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11 November, 1998

Commissioner of Patents and Trademarks  
Box 8  
Washington, D.C. 20231

Attn: Scott A. Chambers

RE: Revised Comments on Written Description Guidelines

Dear Mr. Chambers,

Please accept these revised comments in light of the PTO's extension of the period for response and in light of my oral testimony on 4 November 1998.

Thank you for your consideration of my request.

Respectfully submitted,



Herbert H. Jervis  
Vice President and  
Chief Intellectual Property Counsel

**Pioneer Hi-Bred International's Comments on the PTO's Interim  
Guidelines on Written Description  
(REVISED: 11 November 1998)**

**General Comments:**

Please accept these revised comments in light of the PTO's extension of the period for response and in light of oral testimony provided by Pioneer's representative on 4 November 1998.

First, the PTO is to be commended for this effort. It is extremely helpful to understand the PTO's thinking and even more helpful to be able to express our views. It is this type of proactive exchange that, in the long run, strengthens the patent system and promotes effective prosecution.

It is our opinion that the guidelines should be broadly applicable both as to class of invention (e.g., products and processes) and to art area (e.g., biotech and others). Obviously, the guidelines seek to adapt PTO practice to recent Federal Circuit decisions in the biotech area, however, the that same court on numerous occasions stated that DNA is best viewed as a chemical polymer and that the chemical patent case law should be applied where appropriate. We should refrain from making biotech a special case as was done; unnecessarily some would say, with regard to 35 U.S.C. §103(b).

Although there are cases that tend to blur the distinction, we believe the weight of authority supports the proposition that the written description and enablement provisions of 35 U.S.C. §112 are separate and distinct. A particular specification may or may not satisfy the two provisions, independently. Unfortunately, at times, these proposed guidelines tend to mix the two issues.

Finally, as last general comment, it would appear that an over emphasis is placed on the claims, particularly on the preamble. While five of the six paragraphs that constitute section 112 relate to claims, the first paragraph of section 112, in which the written description provision occurs, is directed to the requirements of the specification not the claims.

### Specific Comments:

#### Section I:

This section is fine as far as it goes, but we think the PTO might be missing an opportunity to highlight in the discussion the other important function of the written description, that is, as an "anti-submarine" patent device. Perhaps the reference to the *Vas-Cath* case could be expanded to illustrate the negative implications of a written description that fails to particularly describe the invention at the time of filing. There is some nice language in that case concerning a drawing that is not specific enough in pointing out the features of the invention.

#### Section II A:

The introductory prepositional phrase in this section illustrates one of the general comments above. Claims don't have to satisfy the written description requirement, specifications do. Footnote 7 immediately before this section cites correctly *In re Koller* for the proposition that originally filed claims constitute their own written description.

At line 7 of this section, the reference to "possession" should be clarified to indicate that one does not necessarily have to have "physical" possession, but must have a complete conception of the invention in mind.

The remainder of the paragraph we find a bit confusing and, therefore, not very helpful. We don't understand how the discussion of predictability is that relevant to written description. We appreciate the inverse relationship as it applies to enablement, but not necessarily to written description. We would think it possible to provide a written description of a complex molecule in an unpredictable art area. One might have other problems relating to utility, enablement, etc., but the structure would stand as a written description.

#### Section II B:

Again, we think there is too much emphasis on claim structure here. The thrust is, almost, as if the claim was the sole source of the written description. Further, we think the PTO should reinforce the notion that "sequences" are not patentable, anymore than "formulas" are patentable. What is patentable is, of course, the isolated composition of matter having the formula or sequence. If the inventor is in possession of a nucleic acid larger than the portion sequenced, he need only describe it in such terms the

skilled artisan will understand that he was in possession of the larger molecule (e.g., mol.wt., size, RE patterns etc.).

In the third paragraph, the person doing the "envisioning" seems misplaced. Isn't the test that written description is sufficient if the artisan can understand that the inventor had envisioned the various members of the genus? The same comment can be made with respect to the last paragraph of this subsection.

#### Section II C:

Subsection C (1) is straightforward and acceptable. Subsection C (2) is also fine and comports with the direction given in the *Fiers* case. The only point that might be stressed is when one is considering "other relevant characteristics" that they must be "identifying" characteristics; that is, they must be sufficient to distinguish the invention.

#### Section II D:

This section calls for greater clarification. It is in this section that the concepts of enablement and written description become the most confused. Also the discussion of open and closed claiming is misplaced and the consequences as proposed by the PTO, we believe are untenable.

A written description of a genus is sufficient when it is described in enough detail that possession is understood. The reference to sufficient number of species relates more to whether the genus is enabled rather than described. Further, the example used is probably not the best choice, because it seeks to associate taxonomic groupings with specific gene sequences. We appreciate this approach was at issue in some of the earlier cases, e.g., *Lilly, Amgen, et al.* Such claim practice is a bit dated and evidences a fundamental misperception of molecular evolution that should not be fostered in these guidelines. Briefly, DNA is DNA. The same four bases, sugar and phosphate moieties are present in all species. In the ruminant mammal example, the DNAs of the species recited would only be distinguishable, if at all, on the broadest of measures such as the C value—the total amount of DNA/ haploid genome or perhaps on the G+C content as measured from the total DNA both coding and noncoding regions. Looking at a particular coding sequence in isolation, one would be hard pressed to uniquely identify its origin. That is to say, just because DNA from a calf has an overall G+C content of 40%, that doesn't mean a particular gene isolated from a calf has a 40% G+C content. In order for one to create a true generic description of the "ruminant mammal gene" one would take the sequence information from as many species contemplated by the inventor and by a

system of "R-groups" account for all of the various differences at each base or amino acid position. Not a consensus sequence where the most frequently occurring base is selected, but a structure that would accommodate all occurrences characteristic of each member species.

