

AMERICAN BAR ASSOCIATION SECTION OF INTELLECTUAL PROPERTY LAW
COMMITTEE NO. 1001 - BIOTECHNOLOGY
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November 12, 1998

Box 8
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
Washington, D.C. 20231

Attention: Scott A. Chambers, Associate Solicitor

Re: Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 P1 "Written Description" Requirement.

Dear Commissioner:

The attached comments are draft comments submitted by the Biotechnology Committee of the Intellectual Property Section of the American Bar Association in response to the above-identified PTO Notice of Proposed Rulemaking, published at 63 Fed. Reg. 32639 (June 15, 1998). They have received the approval of the Biotechnology Committee but have not yet been submitted to, nor approved by the Intellectual Property Section of the American Bar Association, and therefore, should not be construed as representing Association policy until such approval is given. The Biotechnology Committee will submit these comments for approval by the Intellectual Property Section within the next few days and requests the PTO to accept these comments as representing the Intellectual Property Section if their approval is forthcoming within two weeks.

Thank you for your consideration of these comments.

Sincerely,



Nina L. Pearlmuter

Chair

COMMENTS OF THE AMERICAN BAR ASSOCIATION - SECTION OF INTELLECTUAL
PROPERTY LAW - COMMITTEE NO. 1001 - BIOTECHNOLOGY

It is the Committee's view that the proposed rules overall will not clarify the written description requirement or assist Examiners in determining whether an application provides written description support in compliance with substantive law. There are several good reasons why the PTO should withdraw these proposed examination guidelines.

These rules are based, for the most part, on a very narrowly construed decision of the Court of Appeals for the Federal Circuit, *University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). It is the Committee's view that the *University of California v. Eli Lilly and Company (Lilly)* should be treated as a fact-specific case and that the PTO has too broadly interpreted this case as challenging the sufficiency of the written description of a wide range of applications. The Court was constrained to decide the case on the basis of the written description requirement because the lower court (S.D. Indiana) decided the case on that basis. Support for this position can be found in the opinion at 43 USPQ2d 1405 (first column) and 1406 (second column) where the enablement requirement of §112 is briefly brought into the opinion. These guidelines state that one of the objectives of the written description requirement "is to put the public in possession of what applicant claims as the invention." This however is a function of the enablement requirement not the written description requirement.

The Committee believes that the guidelines should not be applicable to all fields of invention. The scope of these guidelines, if adopted, should be very limited. There is certainly no direct applicability of *Lilly* to other technologies, such as the entire field of chemistry, or even other areas of biotechnology such as antibodies, much less to all technologies. In fact, there is no reason to attempt to apply *Lilly* to biomolecules other than DNA. The Court at 43 USPQ2d 1405-1406, distinguishes descriptions of broad classes of cDNA from other chemical materials and compositions. The Court recognized that descriptions of chemical

materials by means of generic formulae are more specific than generic descriptions of genetic material unless there is additional description of the genus; for example, recitation of structural features common to the members of the genus.

For the same reasons, the Committee believes that the scope of these guidelines should not be extended to include processes or product-by-process claims. The Court gives no indication that *Lilly* should be so extended and by attempting to extrapolate a definition for the written description to process or product-by-process claims, the PTO would be required to establish new rules which may not find judicial support in the future. The Court in *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993) held *in dicta* specifically that product-by-process claims would adequately describe DNA, if the disclosed process is enabling. ("Our statement in *Amgen* that conception may occur *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. 25 USPQ2d at 1604-1605).

The Committee further believes that there is no basis to propose guidelines to Examiners that all species must be described to claim certain genera, or that a claim to a specific gene from a group of organisms, such as ruminant mammals, requires a disclosure of any number of species from that group. Further, there is no substantive case law which supports the premise that, if the members of a genus are "expected" to vary widely in identifying characteristics such as structure and activity, each member must be specifically described. It is highly unlikely that an Examiner would find adequate information in the art be able to determine objectively which genera would differ widely in structure and activity for a specific type of gene. The Court in *University of California v. Eli Lilly and Co.* made it clear that it is not necessary to describe every member of a genus to meet the written description requirement. Therefore, the Guidelines should be limited to address the narrow teachings of the Court in *Amgen*, *Fiers* and *Lilly*.

Despite PTO comments that the Guidelines require analysis to determine if claimed subject matter complies with substantive law, these guidelines attempt to establish a new legal standard unsupported by case law to evaluate compliance with the written description

requirement. In Section II(A), Examiners are directed to evaluate the level of skill in the art and the "teachings in the application" to determine "predictability of structure" of a species. This is to be accomplished through a determination of correlation "between structure and function". The ability to predict structure from function is given as a standard in Section II (C) without any citation to authority, indicating that the "written description may be satisfied through disclosure of relevant identifying characteristics, *i.e.*, ... functional characteristics when coupled with a known or disclosed correlation between function and structure." The Examples that follow, however, do not describe any function and structure correlation, but only relate to identifying characteristics. Further, in Section II (D) no authority is cited to support the application of a function-structure correlation as a means to satisfy the written description requirement for a generic claim. No Examples are given in this section to illustrate how such a "function-structure correlation test" can be applied to meet the written description requirement. Thus, the interpretation of this test is left unclear.

Finally, it is the Committee's view that these rules discourage early disclosure of leading-edge technology. It will encourage scientists who ascertain the sequence of one gene to conceal the information until the sequence of other genes is obtained. There are many instances wherein the sequence of a gene common to all organisms, once defined, can be quickly and rapidly obtained from other organisms (including humans) and characterized. The methods to sequence homologs or analogs, given the sequence of the gene in one organism, are well known in the art. Under these circumstances, the Examiners should be able to find that other genes are properly within the scope of the claims if the Applicant(s) claims encompass other genes without providing a sequence. Otherwise, scientists will be reluctant to disclose the sequences of new genes until they have several isolated and sequenced from other organisms.

The Committee appreciates the opportunity to present these comments. If the Committee can be of further assistance, we would appreciate the opportunity to work with the PTO to revise these guidelines.