Exhibit 9

Presentation to Office of Management and Budget by parties including Polestar (June 15, 2007)

Part 1: Meeting Record, Cover Letter, Attachments A-C (P000209-264)

OFFICE OF MANAGEMENT AND BUDGET

Meeting Record Regarding: Changes to Practice

Date: 6/15/2007

Name	Affiliation	Client (if applicable)
David Rostker	OMB/OIRA	
Lisa Branch	OMB/OIRA	
Rob Alderfer	OMB	
Aaron Flynn	OSTP	
Peter Robbins	DOC/OGC	
Carrol Barnes	SBA/Office of Advocacy	
David Boundy	Cantor Fitzgerald	
John Love	USPTO	
Jennifer McDowell	USPTO	
Nikesh Jindal	OMB	
Mike Strickland	GlaxoSmith Kline	

Materials provided to OMB
Enclosure 1 (243k)
Enclosure 2 (1,706k)
Enclosure 3 (7,361k)

CANTOR Fitzgerald

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:

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[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.

110 East 59th Street
New York, NY 10022

(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.

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[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

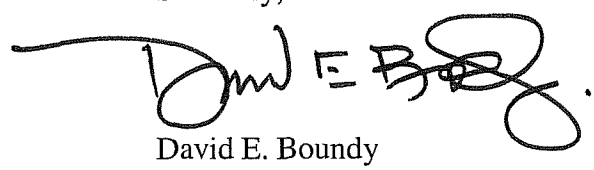
Certain provisions in the proposed rules would impose significant new or expanded paperwork requirements, yet USPTO claims that both rules would *reduce* paperwork burden.

- 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.

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,



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

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

Attachments:

A. Public Comments Submitted by Signatories to USPTO on its Notices of Proposed Rulemaking

B. The Draft Rules are "Economically Significant" under Executive Order 12,866

C. The Draft Rules Are Not Required by Patent Law or Necessary to Implement Patent Law, and are Therefore Impermissible Under EO 12,866 § 1(a)

D. USPTO's Written Rationale is Insufficient

E. The Rules Exceed the Authority Delegated to USPTO under the Administrative Procedure Act and Patent Act

F. Existing Regulations or Administrative Practices Created or Contributed to the Problems USPTO Seeks to Remedy (EO 12,866 Sec. 1(b)(2))

G. USPTO Did Not Rely on the Best Available Scientific, Technical, Economic and Other Information (EO 12,866 Sec. 1(b)(7))

H. USPTO's Claimed Reduction in Backlog Is Unlikely to Materialize

I. USPTO Cannot Show that the Proposed Rules are the "Most Cost Effective" Solution

J. USPTO's Promises of Procedural Remedies Against Substantive Harshness are Illusory

K. USPTO Failed to Comply with Applicable Information Quality Principles and Guidelines

L. USPTO Has Withheld Data and Analysis Essential for Evaluating its Proposals

M. USPTO's Estimates of Paperwork Burden are Invalid and Unreliable (Paperwork Reduction Act)

N. Materials Received from USPTO in Response to FOIA Request, Including Chicago "Town Hall" Slides

O. Relevant Statutes

P. Relevant Provisions of the Code of Federal Regulations

Q. Relevant Sections from the Manual of Patent Examining Procedure (MPEP)

Attachment A

Public Comments by Signatories Submitted to USPTO on its Notices of Proposed Rulemaking

-----Original Message-----
From: Michael K. Kirk [mailto:mkirk@aipla.org]
Sent: Monday, April 24, 2006 1:37 PM
To: AB94Comments
Cc: Clarke, Robert
Subject: AIPLA Comments on Examination of Claims Practice

Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Clarke,

Attached are the comments of the American Intellectual Property Law Association on the proposed rules changes to “Practice for the Examination of Claims in Patent Applications.”

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S Patent and Trademark Office.

Thank you.

Mike Kirk
Executive Director
AIPLA

-----Original Message-----
From: Michael K. Kirk [mailto:mkirk@aipla.org]
Sent: Monday, April 24, 2006 1:36 PM
To: AB94Comments
Cc: Clarke, Robert
Subject: AIPLA Comments on Continuing Application Practice

Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Clarke,

Attached are the comments of the American Intellectual Property Law Association on the proposed rules changes to “Practice for Continuing Applications, RCE Practice, and Applications Containing Patentably Indistinct Claims.”

