

March 27, 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**  
**Stephen Walsh**

**Box Comments**  
**Linda S. Therkorn**

Re: AIPLA Comments on (i) the Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, 64 Fed. Reg. 71427 (December 21, 1999), and (ii) the Revised Utility Examination Guidelines, 64 Fed. Reg. 71440 (December 21, 1999)

Dear Commissioner Dickinson:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to present its views on the Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement (Revised Written Description Guidelines) and on the Revised Utility Examination Guidelines, published in the *Federal Register* on December 21, 1999.

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.

### **Written Description Guidelines**

AIPLA fully appreciates the PTO's efforts to clarify and provide for consistency in the training of its Examiners as to the manner in which the written description requirement is to be applied to the examination of patent applications. We believe the Revised Written Description Guidelines have taken great steps forward in the complex area of written description.

Patent examiners should be instructed in the Revised Written Description Guidelines to exercise vigilance and to make rejections on written description grounds whenever there is a clear and reasonable basis for doing so. If the PTO fails to exercise vigilance in the identification and rejection of written description defects, patents with invalid, overly broad claims could be issued,

spawning litigation that could have been avoided. Similarly, where the *ex parte* appeal process results in a decision that is favorable to inventors on written description grounds, the clear validity of the resulting claims will similarly reduce the litigation and provide useful guidance to examiners.

The Revised Written Description Guidelines begin by defining two policy objectives of the written description requirement. The “essential goal” of the description is “to clearly convey the information that an applicant has invented the subject matter which is claimed.” A second objective is “to put the public in possession of what the applicant claims.” In order to accomplish these goals, and to satisfy the written description requirement, the Revised Written Description Guidelines have clarified means by which the applicant might prove “possession” of the claimed invention, using recent case law as a guide.

As indicated in our December 14, 1998 comments on the initial Written Description Guidelines, 63 Federal Register 32639 (June 15, 1998), a “possession” test does not appear in the statute itself. Its definition and detailed application are not clearly stated in the Federal Circuit cases to date; they are still emerging in the Federal Circuit jurisprudence. We believe the Revised Written Description Guidelines provide a good starting point for a “possession” test. However, the Revised Written Description Guidelines will surely be further delineated by subsequent judicial decisions. Thus, pending a final judicial determination, patent examiners should be directed to use existing judicial precedent to make rejections of claims unsupported by a statutory written description.

AIPLA repeats its understanding that an inventor is “in possession of” an invention when he or she demonstrably has at least a complete conception thereof, and that the section 112, paragraph 1, written description requirement is satisfied when that complete conception is disclosed in the inventor’s patent specification, original claims, and drawings in sufficient detail to communicate to one skilled in the art what the invention is. 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 conception. The Revised Written Description Guidelines include this understanding as one of the methods by which possession might be shown by the applicant.

In addition, methodology step 2 requires that the patent examiner determine what the applicant has identified as the “essential distinguishing characteristics” of the invention. As discussed below, we believe this verbal formulation is best understood in terms of the Federal Circuit’s *Fiers* decision (“Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.” 25 U.S.P.Q.2d 1605). If the PTO intends that its “essential distinguishing characteristics” formulation would have some alternative meaning, we would be concerned that there would be no basis in the patent statute for such a formulation. It would introduce an unnecessary and confusing test into the written description requirement.

The step-by-step guide for consideration of compliance with the written description requirement provided at page 71435 of the Federal Register, asks the patent examiner to first construe each claim as a whole, giving the claim its broadest reasonable interpretation consistent

with the written description. The claim is evaluated to determine if it recited “sufficient structures, acts, or functions” to make clear its scope and meaning.

