

The Honorable Susan E. Dudley
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

June 15, 2007

RE: RIN: 0651-AB93

TITLE: Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims (“Continuations Rule”)

RIN: 0651-AB94

TITLE: Changes to Practice for the Examination of Claims in Patent Applications (“Limits on Claims Rule”)

Dear Administrator Dudley:

We are writing to express our deep concern about these two draft final rules now under review by the Office of Management and Budget (OMB), which were submitted by the U.S. Patent and Trademark Office (USPTO) as required by Executive Order 12,866 (as amended). Both rules were published for public comment on January 3, 2006,¹ and have been the subject of several public meetings in which senior USPTO officials actively participated.² To the best of our knowledge, the draft final rules (which we have not seen) are essentially the same as the Notices of Proposed Rulemaking, despite the fact that USPTO received hundreds of public comments highly critical of both proposals. For your convenience, our comments to USPTO on the Notices of Proposed Rulemaking are included as Attachment A.

Our concerns with these rules are both procedural and substantive, but we believe that procedural defects alone justify returning these rules to USPTO for further consideration. These defects concern:

¹ See 71 Fed. Reg. 48 and 71 Fed. Reg. 61.

² USPTO’s web page on these rules, <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html>, lists 19 “Town Hall” meetings. At these meetings and in several later public presentations, USPTO has steadfastly defended the rules as proposed.

- (1) USPTO's failure to adhere to the regulatory philosophy and principles of Executive Order 12,866;
- (2) USPTO's violation of the Information Quality Act and OMB's implementing guidance; and
- (3) significant discrepancies between USPTO's claimed *savings* in paperwork burden and the *increase in actual* burden specifically mandated by the Limits on Claims Rule.

(1) Failure to adhere to the regulatory philosophy and principles of Executive Order 12,866

These two draft rules, together with a third on related subject matter that has not yet been submitted to OMB,³ should be viewed as a package and deemed economically significant for purposes of review under Executive Order 12,866. It is easy to envision these rules having effects in excess of \$100 million in any one year and adversely affecting the economy in a material way – in particular, its most innovative sectors, which create patentable inventions worth billions of dollars each year. A proper Regulatory Impact Analysis is required to understand fully the likely adverse effects these rules will have on innovation in general and the patent process in particular. We outline our arguments why these draft rules are economically significant in Attachment B.

USPTO has not provided any showing that these draft rules are consistent with the regulatory philosophy set forth in Sec. 1(a) of Executive Order 12,866 (as amended), or the principles of regulation set forth in Sec. 1(b). In particular:

- **NEED FOR REGULATION:** USPTO has not explained in writing why these rules are needed to implement statutory law or are made necessary by a compelling public need.
 - In Attachment C, we show why these draft rules are neither statutorily required nor needed to implement statutory requirements (EO 12,866 Sec. 1(a)).
 - In Attachment D, we show why USPTO's rationales for regulation violate the principles of Executive Order 12,866 (Sec. 1(b)). For example, the preamble to the proposed Limits on Claims Rule has no discernable regulatory rationale. For the proposed Continuations Rule, USPTO alleges that the regulation is needed to reduce agency backlog without regard for the social costs this would have on innovation and the protection of statutory intellectual property rights.

³ RIN 0651-AB95, "Changes to Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808 (July 10, 2006).

