

Genentech, Inc.

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U.S. PATENT & TRADEMARKS

LEGAL DEPARTMENT

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December 4, 1998

Commissioner of Patents and Trademarks
Box 8
Patent and Trademark Office
Washington, DC 20231

Attention: Scott Chambers, Associate Solicitor

Re: Response of Genentech, Inc., to the Invitation for Public Comment on the PTO Interim Written Description Guidelines and Issues Related to Written Description Guidelines (63 FR 32639 and 63 FR 50887)

Dear Dr. Chambers,

This communication comprises the comments of Genentech, Inc., on issues presented for public comment in two Federal Register notices published by the Patent and Trademark Office (PTO) earlier this year at 63 FR 32639 (June 15, 1998) and 63 FR 50887 (September 23, 1998). Attached to this communication is a copy of the oral testimony provided on behalf of Genentech by Mr. Jeffrey P. Kushan, at the PTO public hearing on November 4, 1998.

I. Comments on the Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, First Paragraph "Written Description" Requirement [63 FR 32639]

The interim guidelines represent a well-intentioned effort towards clarifying the process by which PTO examiners will evaluate whether an application satisfies the written description requirement of 35 U.S.C. §112, first paragraph. Certain elements of the guidelines, however, raise some significant concerns for Genentech, as does the overall structure of the guidelines. Our comments will present a number of general concerns or perspectives on the guidelines, and then address specific issues raised in the guidelines. To enhance the value of these comments, we are providing not only our concerns but some suggestions on how to address those concerns.

A. *General Remarks on the Interim Guidelines*

1. *Restructure the Guidelines to Separate the Legal Analysis and Methodology for Evaluation of Applications from Specific Examples of How the Guidelines are to be Applied*

A basic problem with the interim guidelines is that they fail to segregate the explanation of the law and the methodology to be used by examiners in reviewing applications for compliance with the written description requirement from illustrations of how the guidelines are to be applied for specific types of inventions.

For example, in the section II.B, the guidelines attempt to illustrate a distinction between types of nucleotide sequences (genes, cDNA, mRNA) versus a generic definition of a nucleic acid. The choice of this example is remarkable, as it is perhaps one of the most contentious and difficult issues for application of the guidelines. Nevertheless, the guidelines make a sweeping conclusion that one type of claim would appear to present no problems under the guidelines, while the other necessitates a rigorous evaluation. These conclusions on whether the claim examples satisfy the written description requirement are presented *before* any methodology for applying the guidelines are set forth, and as a result, they seriously distort if not completely bypass the analysis that is being suggested later in the guidelines.

We believe a more appropriate approach would be to present the law and procedure in a succinct and clear manner, and then produce separate training materials for the examiners that explain how the guidelines are to be applied for different types of inventions. This approach has been followed in many other guidelines that the PTO has produced, and is probably more effective than trying to simultaneously explain what the law is and answer questions and teach how the law should be applied.

2. *Ensure that the Explanation of the Law and the Guidelines are Subject Matter Neutral in their Scope and Application*

The interim guidelines place an extraordinary emphasis on biotechnological inventions. Nearly all of the examples that are found in the guidelines concern biotechnological products (e.g., monoclonal antibodies, nucleotide sequences, proteins, peptides). The special focus on biotechnology conflicts with the general principle that the patent laws are not tailored in their application or interpretation for specific technologies, but are cast in a general form applicable to inventions in all fields of technology. The special focus on biotechnology also is inconsistent with the general tone of the Federal Circuit in recent cases, including the case of *The Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), in which the court explicitly linked evaluation of cDNA claims for compliance with the written description requirement to the body of law governing application of the written description requirement for chemical and other products. Placing an overtly "biotechnological" cast on the guidelines risks creating a practice in the patent examining corps that subjects

biotechnology applications to "special" procedures from which applications in other technological fields are exempt. The special focus also risks creating the mistaken impression that biotechnological inventions are subject to a higher or even different set of legal requirements than inventions in other fields of technology. Accordingly, the guidelines and any future training materials should remove the emphasis on biotechnology inventions, and provide examples of how the guidelines will be applied in all technological fields of invention.