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S Patent and Trademark Office.

Thank you.

Mike Kirk
Executive Director
AIPLA

-----Original Message-----
From: Alderucci, Dean - Cantor Fitzgerald [mailto:DAlderucci@cantor.com]
Sent: Wednesday, May 03, 2006 6:30 PM
To: AB94Comments; AB93Comments
Subject: Comments to Proposed Rules

These comments are submitted in response to the Proposed Rules of the U.S. Patent and Trademark Office at 71 Fed. Reg. 48 (January 3, 2006) and 71 Fed. Reg. 62 (January 3, 2006).

SUMMARY OF ISSUES

The proposed rules violate several tenets of Administrative Law and, if promulgated, would be clearly in violation of Supreme Court jurisprudence and in excess of statutory authority.

First, those proposed rules which would either shift the burden of proof or the burden of production to patent applicants is in direct violation of Supreme Court jurisprudence. *See, e.g., Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers,* 512 U.S. 267, 275-81 (1994).

Second, critical factual evidence on which the U.S. Patent and Trademark Office would have had to have relied upon in formulating the new rules either does not exist or has not been subjected to informed comment by the public.

Third, the U.S. Patent and Trademark Office lacks the required statutory authority to pass the proposed rules limiting continuation applications.

Fourth, the proposed rules fail to reflect reasoned decision making because the reasoning is extremely flawed.

Please note that if a reasoned response is not provided to every comment, then the proposed rules, if passed, would be subject to invalidation as arbitrary and capricious.

Please also note that a promulgated rule which is not a “logical outgrowth” of a proposed rule would likewise be subject to invalidation for not having been subjected to notice and comment.

-----Original Message-----
From: Butler, James [mailto:james.butler@amylin.com]
Sent: Wednesday, May 03, 2006 8:46 PM
To: AB94Comments
Subject: Amylin Pharmaceuticals, Inc. comments on Changes to Examination of Claims

-----Original Message-----
From: Todd Gillenwater (CHI) [mailto:gillenwater@chi.org]
Sent: Monday, May 01, 2006 1:06 PM
To: AB93Comments
Cc: Clarke, Robert
Subject: CHI Comments on Proposed Changes to Practice for Continuing Applications

Please find attached the formal comments of CHI - The California Healthcare Institute in response to proposed rule changes to the filing of Continuation, Continuation-in-Part, and Divisional applications and the filing of Requests for Continued Examination with the United States Patent and Trademark Office (PTO) published in the January 3, 2006 Federal Register.

Sincerely,

Todd Gillenwater
Vice President - Public Policy
California Healthcare Institute (CHI)
1020 Prospect Street, Suite 310
La Jolla, CA 92037
www.chi.org
O: 858-551-6677
C: 858-395-7956

May 3, 2006

BY ELECTRONIC MAIL TO AB93COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*

Dear Mr. Bahr:

Amylin Pharmaceuticals, Inc. welcomes the opportunity to comment on the proposed rule changes related to the examination of claims in patent applications published in the January 3, 2006 *Federal Register*.

Amylin Pharmaceuticals, Inc. is a biopharmaceutical company located in San Diego, California. Originally founded in 1987, Amylin received approval for two, first-in-class drugs for the treatment of diabetes in 2005. Amylin employs approximately 1200 people and has been issued over 50 United States patents. Amylin is also the assignee or exclusive licensee of numerous additional United States patents. Amylin opposes the proposed rule changes for the reasons that the proposed justification for the changes, decreased pendency, is not supported by objective evidence; the proposed rules will disproportionately have a negative effect on biotechnology and pharmaceutical companies which have legitimate reasons for filing continuing applications; the proposed rules are contrary to statute, case law, and international treaties to which the United States is a signatory; the proposed rules will inhibit innovation, create difficulties in licensing and will diminish the public disclosure function of patents; and the proposed rules will not solve the current problems of patent quality but will simply re-create a backlog at the Board of Patent Appeals.

