

Dear Mr. Walsh:

Thank you and the PTO for the opportunity to comment on the revised Draft Examiner Guidelines on Written Description Requirement. I believe that the PTO has been very responsive to the excellent comments received on the earlier guidelines, and hope you will continue to work with patent applicants and their representatives to develop exemplary written description comments. I know you have received a great many comments from the biotechnology industry, as well as other industries, and wanted to comment on two specific footnotes which I believe require some further clarification.

1. Footnote 13. The guidelines state [citing *Lilly* for support] "the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention."

I believe the above statement is inaccurate, as well as vague and indefinite, to categorically state that "a great deal more than just a process" is needed. It is also inconsistent with the "strong presumption that an adequate written description of the claimed invention is present when the application is filed." All that is needed for written description is "a written description of the invention describing sufficient relevant identifying characteristics such that a skilled person would recognize that the inventor had possession of the invention." That will vary depending upon the nature of the claims, the invention, etc. As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product.

Footnote 14 states that a "laundry list" disclosure of moieties does not constitute a written description of every species in a genus. The guidelines cite chemical cases with generic R-groups where an innumerable number of disparate possibilities exist, and may not truly constitute a functional genus. However, if existence of a functional genus is adequately supported in the specification, or through external evidence, to be interchangeable for the purpose recited in the claims, a laundry list of the species within that genus **must** satisfy the written description.

Thank you for your attention to this important matter.

Steve Lazar,
Senior Patent Counsel, Genzyme Corporation