3. *Emphasize the Well-Settled Nature of the Concept of Proof of Possession of the Claimed Invention as the Principal Purpose of the Written Description Requirement*

The written description requirement of the first paragraph of 35 U.S.C. §112 serves to ensure that the applicant "possessed" the claimed invention at the date the application was filed. This is not a new concept in patent law. As the Federal Circuit held in the recent case of *Gentry Gallery v. Berkline Corporation*, 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998), "[t]o fulfill the written description requirement, the patent specification 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" (citing *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed.Cir.1989)). The guidelines appear to suggest that certain recent cases, particularly the *Eli Lilly* decision, represent a marked departure from this well established principle. This is simply not the case, and suggesting otherwise could wrongly call into question the patents that issued after those recent cases were decided but before the written description guidelines are finalized. Accordingly, we believe that comments in the guidelines suggesting that significant new law has been created by the *Eli Lilly* decision should be removed. In addition, we believe the examiners and the public would be well served if the guidelines cited and endorsed other cases that articulate and define the "possession of the claimed invention" theory of the written description requirement, including for example, *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978).

4. *Identify the Key Legal Requirements of the Written Description Requirement in a Comprehensive, Rather than Abbreviated Manner Before Proposing a Methodology for Reviewing Applications for Compliance*

The guidelines discuss many aspects of the written description requirement in the context of *applying* the guidelines. We suggest that it would be preferable if a summary of all relevant legal criteria were provided before the procedures for review of applications are explained. In particular, we believe the following key issues should be addressed in a section that describes the law governing the written description requirement, separate and apart from explaining how the procedure being proposed for review of applications is to be applied. Doing so will have the benefit of placing all relevant legal criteria in context so that the examiners can appreciate the purpose and essential features of the written description requirement.

The specific points addressed in such an introductory section should include the following:

- the written description requirement is a separate requirement from the enablement requirement in the first paragraph of section 112, which means that the criteria for evaluating whether a disclosure enables practice of a claimed invention cannot be the same as those used to determine if the applicant satisfies the written description requirement;
- the *claimed subject matter* is the “invention” that must be described in the application, which means that the evaluation must begin with an assessment of the claims, rather than an unguided evaluation of the specification;
- compliance with the written description requirement is a question of fact, not law, which means that the inquiry required is one to determine if the written description does or does not show that the applicant possessed the claimed invention; and
- it is the examiner’s burden to establish a *prima facie* case that the claimed invention has not been adequately described (see, e.g., *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578 (Fed.Cir. 1996)).

5. *Restructure the Guidelines to Identify Issues that are Likely to Require Further Analysis for Compliance with the Written Description Requirement*

Written description deficiencies are not encountered in most applications. Recognizing this, the guidelines should help examiners easily detect applications in which a written description deficiency is likely to be found, rather than forcing the examiner to subject every application to a rigorous analytical procedure focused exclusively on written description compliance. The proposed methodology for evaluation of compliance with the written description requirement therefore should be restructured to easily identify problem cases, and then to assess those cases using an accurate legal framework.

We also believe the guidelines could be improved by providing explanations of the two most common types of deficiencies under the written description requirement. The guidelines, when applied, should guide the examiner through a process that is based on the variables that should be considered to determine if there is a deficiency of either type in the application under consideration. The two general types of problems that courts have identified under the written description requirement are:

- where claims are amended or added by an applicant during prosecution of the application, or during an interference, in which case the question is whether there is support in the original disclosure for the newly claimed subject matter, and

- where the applicant presents an original or new claim that (a) attempts to define a group of compounds or compositions as a "genus" but the written description does not demonstrate that the applicant had possession of the genus (e.g., the applicant had possession of a single species that was not sufficient to demonstrate possession of a genus), or (b) defines a group of entities that can not be properly termed a genus (e.g., the claims encompass compounds that do not in fact possess a common structure and function that is linked to the practical utility disclosed by the applicant).

