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November 5, 1998

Box 8  
The Honorable Bruce Lehman  
Commissioner, Patent and Trademark Office  
2121 Crystal Drive  
Crystal Park II / Suite 906  
Arlington, Virginia 22202

Attention Scott A. Chambers, Associate Solicitor

**Comments on Interim Guidelines on the Written Description Requirement:**

The Biotechnology Industry Organization (BIO) represents over 780 biotechnology companies, academic institutions and state biotechnology centers in 46 states and more than 25 nations. BIO members are involved in the research and development of health care, agricultural and industrial and environmental biotechnology products. We have a great interest in strong patent system and predictable patenting as it is imperative for investment decisions in regard to putting valuable research dollars towards particular product development since a products profit is determined by its exclusive position in the marketplace.

We appreciate your publishing "written description guidelines" for comment. The responsiveness of your agency to the uncertainty that occurred with the Court decisions in U.C. v. Eli Lilly is commendable, and the added certainty that these guidelines will provide is a tremendous asset to this industry.

Although the guidelines are helpful in determining how the PTO will be examining the patent applications, the following are comments that we are submitting for the record in hope that the guidelines can be more helpful, more consistent with practice across the PTO and give greater notice to patent applicants regarding the boundaries of patentable subject matter.

1. The guidelines seem to establish a new law regarding the importance of the preamble to the claim and at the same time seem to advocate a seeming contradiction that the broader the preamble the lesser the burden is to satisfy.

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Although it is understood by industry that the written description guidelines are not to be read in a vacuum and that the guidelines do not address the issue of enablement under 35 USC 112, the guidelines still leave open the criticism that the PTO is suggesting broader claim language is easier to satisfy. Industry obviously has great concerns that the PTO would be encouraging broad claims when the disclosure only justifies the narrowest claims. In this regard the industry suggests that the guidelines make the entire requirements of 35 USC 112 more obvious upon reading that is that the PTO in some way explain that the requirements of the written description work against the enablement requirement. That is explicit reference to the increased difficulty in getting broader patent coverage based upon the enablement requirement. Such explicit mention will increase the readers understanding that these guidelines and the court decision act to make claims narrower and not broader.

2. The guidelines further seem to muddle the courts distinction between biotech inventions and all of chemistry

While the Guidelines state that "they are intended to be equally applicable to all fields of invention." <sup>1</sup>the court specifically distinguished the claims in UC v. Lilly, which they described as "complex biotechnological claims" or claims to "genetic material", from claims to "machinery" or "chemical materials." <sup>2</sup>Also, while the Guidelines stated that they did not address the description necessary to support product-by-process claims, it would have been helpful to note that the Fiers Court *in dicta* specifically help product-by-process claims would adequately describe DNA, if the disclosed process is enabling.<sup>3</sup>

In view of the narrow focus of Amgen, Fiers and UC v. Lilly, the Guidelines should be limited to application of these standards to applications for "genetic material," i.e., nucleic acids, vectors, transformed cells and the like. The PTO should not attempt to extrapolate from these holdings, much less to propound

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<sup>1</sup> Guidelines, introduction.

<sup>2</sup> 43. U.S.P.Q.2d at 1406. Although not considered by the Guidelines, UC v Lilly, the Court was clear that, in the case of "chemical materials," generic formulae usually indicate with specificity what the generic claims encompass. This certainly was meant to refer to the conventional structural generic claims employed in e.g. pharmaceutical patent applications.

<sup>3</sup> "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." [U.S.P.Q.2d at 1604-605].

new legal rules for examination.

In particular, we are concerned with the way in which the guidelines discuss support for genus claims, particularly genus claims drawn to predictable subject matter.

For example, on page 13 a claim is presented which is drawn to a genus of polynucleotides which hybridize to a reference sequence (SEQ ID NO:1). A key element supporting possession in this example (i.e., satisfying written description), is the disclosure in the specification of "several sequences to SEQ ID NO:1".

The guidelines leave the reader questioning:

- (a) How many sequences that hybridize must be disclosed (what does "several" mean)? Is one enough?
- (b) Is there a relationship between the size of the genus and the number of species that must be disclosed?
- (c) Do the several sequences need to represent the full spectrum of divergent sequences that will hybridize or are several very similar sequences adequate?
- (d) Are a few oligonucleotide primers adequate or do the probes need to represent a variety of lengths?