In step 2, the total disclosure is reviewed to understand “what applicant has identified as the essential distinguishing characteristics of the invention.” The examiner is then required to determine if there is correspondence between what the applicant has described as the “essential identifying characteristic features of the invention, i.e., what the applicant has demonstrated possession of, and what applicant has claimed.” AIPLA believes that this section of the Revised Written Description Guidelines provides a potentially confusing verbal formulation that should not be construed as adding a new test or requirement. AIPLA recommends clarification of what is intended here. For example, it would be useful to indicate that this formulation is intended merely to represent a mode of “fact finding” by the patent examiner, calculated to identify information contained in the patent specification that would be relevant to establishing that a statutory “written description” is present. This element of the analysis by the examiner could focus on the Federal Circuit’s holding in decisions such as *Fliers v. Revel*, wherein it was not sufficient to identify an alleged “invention” by the desired result or intended function, but was essential to supply the actual structure or structures (or some equivalent characterizing information) sufficient to identify the thing being claimed. Thus, the examiner should be focusing on the nature of the characterizing information that would be applied to reach the ultimate factual conclusion described in step 3.

AIPLA suggests that the intent of the Revised Written Description Guidelines should be to have the patent examiner make the ultimate fact-finding on the “written description” by comparing the scope of the claim (step 1) with the scope of the characterizing information (step 2) to reach the conclusion (step 3) that there is or is not a statutory “written description” or “demonstrated possession.”

The articulated tests for proof of “possession” include actual reduction to practice, and a clear depiction of the invention in detailed drawings. A written description of the invention describing sufficient relevant identifying characteristics such that a person skilled in the art would recognize the inventor had possession of the invention is also acceptable “proof.” AIPLA submits that the type and amount of “relevant identifying characteristics” needed to satisfy the written description requirement will vary on a case by case basis, and also with the state of the claimed technology at the time of the invention. Stated “relevant identifying characteristics” include: complete or partial structure; other physical and/or chemical properties; functional characteristics coupled with known or disclosed correlation between function and structure; or, some combination of these characteristics.

AIPLA would also like to note an apparent inconsistency between the comments in paragraphs (34) and (35) in the Federal Register notice preceding the Revised Written Description Guidelines and Example 7 in the Training Materials on the Revised Written Description Guidelines. If an EST claim is “open ended” (i.e., potentially enormously broad) and lacks a “written description,” we do not see how this could be cured by the additional disclosure of a *single species* (disclosing a single cDNA). This is inconsistent with the “representative number of species” test stated in the guidelines themselves. Moreover, such a result would be difficult to reconcile with the Federal Circuit’s decision in *University of California v. Eli Lilly and Company*.

## **Revised Utility Examination Guidelines**

We believe that these Revised Utility Examination Guidelines should be adopted by the Office in their current form, with one possible clarification that we have set out below. We believe they provide examiners with an accurate restatement of the basic principles underlying the requirement for a practical utility for inventions for which a patent is sought and the further requirement that the patent specification itself actually enable such a meaningful utility.

We would suggest that the “nexus” referred to at Federal Register page 71442 in item B.2.(d) (2) be explained more fully. It would appear that the nexus referred to simply means that the specific and substantial utility that is the basis for establishing operability under section 101 be enabled by the patent specification under section 112.

### **Conclusion**

AIPLA would strongly urge the PTO to follow the decisional law of the past decade that in certain respects has elevated the importance of the written description and utility requirements and use these requirements to reject claims in applications or invalidate claims in patents. AIPLA believes that it would be preferable for the law on the written description and utility requirements to be developed at an early stage through *ex parte* appeals from the PTO rather than through later, more expensive post-issue litigation in the Federal Courts. This belief necessarily translates into a desire to see the PTO rigorously apply the statutory written description and utility requirements as applied by the Federal Circuit. Moreover, the PTO is urged to identify appeals on these issues and expedite their disposition within the PTO, to the extent consistent with law and regulation.

In summary, we congratulate the PTO on the Revised Written Description Guidelines and the Revised Utility Examination Guidelines as well as the Training Materials for each. We appreciate the opportunity to provide comments on these important and complex topics. We would be pleased to work with the PTO in any further elaboration of the guidelines in the future.

Sincerely,

Louis T. Pirkey  
President