Examples of deficiencies of the first type tend to arise in situations such as interferences (when a party attempts to justify entitlement to a count) or through amendments that attempt to claim new subject matter that does not have literal or implicit support in the application as originally filed. For example, in a chemical case, the problem could arise by a post-filing presentation of a claim to a species of a compound, where only a genus of compounds or one or more other species have been specifically disclosed.

The second type of problem can arise in relation to compounds or compositions defined in primarily functional terms, rather than through the structural or physical characteristics. For example, in *Eli Lilly*, this problem arose with a claim to a genus of compounds ("vertebrate" or "mammalian" cDNA encoding insulin), as to which the court stated:

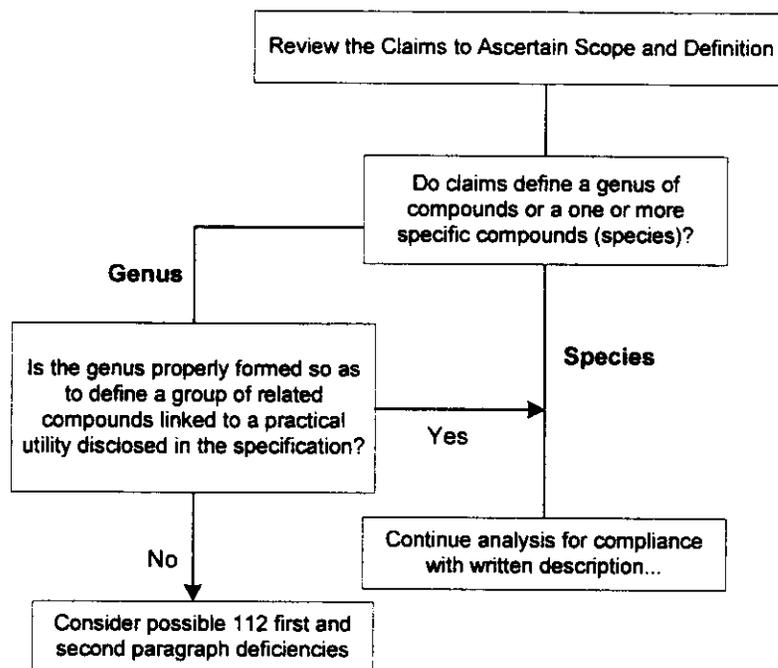
In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Similarly, if a claim defines a large number of unrelated chemical compounds as a genus, but the vast majority of compounds do not share a common function and/or structure, the "claimed invention" (i.e., the genus as defined by the applicant) cannot be shown to have been "possessed" by the applicant at the time of filing (or at any time).

The flowchart describing how examiners are to evaluate applications for compliance with the written description requirement could be substantially improved by requiring the examiners to evaluate the claims to determine if one of the situations described above is present. Situations

in which new subject matter has been added by a claim amendment should be fairly easy to identify. Similarly, it should be a relatively straightforward matter to determine if a species added by a new claim is not literally described. Situations where a claim improperly attempts to define a group of compounds as a genus when a vast majority of compounds within the alleged genus are not in fact related other than through possession of an immaterial physical characteristic, may require additional consideration.

Noting this, the process for evaluation of compliance with the written description requirement should begin with an analysis of the claims that is sufficient to provide the examiner with a clear understanding of what the claims define and encompass. An amendment to the flowchart that would insert a simple test for determining whether a genus has been properly defined is shown below.



A finding that a claim does not properly define a group of related compounds could be the basis of a rejection under the written description or enablement requirement (35 U.S.C. 112, first paragraph) or claim definition (35 U.S.C. 112, second paragraph). For this reason, evaluation of the claim language should precede assessment of the claim for compliance with any of the requirements of 35 U.S.C. 112, first or second paragraphs.

In any case, we believe there is a clear need to improve the analytical process specified in the guidelines to focus on issues in a proper sequence. The present logic of the guidelines suggests that an improperly formed genus will be evaluated for written description compliance as part of the search for species that might suggest that the applicant was in possession of a genus. By deferring the assessment of the claim as a genus or species to this later point in the analysis,

the examiner can omit a critically important evaluation as to whether there is in a fact a genus of compounds that exists as presented by the applicant.

