patent specification, claims and drawings, which written description includes sufficient detail communicating to one skilled in the art what the invention is and how to make and use it.

6. How should the transition terms "having" and "consisting essentially of" be treated within the context of nucleotide and amino acid sequence claims?

An overall principle of patent law is that the claims are to be given their broadest reasonable construction, consistent with the specification. Accordingly, the term "having" is understood to mean "comprising," whereby the sequence comprises or includes the stated sequence and may contain additional sequences.

The phrase "consisting essentially of" is understood to mean having the stated sequence and excluding any alterations which materially change the structure and/or function of the specified sequence.

7. How should the guidelines be expanded to specifically address process and/or product-by-process claims?

As discussed above in paragraph 2, the guidelines should be sufficiently generic with regard to the type of claimed invention. Whether the invention is embodied in a product claim, a product-by-process claim, or a process claim should not alter the test of invention.

8. How should the guidelines address the deposit of a biological material made under 37 CFR 1.801?

(a) Please suggest how the date of deposit should be considered with respect to establishing possession of the invention at the time of filing;

We are not sure we understand the question; however, to the extent that it raises the issue of whether *In re Lundak*, 773 F2d 1216 (Fed. Cir. 1985), should be followed, we do not believe the PTO can limit *Lundak* by rule.

(b) Suggest what significance should be assigned to a deposit in assessing compliance with the written description requirement.

The deposit may be evidence of completion of an invention.

(c) Comment on the extent to which a deposit of biological material may be relied on to support the addition of sequence information or the correction of sequence information in the ordinarily filed application.

AIPLA has no comment at this time to question 8 (c).

9. What impact will the guidelines have on issued patents, currently pending applications, or applications to be filed after publication of the final written description guidelines?

Issuance of the guidelines should have no impact on issued cases (save reissues). The Guidelines will impact pending and newly filed applications, and in their present form, provide a narrowed stance on written description, limiting the scope of patent protection.

10. Is there any basis in law or fact for treating expressed sequence tags (ESTs) differently than any other nucleic acid under the written description requirement?

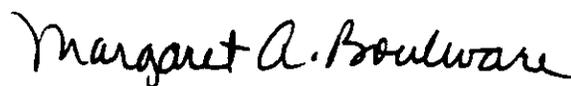
There is no readily apparent reason for treating ESTs any differently.

11. Are there additional issues related to other statutory requirements of Title 35 invoked in the patenting of ESTs?

All the requirements of Title 35 apply equally to EST inventions as they do to all other inventions.

We appreciate the opportunity to provide comments on this important and complex topic. We regret the lateness of these comments, but believe the extra time helped us to provide more thoughtful comments. We would be pleased to work with the PTO in further elaboration of the guidelines in the future.

Sincerely,



Margaret A. Boulware
President