- In Attachment E, we show why USPTO lacks the authority to promulgate these draft rules and that the way it has gone about it almost certainly violates the Administrative Procedure Act.
- REGULATORY AND NONREGULATORY ALTERNATIVES: Neither of the rule preambles identifies reasonably available alternatives, and there is no public evidence that USPTO considered any. Moreover, at the roughly two dozen subsequent public meetings in which senior USPTO officials participated, we know of no evidence to suggest that any alternatives were seriously discussed, except by *retired* USPTO officials.
 - In Attachment F, we show that other factors have caused or contributed to the backlog USPTO seeks to reduce by regulation, most notably the flawed metrics by which the Office evaluates and incentivizes its patent examiners (the “counts” system).
 - In Section IV of Attachment H, we explain that the backlog problem is best understood as a congestion externality and why that model offers keen insight concerning how it could be solved in a way that enhances rather than compromises the protection of property rights.
- REGULATORY ANALYSIS: USPTO’s proposed rules were accompanied by no analysis of social benefits and costs – only the assertion that they would simultaneously reduce Office backlog and benefit innovators.
 - In Attachment G, we show that USPTO did not rely on the best available scientific, technical, economic and other information, as Sec. 1(b)(7) requires. The Office has a database containing millions of patent applications, each of which has followed a specific path through the examination process. There’s no public evidence that USPTO analyzed this database beyond generating the coarsest descriptive statistics.
 - In Attachment H, we show why the coarse descriptive statistics USPTO reported are invalid and unreliable.
- SELECTING THE MOST COST-EFFECTIVE ALTERNATIVE: Even if it is assumed that regulation of some sort is needed, USPTO has disclosed no evidence that its regulatory approach is the most cost-effective, as Sec. 1(b)(5) requires. The “benefits” USPTO emphasizes are reductions in Office backlog. Until it has considered and analyzed a range of reasonably available alternatives, USPTO could not have any idea which of the available actions that it *could* take offers the greatest net social benefit.
 - In Attachment H, we show that even these “benefits” are largely illusory. The Limits on Claims Rule will result in a significant increase in patent applications to accomplish the same level of protection of intellectual property. The Continuations Rule will overload senior members of the examining corps and the Board of Patent Appeals and Interferences.

- In Attachment I we show why we believe these draft rules are clearly *not* cost-effective. (Nevertheless, we are confident that a Regulatory Impact Analysis that adheres to Circular A-4 is the best way to find out for sure.)
- In Attachment J, we provide evidence strongly suggesting that the remedy USPTO offers to avoid the otherwise unduly harsh effects of the Continuations Rule does not actually exist.

(2) Violation of the Information Quality Act and OMB's implementing guidelines

USPTO has supported and defended its proposed rules in ways that violate the Information Quality Act and OMB's (and USPTO's) Information Quality Guidelines. In both the preambles and the regulatory dockets, the limited information that USPTO disclosed is not transparent, reproducible or objective. USPTO officials subsequently promoted the proposed rules in almost two dozen public forums, in each instance citing influential information that was not transparent, reproducible or objective. USPTO officials refused to publicly disclose the analyses on which it says it based its preferred (and only discussed) alternative, asserting that these analyses were pre-decisional and thus exempt from disclosure and public review.

- In Attachment K, we show that the influential information USPTO has disclosed in support of its proposed regulatory actions does not adhere to applicable information quality principles and guidelines.
- In Attachment L and Attachment N, we document our efforts to obtain the information on which USPTO relied in crafting these rules, and its refusal to make this critical information public – except in confidence to a handpicked group of trade association representatives.

(3) Discrepancies between USPTO's claimed *savings* in paperwork burden and the *increase in actual* burden specifically mandated by the Limits on Claims Rule

Certain provisions in the proposed rules would impose significant new or expanded paperwork requirements, yet USPTO claims that both rules would *reduce* paperwork burden.

- In Attachment M, we show that USPTO's paperwork burden estimates are invalid and unreliable. If properly estimated, we are quite confident that the actual burdens would be revealed to be much higher than what USPTO's claims. In addition, we show why these rules would significantly increase burden, rather than decrease it as USPTO has predicted, especially if applicants followed the proposed new procedures for applications containing more than 10 claims.

We would like to work with your staff (as provided for by the Paperwork Reduction Act) to help ensure that USPTO's burden estimates are realistic. Because applicants bear the paperwork burdens *and* pay user fees at a cost-recovery level for USPTO examining applications, we believe we are best equipped to identify ways to reduce both paperwork burden and total cost.