B. Remarks on Specific Points in the Interim Guidelines

1. Examples Provided Yield Illogical Results

A very troubling aspect of the guidelines is that a number of the examples teach results that are inconsistent or illogical. The most confounding scenario is found in the discussion under section II(B), in which the PTO seems to be suggesting that a claim encompassing a larger number of species of chemical entities is likely to face a lower burden of proof for compliance with the written description requirement than a claim that defines a genus of compounds using both structural and functional terms (i.e., that encompasses a smaller number of compounds). Thus, the guidelines suggest that an unbounded claim in the form of "a nucleic acid comprising sequence ID 1" will more easily satisfy the written description requirement than a claim drawn to a genus of mRNA comprising sequence ID 1. Yet, the first example encompasses all the species identified in the second example. Nonetheless, in an almost *de facto* manner, the PTO declares that only the applicant that presents the *narrower* claim is likely to encounter problems with the written description requirement. This makes no sense.

It should be noted that either claim cast in an open format may literally encompass billions of potential sequences, without any restriction as to size or functional characteristics of any particular sequence within the scope of the claim (other than possession of the common nucleotide sequence that is recited). As a result, relatively few sequences that fall within the scope of a claim in the form "nucleic acid comprising ..." are likely to have the same or similar functional attributes as the specific sequence that is defined in the claim. Merely sharing a common sequence element is not likely to impart to all the members of the purported genus common functional characteristics, as a matter of science or law. Therefore, such claims clearly raise a question with respect to written description, and in particular whether the applicant could possibly be said to have possession of such a multitude of functionally different compounds.

As suggested earlier, the guidelines should be reformulated to eliminate specific examples from the legal analysis and the description of the evaluation process. Once this is done, the training materials can take up application of the guidelines to specific fact patterns that will be of assistance to examiners seeking to understand how to apply those general criteria. With respect to claims concerning nucleotide sequences, the examples should not yield the inconsistent results noted above. We believe the basic criteria for the legal analysis and the guidelines should be promulgated first, and then the PTO can work within interested technology groups to elucidate useful and accurate training materials.

2. *The Guidelines Should Emphasize that "Functional Characteristics" Can Be Relied Upon to Establish Possession of a Compound*

The guidelines, particularly in the section concerning the analysis of genus claims, discount the relevance of functional characteristics of a biologically active compound as a means of establishing possession of a compound (except with respect to antibodies and enzymes, which are characterized as "well-developed arts"). The guidelines should not preclude the recitation of functional features in a claim as a means of establishing that the claimed compound was in fact in the possession of the applicant. We believe the use of functional characteristics in combination with certain objectively defined physical characteristics can serve to characterize the compound sufficiently to establish possession, even in cases where the relevant art is regarded as "less-developed." Therefore, we suggest that the guidelines should point out that for purposes of characterization necessary to establish possession of a compound, functional characteristics can be appropriate in all arts.

3. *Additional Guidance is Needed to Address Further Characterization of a Compound or Composition That Has Been Partially Characterized but Deposited*

The guidelines do not provide adequate guidance to the examiners in dealing with a situation where a compound has been deposited by an applicant (i.e., thus unambiguously proving "possession" of the compound), yet the disclosure only provides a partial characterization of the compound. We believe a combination of actual possession established through a deposit with a partial characterization (i.e., to correlate the physical description to the material that has been deposited) should be sufficient to avoid problems with "new matter" where the information added to a disclosure is an inherent characteristic of the compound or composition. The guidelines should provide guidance as to how to evaluate information not originally presented that provides an additional characterization of a deposited composition or compound.

II. *Comments on the Topics Raised in the September 23, 1998 Federal Register Notice (63 FR 32639)*

The oral testimony provided by Jeffrey P. Kushan on behalf of Genentech at the November 4, 1998, hearings conducted at the PTO in Arlington, Virginia, is provided as an attachment to this letter. In addition to those comments, Genentech is pleased to offer the following general comments on the issues presented for discussion.

A. *Responses to Specific Questions Posed*

1. *Is the methodology in the interim guidelines accurate? If not, please comment:*

Comments on the issues raised by this question are provided in Section I of these comments.

