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July 30, 1998

VIA FACSIMILE (703-305-9373)

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

CONFIRMATION C

Attn: Mr. Scott A. Chambers
Associate Solicitor

Re: Comments on Interim Guidelines for
Examination of Patent Applications
Under 35 USC 112, Paragraph 1,
"Written Description" requirement

Dear Mr. Chambers:

These are the undersigned's personal views. The undersigned is a shareholder in the above-identified law firm.

I have been thinking how to present my position and had intended to give maximum consideration by responding in September. However, having learned yesterday at the Group 1600 Open House that the guidelines are already in use despite the time for comments not having been completed, it seemed that I should give my comments now and add to them later if I have further thoughts.

U.S. PATENT AND TRADEMARK OFFICE

58 AUG -4 AM 11:35

ASSISTANT SECRETARY

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In summary, my view is the guidelines are defective from a public policy standpoint and from a legal standpoint and will result in a great increase in the number of appeals until the CAFC makes clear that the law is quite different.

I turn firstly to the public policy issue. Most of my biotechnology work is for universities. The disclosures that come to me would not permit obtaining meaningful (broad) patent coverage so far as biotechnological inventions are concerned; that is, the coverage allowed under the present guidelines could be avoided by mutated or altered genes or altered peptides and proteins. While a hybridization limitation could provide broad coverage, a gene is not necessarily isolated by a method involving hybridization.

While large companies may be able to back the kind of work necessary for meaningful coverage under the guidelines, the inventors I deal with just do not have the financial support to provide the exhaustive kind of work the guidelines can require for meaningful coverage. The upshot will be that patents will not be obtained, in many cases, that provide meaningful coverage, and this will mean that many biotechnology inventions will not be commercialized.

Before now, the PTO tried to limit coverage by applying the enablement requirement. Now that the CAFC has clearly indicated that the PTO position on enablement has been wrong, the PTO is switching to a different ground for limiting coverage. This has never made sense to me and does not make sense to me now. Commissioner Lehman gave a talk yesterday indicating meaningful patent coverage is required for commercial exploitation of biotechnological inventions and suggested that many will die or not be cured without this, and yet the PTO has long taken a position and continues to take a position that leads away from what Commissioner Lehman espouses.

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I turn now to the law. In my view, the PTO is trying to make law here, and in my view, this is not a proper allocation of PTO resources. My opinion is that generally the law is represented by In re Bowen, 181 USPQ 48 (CCPA 1974) which holds that a description requirement rejection will be defeated by a specification which describes an invention in the same terms as the claims. In my view, California v. Lilly, Fiers and Amgen represent exceptions to the general rule carved out by the CAFC for a few exceptional cases involving DNA where it considered the work done did not justify the coverage sought, i.e., isolation of a rat gene should not be basis for coverage on a human gene, a few analogs of a gene should not provide coverage on every possible analog when it is not predictable what utility will be possessed by each analog, and reference to a potential method of isolation of a sequence does not justify coverage on a sequence. In my view, not only should the PTO not extend the guidelines to other technologies, it should restrict them to the specific instances where the CAFC has spoken.

I turn now to what I predict will be the result of continuation of the interim guidelines. There will be many instances where applicants will not be able to meet what the guidelines will require for meaningful patent coverage and yet will have carried out work that will allow therapeutic results. In these instances, there will be many cases where there will be no choice but to appeal, to try for coverage which will protect commercial exploitation. This will mean an increase in the already high backlog at the Board of Appeals and Interferences and a delay in putting into use many potentially life improving and life-saving inventions.

Very truly yours,



Eric S. Spector

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