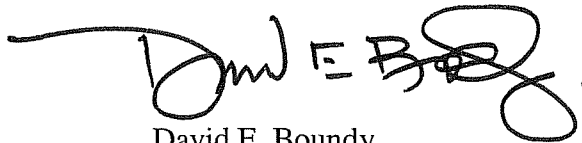
Honorable Susan E. Dudley

June 15, 2007

Page 5

Because of these myriad procedural defects, we believe that OMB should return these draft rules to USPTO and designate them as economically significant. A Regulatory Impact Analysis fully compliant with OMB Circular A-4 ought to be prepared and published for public comment. All influential information used to support this analysis should adhere to the principles of OMB's (and USPTO's) Information Quality Guidelines. With these tasks completed, USPTO would be able to propose an informed set of reasonably available regulatory and nonregulatory alternatives and identify the one that maximizes net benefits to society. If USPTO has a compelling reason for preferring a different alternative, the Office can make the case that the United States ought to bear these opportunity costs and those who disagree can engage in a proper public policy debate.

Sincerely,

A handwritten signature in black ink, appearing to read "David E. Boundy". The signature is stylized and includes a long horizontal flourish extending to the left.

David E. Boundy
Vice President, Intellectual Property
Cantor Fitzgerald L.P.
110 East 59th St.
New York, NY 10022

On behalf of the undersigned companies

SIGNATORIES

Bryan P. Lord
General Counsel
AmberWave Systems Corp.
Salem, NH

Dr. James E. Butler
Senior Director, Patents
Amylin Pharmaceuticals
San Diego, CA

Michael C. Schiffer
Vice President, General Patent Counsel
Beckman Coulter Inc
Fullerton, CA

Karin Eastham
Executive Vice President and COO
Burnham Institute for Medical Research
La Jolla, CA

David L. Gollaher
President & CEO
California Healthcare Institute
La Jolla, CA

Dean Alderucci
Chief Operating Officer and Assistant
General Counsel
Innovation Division
Cantor Fitzgerald L.P.
New York, NY

Janet E. Hasak
Associate General Counsel – Director
Genentech, Inc.
South San Francisco, CA

Sherry M. Knowles
Senior Vice President
Corporate Intellectual Property
GlaxoSmithKline
King of Prussia, PA

Shirley Hubers
Vice President
Heritage Woods, Inc.
Alto, MI

Marcus J. Millet, on behalf of the firm
Lerner, David, Littenberg, Krumholz &
Mentlik, LLP
600 South Avenue West
Westfield, NJ 07090

Michael Erlanger
Chairman and CEO
Marketcore, Inc.
Westport, CT

Mark Nowotarski
President
Markets, Patents & Alliances LLC
Stamford, CT

Joe Kiani
Chairman and CEO
Masimo Corp.
Irvine, CA

Mark Leahey
Executive Director
Medical Devices Manufacturers' Assn.
Washington, D.C.

Neal Gutterson, Ph.D.
President and Chief Executive Officer
Mendel Biotechnology, Inc.
Hayward, CA

Paul K. Laikind
Director, President, and CEO
Metabasis Therapeutics, Inc.
La Jolla, CA

Honorable Susan E. Dudley

June 15, 2007

Page 7

Reza Green
Chief Patent Counsel
Novo Nordisk Inc.
Princeton, NJ

Douglas G. Lowenstein
Chairman & CEO
Polestar Capital Partners LLC
New York, NY

Liza K. Toth
Associate Chief Intellectual Property
Counsel
Senior Director
SanDisk Corporation
Milpitas, Ca. 95035-7932

Thomas Fitting
Chief Patent Counsel
The Scripps Research Institute
La Jolla, CA

Kerry A. Flynn
Vice President, Intellectual Property
Shire
700 Main St.
Cambridge, MA

Michael M. Wick, Chairman
CEO & President
Telik, Inc.
Palo Alto, CA

David A. Manspeizer
Vice President--Intellectual Property and
Associate General Counsel
Wyeth
Madison, NJ

Jennifer K. Johnson
Senior Associate General Counsel, Patents
ZymoGenetics, Inc.
Seattle, WA