2. *Do the guidelines list the appropriate relevant factors and descriptive attributes to consider in determining whether the written description requirement of 35 U.S.C. §112 para. 1, is satisfied? If not, please comment:*

Comments on the issues raised by this question are provided in Section I of these comments.

3. *Should the scope of these guidelines be limited to certain technologies? If so, please comment:*

The general legal principles that govern the written description requirement should be presented in a technology-neutral fashion to make clear that these principles apply equally to all technologies. Having said this, the law does draw a distinction in *application* of the law governing the written description requirement to certain types of inventions, particularly chemical structures. As a result, certain types of inventions do have a more specialized body of law to draw from with respect to the written description requirement.

The guidelines should be restructured as suggested in section I of these comments to provide a technology-neutral description of the legal requirements of the written description requirement. The methodology for evaluating applications for compliance with the written description should likewise be presented in a form applicable to all areas of technology. As mentioned above, we suggest that the PTO should use training materials to illustrate how the guidelines would be applied to specific types of inventions.

4. *Should the scope of these guidelines encompass all technologies? If so, please comment:*

Please refer to our answer to question 3, above.

5. *How should "possession of the invention" be defined for purposes of applying the written description requirement?*

As specified in numerous cases, "possession of the invention" is to be evaluated by looking to the claims, which define the invention. *See, Hyatt v. Boone*, 146 F.3d 1348, 47 U.S.P.Q.2d 1128 (Fed. Cir. 1998), citing *In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. (BNA) 465, 467 (CCPA 1978) ("[i]n all cases, the purpose of the description requirement is "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.") The fairly recent decision of the Federal Circuit in *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996), succinctly summarizes how this possession question is to be assessed:

In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008,

1012, 10 U.S.P.Q.2d (BNA) 1614, 1618 (Fed. Cir. 1989) (citation omitted). Put another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath*, 935 F.2d at 1563-64, 19 U.S.P.Q.2d (BNA) at 1117. Finally, we have stated that "precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." *Eiselstein v. Frank*, 52 F.3d 1035, 1039, 34 U.S.P.Q.2d (BNA) 1467, 1470 (Fed. Cir. 1995) (quoting *Vas-Cath*, 935 F.2d at 1561, 19 U.S.P.Q.2d (BNA) at 1116).

Given that the question of compliance with the written description is one of fact, rather than law, it is imperative that compliance be assessed on a case-by-case basis. The fact-specific nature of the inquiry further justifies reliance on training materials to illustrate the proper application of the guidelines to certain types of cases and issues.

6. *How should the transition terms "having" and "consisting essentially of" be treated within the context of nucleotide and amino acid sequence claims?*

Generally speaking, the meaning of the two terms will be governed by the definition or manner of use of them by the applicant in the specification and/or through statements made by the applicant during prosecution. The practice of the PTO of giving claims their broadest possible interpretation during examination should be followed in interpreting claims that use these types of terms. In certain well-settled technology areas, an art-accepted meaning of the phrases such as "having" or "consisting essentially of" can be identified. In those cases, these phrases, without an explicit definition in the specification, can be given the art accepted meaning by the examiner during prosecution of the application. The applicant's reaction to the examiner's interpretation can be then addressed during the prosecution and evaluation of the claim breadth.

If there is no such art-accepted meaning, and no definition is provided in the specification, then we suggest that:

- the use of the term "having" would imply an open-ended claim format; meaning the same as "comprising"; while
- the use of the phrase "consisting essentially of" would imply a closed claim format that is essentially limited to the compound or composition defined explicitly following the transitional phrase.

In fact, we do not believe that there is any consistent art-accepted meaning for the terms "having" or "consisting essentially of" with respect to the two classes of inventions noted in the question. Both terms could imply that the applicant sought protection over either a composition comprising the identified sequence, or a large class of species of chemical structures that include

within a larger sequence a specified sub-sequence. Therefore, in the absence of an explicit definition of what the terms are intended to mean, we believe the PTO should interpret the terms as described above.