The same analysis is equally applicable to the monoclonal antibody example on page 14. Here the claim presented is to a genus of monoclonal antibodies specific for a particular protein. Again, as in the example on page 13, possession was allegedly satisfied through the disclosure of "multiple monoclonal antibodies" in the specification. However, no details of the disclosure were provided.

Without specifically pointing out what the specification in this example disclosed we are left with more questions than answers. While it is clear that rejections for insufficient representation can be properly made, no guidance is provided for what would constitute a sufficient disclosure. Clear examples need to be given for a variety of genus claims showing both sufficient and insufficient disclosure for each example.

The guidelines correlate sufficiency of disclosure with predictability in the art. No understandable basis is proffered, however, for distinguishing predictable from unpredictable arts within biotechnology. For example, the genetic code is known. Does a practitioner need to disclose a representative number of degenerate polynucleotides encoding an identical polypeptide to satisfy the written description

requirement for a claim reciting all DNAs encoding the polypeptide?

Although the degeneracy of the genetic code is an extreme example, hybridization technology is also a well developed and predictable art. The disclosure of representative species within a genus of probes adds little to evidencing possession of a genus within this technology.

In summary, saying that disclosure was sufficient in a given example without saying precisely what the applicant had disclosed provides no guidance whatsoever. Because the distinction between predictable arts and unpredictable arts is not well developed or supported, the guidelines provide little help in determining what level of disclosure is required for any particular genus claim. The failure of the guidelines in these respects defeat the stated objective of the guidelines. Rather than provide guidance to practitioners and examiners, they create confusion and a likelihood of arbitrary application.

3. The guidelines do not provide adequate guidance for industry regarding the middle ground

Two examples of statements that Examiners may well consider "rules" occur in section II(D) of the Guidelines, where it is suggested that nine species may be needed to support a generic claim to "a specific gene from ruminant mammals" and in the statement: "In fact, if the members of a genus are expected to vary widely in their identifying characteristics...written description for each member within the genus may be necessary." The Court in UC v. Lilly affirmed that "every species in a genus need not be described in order that a genus meet the written description requirement."<sup>4</sup>

4. The guidelines do not provide adequate criteria for the selection of appropriate genus for claims.

A proper application of the written description requirement requires as a first step an accurate assessment of whether the genus claimed by the patent applicant is appropriate for the subject matter disclosed in the patent application. Yet in the proposed guidelines, the PTO has failed to articulate a clear and legally defensible approach for PTO personnel to use to determine if an applicant has presented a properly formed genus. For example, the guidelines state that a claim to a "gene", "mRNA", or "cDNA" genus may present a written description problem, and that a claim to a "nucleic acid" genus typically will not. The guidelines, however, present no criteria to arrive at this conclusion, yet place an inordinate amount of

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<sup>4</sup> 43 U.S.P.Q.2d at 1405

emphasis on evaluation of whether "members" within the genus have support in the specification. To correct this problem, the guidelines should be revised to include a discussion of how PTO personnel are to assess whether a genus has been properly claimed. (In our view, a genus designation should be strictly tied to the disclosed properties of the structures being claimed. We believe that taking such an approach with EST sequence inventions necessarily would have the effect of narrowing the scope of claims granted for such inventions. For example, whereas the disclosure of an EST sequence, without more, may support a claim to an "EST", "hybridization probe", or "genetic marker" genus, it would not support - under properly applied written description criteria - a "gene", "mRNA", "cDNA" or other downstream product genus).

5. The guidelines should be redrawn closer to existing Court of Appeals for the Federal Circuit precedent.

The guidelines, if they are to achieve their intended effect, must be straightforward and consistent with applicable law. It is not clear that either of these criteria is met by the guidelines in their current form. For example, the process of evaluation described in the guidelines addresses key questions (e.g., what is the genus and has it been properly defined) only in certain situations, rather than as an initial necessary step in the review process. The guidelines should be revised to include more practical examples and applications of the guidelines, and citations to relevant rules, statutes, and case law.

In doing so the guidelines should not impose significant new burdens on patent applicants that have filed applications on biotechnology inventions, or give rise to a new "anti-patenting" posture in the biotechnology examination group. At the same time, it is critical that the guidelines emphasize the importance of patent examiners conducting a comprehensive and rigorous examination of applications. The PTO should not be misled into adopting "customer-friendly" examination standards that do not subject applications to a thorough and rigorous examination.

We appreciate the opportunity to comment on these interim guidelines and look forward to the final guidelines.

Thank you for taking the time to consider our thoughts in this matter.

Sincerely,



David Schmickel  
Patent and Legal Counsel