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SOLICITOR

AUG 13 1998

U.S. PATENT & TRADEMARK

Re: Comments on Proposed Guidelines for Examination of Patent  
Applications under the "Written Description" Requirement  
Our Reference: 99990-5

Dear Scott:

The following are my personal views regarding the above-referenced Guidelines. Much in the Guidelines makes sense, and I will limit my comments to those areas where I feel they do not. I have three main criticisms:

1. There is no instruction to analyze the claim for the nature of the invention in terms of whether the descriptors at issue relate to an essential feature or are irrelevant to what the invention actually is.
2. There is no distinction made between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself.
3. The guidelines would permit domination of a huge genus on the basis of minimal information while denying domination of a more limited subspecies of the genus. This is not a new concept, but in the present context it may not make sense.

I would like to discuss each of these briefly.

1. The Guidelines fail to focus on the invention being claimed

All of the examples in the Guidelines relate to compositions which are themselves the invention – e.g., “a gene comprising SEQ ID NO: 1” (the invention is the gene); “an isolated nucleic acid which is the reverse transcript of human insulin mRNA” (the invention is the isolated nucleic acid).

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But there are many instances where undefined portions of the composition are really not essential elements of the invention and do not go to the invention at all. One example of this was mentioned, I believe, by Doug Robinson in the Open House -- "an expression system comprising promoter X operably linked to a desired gene." Here, the invention resides in the promoter, not in the desired gene. Therefore, failure of the applicant to provide the structure of the "desired gene" should not result in a finding that a claim to an expression system containing it fails to meet the written description requirement.

Other claims that have not been problems in the past perhaps would be in the face of these Guidelines. For example, a claim to "a pharmaceutical composition comprising compound X as the active ingredient along with at least one pharmaceutically acceptable excipient" should not fail the written description requirement even if no excipients were set forth in the specification. Methods of formulation are well known, and the invention is not directed to how to formulate X, but rather to the active ingredient X itself.

There was a recent instance of this in a case I have been prosecuting where I will change the names of the substances since the patent has not yet issued. The claim was directed to a cell line which harbored an expression system for high-level production of a particular enzyme, "Xase." The cell line was described in the claim as containing the expression system which comprises a specified promoter operably linked to the gene encoding Xase, where the cell was of type Y. After the Guidelines were promoted, the claim was rejected as lacking an adequate description even though the combination of promoter and cell line which were essential to the high-level expression of Xase were noted whereas the exact amino acid sequence of Xase was not specified. There are a number of forms of Xase, none of which appears to be so different from the other that its expression levels would be in any way influenced by which one was chosen. The Examiner believed that according to the Guidelines, only the cells containing the nucleotide sequence encoding the specific amino acid sequence of Xase disclosed in the specification could be included in the claim. On the other hand, a claim to a method to produce Xase using cell lines of this description was allowed. This brings us to my next comment. However, I should remark that while the Examiner, using the Guidelines as a basis, was very concerned that the specific sequence for Xase be included in the claims, there seemed to be no equivalent concern for the really relevant elements in the invention -- the nature of the cell line and the nature of the promoter which were key to the invention!

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2. The Guidelines perhaps properly exclude claims to methods where patentability resides in the method steps. However, a distinction makes no sense where the patentability of the method resides in the patentability of the composition used to conduct it or that is obtained through it.

A specific example is that set forth above. Once the cell line is available, culturing it to obtain high expression of Xase is simply a matter of routine culture. It is this type of claim that was addressed by *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995), of course. The requirements for description in the case of such method claims ought to be exactly the same as those for compositions. For example, a routine claim in applications for patents on cloned genes includes that directed to a method to produce a protein encoded by the gene by culturing cells containing an expression system containing the gene. If the applicant is considered to be limited, in claims to the recombinant materials, only to, for example, expression systems for proteins encoded by the gene retrieved and for proteins encoded by genes that hybridize to the retrieved gene under specified conditions, then it would appear that the same requirement should be applied to claims to a method to produce the protein.

### 3. Scope of Subject Matter Claimed

I am well aware that there are many instances in which a description is adequate to describe a genus but not a particular species contained therein, and that, indeed, the particular species may be patentable over the genus. However, the ability of an applicant to dominate a claim to a gene containing a specified sequence based only on a small portion of the gene sequence seems somehow unfair. I believe BIO is particular concerned about this and I will not comment further.

I appreciate your consideration of these comments. One last remark. In my opinion, it is premature to instruct Examiners in the proposed Guidelines before comments are received and taken account of. I am well aware of the distinction between guidelines and rules and realize that the Patent Office is within its legal authority in doing so. However, unless the Office intends completely to ignore the comments solicited from the public, it should be evident that the Guidelines may change dramatically as a result of these comments. It seems counterproductive to provide instruction to examiners in the interim when the instructions may, then, have to be undone. Alternatively, it creates the appearance that the comments will simply be disregarded since the Guidelines have already been implemented anyway.

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Thanks again for considering these comments.

Best regards,



Kate H. Murashige

Enclosure(s)

cc: David Schmickel, Esq.