7. *How should the guidelines be expanded to specifically address process and/or product-by-process claims?*

Process claims tend to not implicate many written description issues because processes are usually adequately described by reciting the particular process steps and the order in which they are to be executed. It may be useful in the guidelines to point out that if there is a question about whether the process is capable of producing the indicated product or result, the deficiency may be one of enablement, rather than written description. This also applies to product-by-process claims.

8. *How should the final guidelines address the deposit of a biological material made under 37 CFR 1.801?*

As noted above in section I, the guidelines should clarify that deposit of a compound or of biological material can be one means of demonstrating possession of a specifically claimed compound that has not otherwise been described in a complete manner in the specification. Thus, isolation of a *claimed* nucleotide sequence, coupled with disclosure of certain physical characteristics of the compound (i.e., molecular weight, partial sequence) and a deposit of that sequence should be adequate to demonstrate *possession* of the compound (i.e., the isolated nucleotide sequence). If an applicant further characterizes the isolated sequence (e.g., by providing additional sequence data), and provides information concerning inherent physical characteristics of the isolated sequence, that should not be viewed as introduction of new matter.

9. *What impact will the guidelines have on issued patents, currently pending applications, or applications to be filed after publication of the final written description guidelines?*

As discussed above, we believe it is important for the PTO to clearly state that the guidelines are not intended to create new law, but are merely a tool for conducting the evaluation of applications for compliance with the written description requirement under existing law. To that extent, the guidelines *per se* should not be regarded as having any impact on issued patents, currently pending applications, or applications to be filed after publication of the final written description guidelines. What does have an impact is the underlying statutory and case law, and changes in that law.

10. Is there any basis in law or fact for treating expressed sequence tags (ESTs) differently than any other nucleic acid under the written description requirement?

As we see it, the problem posed by ESTs has to do with how they are claimed. The problem arises when an applicant seeks a claim to a broad genus of nucleic acid sequences (for example, nucleic acid comprising . . .), for which the only known and disclosed common feature is the sequence of the EST. As discussed above, that problem is not unique to ESTs. We believe that any genus that is claimed merely by reciting some common sequence element (whether that element is an EST or something else) raises a serious question with respect to written description, because of the multitude of functionally different compounds that are encompassed by such a claim.

A claim to "nucleic acid comprising an EST" clearly would dominate a wide range of "downstream" products, including the full-length gene of which the EST is a part and even a polypeptide encoded by the gene. To be entitled to such a claim under the current law on written description, the application would have to show that the applicant had possession of that functionally disparate subject matter. But that simply cannot be the case if all the applicant has done is identify an EST. The mere identification of an EST, without more, clearly does not place one in possession of any full-length gene or its encoded polypeptide. Furthermore, such a claim may also fail to satisfy the written description requirement on the grounds that it is not directed to a properly formed genus, if the members of the purported genus do not in fact possess any common structure or function that is linked to the disclosed utility of the EST.

In view of the particular written description problems presented by genus claims, we suggest that the guidelines should include some guidance to examiners on how to determine whether a genus has been properly claimed. For example, we believe that a genus that is based merely on the identification of an EST may properly be claimed by the use of "consisting of" or "consisting essentially of" transition terms, since that would have the effect of limiting the genus to a group of compounds having the same or essentially the same structure as the EST, and thus presumably having the same or essentially the same function as the EST.

11. Are there additional issues related to other statutory requirements of Title 35 invoked in the patenting of ESTs? If so, please set forth those issues separately and specifically.

Such additional issues are mentioned in the attached copy of oral testimony provided on behalf of Genentech at the PTO public hearing on November 4, 1998.

III. Concluding Remarks

Genentech believes that the interim guidelines will require a substantial revision to address the concerns expressed above and by other commentators. If such substantial changes are made,

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Genentech respectfully requests that the PTO publish the new version of the guidelines in an interim format to afford the public yet another opportunity to provide input prior to the development of a final form of the guidelines. Needless to say, Genentech would be pleased to be involved in the further efforts to refine and improve the guidelines.

Thank you for your consideration.

Very truly yours,
GENENTECH, INC.



Sean A. Johnston
Vice President, Intellectual Property