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From: JENJ (Jennifer Johnson) [mailto:johnsonj@zgi.com]

Sent: Friday, April 28, 2006 7:21 PM

To: AB93Comments

Subject: ZymoGenetics' CEO Comments to Proposed Rules on Continuation Practice

Importance: High

Attn: Robert W. Bahr

Senior Patent Attorney

Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Bahr,

Please post the attached .pdf on the Comments Regarding Proposed Rules for "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 F.R. 48 (January 3, 2006).

Sincerely,

Jennifer K. Johnson

Jennifer K. Johnson

Associate General Counsel, Patents

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ZYMOGENETICS

April 28, 2006

Jon W. Dudas, Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office

USPTO

Madison West, Suite 10D44
600 Dulany Street
Alexandria, VA 22314

RE: USPTO Proposed Rules Limiting Multiple Continuing Applications (71 F.R. 48)

Dear Under Secretary Dudas:

We hope that the USPTO will consider the impact of the proposed rules on innovation, public benefit, and finances for all industries and would not create a rule that may severely damage one industry. We are concerned that these rules will stifle the biotechnology industry's ability to obtain meaningful drug patents that would protect our drugs that help patients with medical conditions and diseases, and attract investors that enable us to develop such drugs.

Historically, biotechnology companies like ZymoGenetics have used multiple continuing applications to obtain a meaningful scope of drug patents that both narrowly cover a drug itself and that more broadly cover an area of protection surrounding the drug. Multiple applications allow us the opportunity to provide specific data and information to the USPTO as we advance a drug from discovery into clinical trials and eventually to patients. If we are denied this opportunity, we could be caught in a predicament where we cannot obtain needed scope of patent protection for drugs because continuing applications have been denied; and we are forced to accept very narrow patents prior to knowing the precise form of the therapeutic drug. Resulting patents might not cover the actual form of the therapeutic drug used in patients nor provide adequate broader protection against potential infringers making minor modifications to the drug.

ZymoGenetics' patents have enabled us to develop drugs which hopefully will help patients with deadly diseases, such as lupus and cancer, and disabling diseases such as rheumatoid arthritis and multiple sclerosis. As a small business, our patents have enabled us to attract investors who believe in the pursuit of such cures; and this investment has enabled us to advance drugs into the clinic. Without meaningful drug patents, investors may no longer support biotechnology industry efforts needed to make drugs, which could severely damage the business. Without the biotechnology industry fewer new drugs would be developed to help patients fight their diseases.

To avoid weakening our portfolio of over 190 patent families, which are each divided by the USPTO into 5 to 50 or more applications, we will need to file many continuing applications before the proposed rules go into effect. This year we would likely have to file at least 881 applications costing at least \$1.762 million in filing fees alone. This cost does not include the cost of personnel resources at ZymoGenetics needed for their preparation. These applications will certainly add to the current backlog of unexamined applications at the USPTO, but more importantly this unanticipated cost will immediately injure our business.

We urge you *not* to go forward with the proposed rule changes.

Sincerely,

Bruce L.A. Carter
President and CEO
ZymoGenetics, Inc.

CC: Commissioner of Patents, John Doll