

Chambers, Scott

From: Watkins, William
Sent: Sunday, September 13, 1998 5:20 PM
To: Chambers, Scott
Subject: Comments 112 Written Description Interim Guidelines

Mr. Chambers,

I am not sure if I am allowed to comment on the proposed guidelines as I am a PTO employee. Please treat my personal comments on the guidelines published at 1212 OG 15 on July 7, 1998 as formal or informal as is appropriate.

- 1) Section II A. states that the application should be reviewed to determine the state of skill in the art and the degree of predictability in the art. This may differ from the "Enablement Decision Tree" on page 45 of the Enablement Training Manual dated August 1996 which requires that a search of the prior art be made, after the analysis of the application specification and claims, before a determination of the predictability of the art for purposes of enablement. It is unclear if a full search to locate prior art must be made before a determination of the predictability in the art for the purpose of analysis of the written description requirement.
- 2) Regarding product by process, and process claims it appears in general to be illogical not to extend the guidelines to these areas. As the same product can be either claimed directly by a product claim, or indirectly by a product by process claim, it would produce a bad result if the guidelines apply to only one form of claim. As 35 U.S.C. 103(b) allows patentability of processes based on product patentability, it would again produce an uneven result if the guidelines do not also apply to the process claims. Of course product by process claims started as a way to claim substances that could not be easily characterized. This purpose is somewhat eviscerated if a full structural determination of the product is required. I would suggest that product by process claims in areas of poor structural predictability be limited to the substances produced by the processes used to produce the actual working examples in the specification or to as broad a scope as the structural predictability of the art will allow. The applicant obviously has possession of any substances actually produced even if they are not fully characterized. The same goes for process claims that rely for patentability on the manipulation or production of products that are in areas of poor structural predictability. Absent an adequate structural determination they should be limited to the scope of the working examples or to the scope allowed by the structural predictability of the art.
- 3) The guidelines should take a position as to the substance of the guidelines applying to the determination of new matter and declaration practice under 37 C.F.R. 131 (M.P.E.P. 715.03) as these are closely related areas where examiners will be tempted to extend the guidelines.
- 4) I agree that the guidelines should extend to all unpredictable structural areas. It would be helpful, however, to distinguish mechanical areas such as the sofa art described in *The Gentry Gallery Inc. v. The Berkline Corp.*, 45 USPQ 2d 1498 from the level of unpredictability in biotechnology.

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