1. The Patent Office Has Presented No Objective Evidence That the Proposed Rules will Result in Decreased Pendency.

In its Notice of Proposed Rule Making, the Office states that the filing of continuing applications has had a "crippling effect on the Office's ability to examine 'new' applications" and that the new rules will allow it to "reduce the backlog of unexamined applications." These statements, however, are not supported by the Office's own statistics. The Office reports that of the 317,000 non-provisional applications, just under 10,000 or 3% were second or more requests for continued examination. It stretches credibility that a mere 3% of the applications are responsible for the Office's current backlog. Moreover, if the backlog were in fact due to continuing applications one would

-----Original Message-----
From: Butler, James [mailto:james.butler@amylin.com]
Sent: Wednesday, May 03, 2006 8:49 PM
To: AB93Comments
Subject: Amylin Pharmaceuticals, Inc. comments on changes to continuation practice

<< File: AB93COMMENTS.pdf >>

May 3, 2006

BY ELECTRONIC MAIL TO AB94COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert A. Clarke

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for the Examination of Claims in Patent Applications*

Dear Mr. Clarke:

AMYLIN PHARMACEUTICALS, INC. welcomes the opportunity to comment on the proposed rule changes related to the examination of claims in patent applications published in the January 3, 2006 *Federal Register*.

Amylin Pharmaceuticals, Inc. is a biopharmaceutical company located in San Diego, California. Originally founded in 1987, Amylin received approval for two, first-in-class drugs for the treatment of diabetes in 2005. Amylin employs approximately 1200 people and has been issued over 50 United States patents. Amylin is also the assignee or exclusive licensee of numerous additional United States patents. Amylin opposes the proposed rule changes for the reasons that they disproportionately have a negative effect on biotechnology and pharmaceutical companies; are contrary to statute and case law; are contrary to international treaties to which the United States is a signatory; will create a substantial financial burden, especially on the biopharmaceutical industry and small entities; will create greater uncertainty and increased litigation; and will not substantially improve patent quality.

1. The Proposed Rule Disproportionately Have a Negative Effect on Biotechnology and Pharmaceutical Companies.

The very nature of pharmaceutical and biotechnology inventions dictates a number of useful embodiments. For example, a pharmaceutical composition may be useful to treat several indications, be formulated for different modes of administration, have different dosing regimes, and alternative means of manufacture. Likewise, a biopharmaceutical innovation may encompass numerous variants each with its own set useful properties. In its Notice of Proposed Rule Making, the Patent Office provides data to support its allegation that the proposed rule changes will affect only a limited number of applications. The use of these numbers by the Patent Office is disingenuous. The Office reports that only 1.2 percent of applications contain more than 10 independent claims. This number would be meaningful if the proposed rules restricted examination to 10 independent claims, but the proposed rules are much more limiting. The proposed

-----Original Message-----
From: Alderucci, Dean - Cantor Fitzgerald [mailto:DAlderucci@cantor.com]
Sent: Wednesday, May 03, 2006 6:30 PM
To: AB94Comments; AB93Comments
Subject: Comments to Proposed Rules

These comments are submitted in response to the Proposed Rules of the U.S. Patent and Trademark Office at 71 Fed. Reg. 48 (January 3, 2006) and 71 Fed. Reg. 62 (January 3, 2006).

SUMMARY OF ISSUES

The proposed rules violate several tenets of Administrative Law and, if promulgated, would be clearly in violation of Supreme Court jurisprudence and in excess of statutory authority.

First, those proposed rules which would either shift the burden of proof or the burden of production to patent applicants is in direct violation of Supreme Court jurisprudence. *See, e.g., Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers,* 512 U.S. 267, 275-81 (1994).

Second, critical factual evidence on which the U.S. Patent and Trademark Office would have had to have relied upon in formulating the new rules either does not exist or has not been subjected to informed comment by the public.

Third, the U.S. Patent and Trademark Office lacks the required statutory authority to pass the proposed rules limiting continuation applications.

Fourth, the proposed rules fail to reflect reasoned decision making because the reasoning is extremely flawed.

Please note that if a reasoned response is not provided to every comment, then the proposed rules, if passed, would be subject to invalidation as arbitrary and capricious.

Please also note that a promulgated rule which is not a “logical outgrowth” of a proposed rule would likewise be subject to invalidation for not having been subjected to notice and comment.

-----Original Message-----
From: Margaret Dunbar [mailto:mdunbar@burnham.org]
Sent: Wednesday, May 03, 2006 5:37 PM
To: AB93Comments
Subject: comments on proposed rule changes

May 3, 2006

BY ELECTRONIC MAIL TO AB93COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*

Dear Mr. Bahr:

Burnham Institute for Medical Research welcomes the opportunity to comment on the proposed rule changes related to the examination of claims in patent applications published in the January 3, 2006 *Federal Register*.

