

Chambers, Scott

From: LAWRENCE.M.LAVIN.JR@monsanto.com[SMTP:LAWRENCE.M.LAVIN.JR@monsanto.com]
Sent: Monday, September 14, 1998 4:23 PM
To: Chambers, Scott
Subject: Comments on Written Description Guidelines

Dear Mr. Chambers:

I would like to submit the following comments to the written description guidelines published in the Federal Register, Vol. 63, No. 114, pages 32639 et seq. These comments are made on a personal basis, and are not necessarily the views of my company.

I would particularly like to address the example on page 32640 carrying over to page 32641. There the guidelines seem to suggest that one can have written description support for a genus - i.e., a DNA sequence comprising Sequence ID No. 1, yet not have written description support for the species, e.g., a gene comprising Sequence ID No. 1. This situation can arise in a number of situations where one has a piece of DNA early in a research program, but as yet has no idea what the piece of DNA is part of or how it functions, other than as a probe to find other similar pieces of DNA. One further may not be able to articulate clearly with what other pieces of DNA this piece can be used (other than through standard hypotheses of uses for other undefined pieces of DNA.) In that situation, I'd agree that the researcher does not have written description for a gene containing that piece of DNA, but I am also of the view he does not have written description support for a genus claim as proposed in the example - a DNA sequence comprising Sequence ID No. 1, which encompasses the DNA sequence wherever it occurs. He has no evidence for possession of that invention.

As I read cases such as *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), written description requires evidence of possession of the invention. In the case where a researcher has a piece of DNA from random sequencing, such as an EST, the researcher only has possession of that piece of DNA as it sits - as a defined-length sequence. Therefore, he may have written description support for a probe consisting of that piece of DNA or of that piece of DNA itself, but in no manner has the researcher possession of the DNA sequence wherever it occurs, including flanking sequences fore and aft. Indeed, as is often the case, thousands of pieces of DNA may have been sequenced by or on behalf of the researcher and the researcher probably could not even identify, without additional information, the particular DNA sequence as being his invention, let alone having possession of an invention comprising that piece of DNA wherever it occurs.

The rest of the guidelines clearly state that written description support requires either the structure of the thing claimed or sufficient characteristics to evidence possession of the thing claimed. This example seems to contradict the guideline as it permits a claim that neither sets forth the structure claimed (using the comprising language) nor requires provision of any additional evidence of characteristics similar to those set forth in section C of the guidelines. I would recommend removal or revision of this example from the guidelines.

Respectfully submitted,
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