For example consider the following five sequences representing five species from five different ruminant sources:

MET PHE LYS SER ARG

MET TYR ARG SER ARG

MET TRP LYS SER ARG

MET PHE LYS SER LYS

MET PHE LYS SER LYS

A consensus sequence would be written as:

MET PHE LYS SER ARG

A generic sequence, however, would be written as:

MET XAA XAA SER XAA

wherein, the XAA in position 2 is defined as PHE or TYR or TRP, the XXAs in positions 3 and 5 are defined as ARG or LYS.

Assuming free substitution at each position, the generic formula contemplates additional peptides, for example:

MET TYR LYS SER ARG

MET TYR LYS SER LYS

MET TRP ARG SER ARG

MET TRP ARG SER LYS

Whether these additional species are legitimate members of the genus might involve issues of utility (do they possess the appropriate function?) or enablement (is the art unpredictable?) or novelty (if one might represent a prior art sequence from a non-ruminant source). In such cases a claim to the generic class may need to include "proviso" language to specifically rule out certain species.

Returning the example in Section II D, the sequence variation very much depends on the gene/protein in question. Consider a highly conserved protein such as cytochrome C (there have been only about 40 amino acid changes in all of God's critters in the last 21.4 million years). As a result there are no differences in amino acid sequence from cow, sheep or pigs. Thus a claim "sheep" cytochrome C would be anticipated by the "cow" sequence. Viewed from this perspective the references to "sheep" DNA or "cow" DNA are really only shorthand way of saying DNA "when isolated from a sheep or cow. As such they are a form of "process" limitation not product description.

This situation is just another illustration of the differences between biologists and chemists in how they tend to describe things. Biologists tend to talk functionally, describing things in terms of what they do or how they are obtained, whereas chemists talk structurally and describe things in terms of what they are.

One way to claim molecules more generically, is by using the identified sequence as a reference and claim other molecules that are structurally related such as by % identity or similarity as those terms are used and measured in the art. We appreciate that the PTO currently favors claims based on "hybridizing" to the reference sequence under a specified set of hybridization conditions. While such a claim satisfies the PTO's concern regarding definiteness, etc., we think such claims will be tough to litigate because the opposing side (notoriously nefarious so-and-sos) will find "experts" to testify that the alleged infringing compound doesn't hybridize in the conditions specified. We also appreciate the same argument could be made about % identity, but if one uses the same referenced mathematical process to determine the identity value, the result should be less susceptible to challenge.

**Subsection D (1):**

This section appears to raise more problems than it solves. There is a preamble issue. Does the term "probe" explicitly or inherently place a size limitation on the DNA hybridizing to the reference? Could it read on the whole gene? It might be a lousy probe but still work. What if the several additional sequences were not described, would the stringency limitations alone be enough to describe the genus?

**Subsection D (2):**

Reference is made in the discussion of the antibody example to the "isotype claimed". In the sample claim given, there is no isotype limitation recited.

In the example of the DF3, the use of the term "novel" is inappropriate in a claim and should not be encouraged by the PTO. All patentable inventions are by definition novel and merely reciting it doesn't make it so. The estoppel consequences of deleting the word during prosecution stagger the imagination!!! Also in the example isn't there more of a problem with the written description of the species of "heterologous genes" than with the enhancer?

Finally, the last example of "a DNA comprising a SEQ ID..." is the EST claim scope problem. There is simply no way an inventor can have a complete conception of the entire gene from the EST, assuming, as we must, the opinions in *Amgen* and *Fiers* provide the law on conception of nucleic acids. Therefore, granting a claim covering such is dead wrong. For example, there are well known cloning strategies for the 5' end of a gene and the 3' end of a gene. Also there are motif cloning strategies base on internal gene sequences. Apparently, under the PTO proposed position, patentee 1 could claim DNA comprising 5'EST, patentee 2 could claim DNA comprising 3'EST and patentee 3 could claim DNA comprising internal EST. Each claim could read on the same piece of DNA. We understand the law in the United States to be one patent per invention and that patent should vest in the first inventor. The open language proposed for ESTs does violence to these fundamental concepts. What about the poor sole that does all the work and invents the entire gene, is she saddled with three royalties?

Granting such open-ended claims in the absence of an adequate disclosure represents an end run around these very guidelines. In traditional chemical practice one does not encounter claims of the form: a compound comprising...". Composition claims may use such transitions, e.g., a pharmaceutical composition comprising a compound of formula X, but not the compound claims. The breath of a compound claim arises from the ability of the inventor at the time of filing to conceive of a large number of structurally related species. It does not arise from open claim language. The chemical practice equivalent of the EST claim proposed by the PTO would be: "A compound comprising a half a benzediazapine molecule". Implicit in such a claim is the statement "trust me on the other half, I'll let you know if I or anyone else finds it". We believe that the current Federal Circuit opinions give fair guidance for the crafting of DNA claims. The proposal to grant open-ended claims for ESTs appears on its face, to conflict with those opinions. Applicants should not be placed in the position to have to reconfirm this proposition through extensive and expensive court proceedings.

Again, we very much appreciate the opportunity to respond to these guidelines and would be happy to discuss our views further.