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September 14, 1998

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Commissioner of Patents and Trademarks
Patent and Trademark Office
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Attn: Scott A. Chambers
Associate Solicitor

Re: Comments on Interim Guidelines
for Examination of Patent
Applications under the 35 U.S.C. 112
"Written Description" Requirement

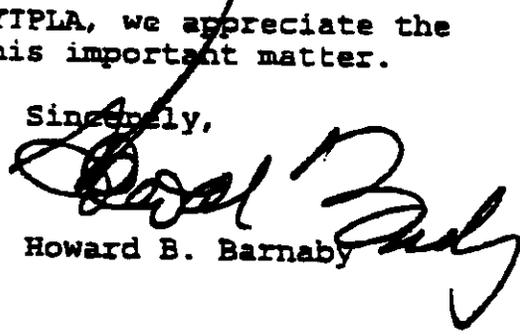
Dear Mr. Chambers:

As President of the New York Intellectual Property Law Association, I respectfully submit the attached comments of the NYIPLA Committee on Patent Law and Practice on the Patent and Trademark Office's recent interim guidelines to be used by PTO personnel in their review of biotechnological patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, par. 1, the notice as published at 63 Fed. Reg. 32639 on June 15, 1998.

This Committee report supports the interim guidelines as in accordance with the written description requirement generally. Therefore, to promote consistency and to minimize disputes as the guidelines impact pending and future applications, the Committee believes the scope of the guidelines should be expanded to include all technologies generally, including processes and product-by-process claims. In addition, the Committee believes that the methodology in the guidelines is accurate, but will benefit from clarification and elaboration as set forth in the attached comments.

On behalf of the NYIPLA, we appreciate the opportunity to be heard on this important matter.

Sincerely,


Howard B. Barnaby

HBB:clk
Attachment

New York Intellectual Property Law Association
Committee on Patent Law And Practice

Comments on the PTO Interim Guidelines concerning the
"Written Description" Requirement
(Notice Published on June 15, 1998 at 63 Fed. Reg. 32639)

1. The Accuracy of the Methodology

The Committee believes that the methodology in the guidelines is accurate, but will benefit from clarification and elaboration as discussed below.

For example, in determining whether species claims satisfy the written disclosure requirement, the guidelines provide for determining whether sufficient identifying characteristics of the claimed species are disclosed. However, the guidelines do not expressly consider the situation where the application (1) discloses a generic structure that includes the species and (2) lists examples of particular moieties in that structure, including the moieties of the claimed species, but (3) does not expressly disclose the particular combination that is the claimed species.

In Fujikawa v. Wattanasin, 93 F.3d 1559 (Fed. Cir. 1995), the Federal Circuit upheld the Board's determination that a claimed subgenus was not described in the specification even though (1) a generic structure that included the subgenus was disclosed, (2) with the exception of two constituents, all constituents of the subgenus were disclosed, and (3) as for the two exceptions, one was disclosed as a preferred choice and the other was listed as a possible choice. The Federal Circuit reasoned that the written description requirement was not

satisfied because the application did not sufficiently direct one to the proposed subgenus in particular, as follows at page 1571:

"just because a moiety is listed as one possible choice for one position does not mean there is ipsis verbis support for every species or sub-genus that chooses that moiety. Were this the case, a 'laundry list' disclosure of every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not 'reasonably lead' those skilled in the art to any particular species."

Clarification of the guidelines to address the situation in Fujikawa therefore seems helpful. The guidelines should make clear that disclosure of a "complete structure of the claimed species" is not satisfied by a mere recitation of a generic structure and lists of choices for elements in that structure.

2. **Relevant Factors to Consider in Determining Whether the Written Description requirement of 35 U.S.C. 112, par. 1 is Satisfied**

In determining whether a patent application satisfies the written description requirement, the Committee believes that a relevant factor to consider is whether the claims cover embodiments broader than the essential elements of the embodiments described in the specification. See Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1478 (0 (Fed. Cir. 1998).

For example, a claim to a genus in which the specification discloses a representative number of species may nonetheless run afoul of the written description requirement if all species share a common characteristic that is not a limitation of the genus claim. In such case the written

description requirement should not be considered satisfied unless one skilled in the art would understand that the common characteristic has no importance to the invention. The guidelines do not address this issue.

3. **Whether the Scope of These Guidelines Should Be Limited to Certain Technologies**

The Committee believes that the scope of the guidelines should include all technologies generally.

In Regents of the University of California v. Eli Lilly & Co., 119 F. 3d 1559, 1569 (Fed. Cir. 1997), the Federal Circuit looked to cases involving other technologies in reaching its decision that the recombinant DNA patent claims before it did not satisfy the written description requirement. For example, in instructing that a description of a genus of cDNAs may be achieved by reciting either (1) a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or (2) a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus, the Court found support in In re Angstadt, 537 F.2d 498 (C.C.P.A. 1976), which involved claims for organometallic complexes as alkylaromatic oxidation catalysts, and In re Robins, 429 F.2d 452 (C.C.P.A. 1970), which involved claims for urethane elastomers.

Accordingly, the scope of these guidelines should not be restricted to certain technologies because the Federal Circuit applies principles from cases involving other technologies. Having the guidelines apply to other technologies also promotes

consistency in the law governing the written description requirement.

4. Whether the Scope of These Guidelines Should Be Expanded to Include Processes and/or Product-By-Process Claims

For similar reasons, the Committee believes that these guidelines should exclude processes and/or product-by-process claims.

5. The Impact These Guidelines May Have on Currently Pending Applications as well as Future Applications

The Committee is of the opinion that the guidelines will have the most beneficial impact on pending and future applications if they apply to the written description requirement generally. Otherwise, inconsistencies and anomalies may result in the implementation of the written description requirement if the guidelines are limited to certain technologies.

The Committee believes that the guidelines are consistent with long-established practice, particularly in the chemical area. Accordingly, the potential for these guidelines to generate disputes will be greatly reduced, if not eliminated, if the guidelines provide that they are in accordance with established law generally pertaining to the written description requirement.