Burnham Institute for Medical Research a 501c(3) non-profit corporation. Federal grants make up about 80% of our operating budget. Other important sources of funding include private foundations and philanthropy. The outstanding quality of our scientists allows them to compete for research funding from various government agencies, particularly the National Institutes of Health (NIH). These funds support the majority of the research. The Institute scientists currently contribute more than 300 scientific publications annually to the medical literature. The Institute has over 180 issued patents and 130 pending patent applications. The Institute has been ranked as one of the top 15 organizations worldwide in its field by the Institute for Scientific Information for the impact of its research. Discoveries by our Scientists have laid the foundation for multiple therapeutic agents and diagnostic tests currently in use or in clinical testing. It is the Institute's mission to conduct world-class, collaborative medical research to cure human disease, improve quality of life, and thus create a legacy for our employees, partners, donors, and community. More than 500 scientists, out of 725+ employees, work at the Institute. Currently the Institute has 69 faculty members, and each of these scientists runs a staffed research laboratory.

The Burnham Institute for Medical Research opposes the proposed rule changes for the reasons that the justification set forth by the Patent Office for the changes, i.e. decreased pendency, is not supported by objective evidence. The rules, as proposed, will disproportionately and negatively impact the biotechnology and pharmaceutical industries which have legitimate reasons for filing continuing applications. The changes would be particularly devastating for non-profit and academic research institutions and small businesses. The proposed rules are contrary to statute, case law, and international treaties to which the United States is a signatory; the proposed rules will inhibit innovation, create difficulties in licensing and will diminish the public disclosure function of patents; and the

-----Original Message-----
From: Todd Gillenwater (CHI) [mailto:gillenwater@chi.org]
Sent: Monday, May 01, 2006 1:06 PM
To: AB93Comments
Cc: Clarke, Robert
Subject: CHI Comments on Proposed Changes to Practice for Continuing Applications

Please find attached the formal comments of CHI - The California Healthcare Institute in response to proposed rule changes to the filing of Continuation, Continuation-in-Part, and Divisional applications and the filing of Requests for Continued Examination with the United States Patent and Trademark Office (PTO) published in the January 3, 2006 Federal Register.

Sincerely,

Todd Gillenwater
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TELIK

3 May 2006

By e-mail

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments
P. O. Box 1450
Alexandria, VA 22313-1450

Re: Comments on Proposed Rules:
"Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims", 71 Fed. Reg. 48; and
"Changes to Practice for the Examination of Claims in Patent Applications", 71 Fed. Reg. 61

Dear Under Secretary Dudas:

I write to comment on the U.S. Patent & Trademark Office ("Office") proposed rules.

By way of background, I am presently the in-house patent counsel at Telik, Inc., a biopharmaceutical company of 180 employees in Palo Alto, California, developing drugs to treat cancer. I have more than 25 years' practice as a patent agent and attorney at a specialty manufacturing company, a major oil company, and a major pharmaceutical company, and as a special counsel and shareholder at a major law firm. The views I express here are my own and not those of Telik.

The systems in the Office ("compact prosecution" and the examiner productivity compensation scheme) encourage examiners to make multi-way restriction requirements, to make Office Actions final, and to refuse entry of after-final amendments, all often inappropriately under the controlling statute and rules.

Applicants' "solution" to inappropriate restriction requirements largely has been to file divisional applications, not to petition – better to move forward and prosecute claims in a divisional than waste energy on the petition and time waiting for it to be decided, especially in this post-URAA world. Similarly, applicants' "solution" to inappropriate final rejections and refusals of after-final amendments largely has been to file continuations or, more commonly, RCEs – all too often the examiner will allow the application when the RCE is filed, so why petition or appeal unless he/she won't? I believe that this is the source of the vast majority of the continuing or "rework" applications complained of in the Notices of Proposed Rulemaking.

What the Office is proposing now, though, will penalize applicants who have gone along with the Office's system, and force applicants to contest restriction requirements, finality, and non-

-----Original Message-----
From: Derek Freyberg [mailto:dfreyberg@telik.com]
Sent: Wednesday, May 03, 2006 8:27 PM
To: AB93Comments; AB94Comments
Subject: Comments of Derek P. Freyberg on the Notices of Proposed Rulemaking

I enclose my comments in response to the Notices of Proposed Rulemaking at 71 FR 48 and 71 FR 61.

Derek P. Freyberg, PhD
Senior Patent Counsel
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3165 Porter Drive, Palo Alto CA 94304-1213
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-----Original Message-----
From: Danielle Pasqualone [mailto:pasqualone.danielle@gene.com]
Sent: Monday, May 01, 2006 3:24 PM
To: AB93Comments
Subject: Comments on Notice of Proposed Rule Making, 71 Fed. Reg. 48

Dear Mr. Bahr,

Please see the attached comments from Genentech, Inc., on the Notice of Proposed Rule Making entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (January 3, 2006).

Thank you,

Danielle Pasqualone, Ph.D.
Patent Counsel
Genentech, Inc.
1 DNA Way, MS#49
South San Francisco, CA 94080

email: dpasqual@gene.com
Tel: (650) 467-0594
Fax: (650) 952-9881

Genentech
IN BUSINESS FOR LIFE

1 DNA Way
South San Francisco, CA 94080-4990
(650) 225-1000
FAX: (650) 225-6000

May 1, 2006

By electronic mail – AB93Comments@uspto.gov

Attn.: Robert W. Bahr
U.S. Patent and Trademark Office

Re: Notice of Proposed Rule Making Entitled "*Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*," 71 Fed. Reg. 48 (January 3, 2006)

Dear Mr. Bahr:

Genentech, Inc. ("Genentech") welcomes the opportunity to comment on the above-captioned Notice of proposed rule making. Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for almost 30 years, using human genetic information to discover, develop, commercialize and manufacture biotherapeutics that address significant unmet medical needs. Today, Genentech is among the world's leading biotech companies, with multiple products on the market for serious or life-threatening medical conditions and over 40 projects in the pipeline. We are the leading provider of anti-tumor therapeutics in the United States. Of course, Genentech is not alone in its efforts to develop new biotherapeutics. Recent data from the Biotechnology Industry Organization indicates that there are currently more than 300 biotechnology-based products in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis.

Genentech invests over a billion dollars annually in its research and development programs. Strong patent protection is essential for recouping that investment, encouraging innovation, and sustaining future research and development. For a number of reasons, we believe that the proposed rule changes will have a profoundly negative impact on Genentech's ability to obtain commercially relevant patent protection for its discoveries. Indeed, we believe that the proposed rule changes will disproportionately harm the biotechnology industry as a whole.

Accordingly, we believe that the Office should not enact the proposed rules. If the Office does proceed with enacting rules changes of the type proposed, we respectfully request that it at

-----Original Message-----
From: mike.m.strickland@gsk.com [mailto:mike.m.strickland@gsk.com]
Sent: Tuesday, May 02, 2006 4:23 PM
To: AB94Comments
Subject: GSK Comments on Examination of Claims Practice

Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Clarke,

Attached are the comments of the GlaxoSmithKline on the proposed rules changes to “Practice for the Examination of Claims in Patent Applications.”

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S Patent and Trademark Office.

Thank you.

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline

Comments on Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

Mail Stop Comments - Patents
P.O. Box 1450 Alexandria, VA 22313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48 (January 3, 2006)

Dear Under Secretary Dudas:

In response to the Proposed Rulemaking published January 3, 2006, at Federal Register, Vol. 71, No. 1, p. 49-61, GlaxoSmithKline ("GSK") submits the following comments. Separate comments are submitted concurrently herewith directed to the related claim examination proposed rulemaking.

Executive Summary:

As one of the world's leading research-based pharmaceutical and healthcare companies, GSK has a keen appreciation for the importance of a strong and effective patent system that efficiently produces patents of the highest quality. Through attendance at one of the many town hall meetings recently held by the Patent Office to further inform the public of the crisis facing the Patent Office and the need for patent reform, GSK has gained insights into the difficulties facing the Patent Office as it tries to cope with an ever increasing backlog of newly filed applications in the midst of a very tight job market for skilled workers to fill the growing ranks of the corps of examiners.

While GSK appreciates the position in which the Patent Office currently finds itself, GSK must oppose the proposed rulemaking because: (1) the Patent Office lacks authority to implement the proposed rulemaking; and (2) even if the Patent Office were to have authority, the proposed rulemaking will not work to meet the stated goals of the Patent Office of reducing workload and improving quality of examination. If the Patent Office decides to enact the proposed rules despite the lack of authority to do so, GSK requests consideration of alternatives, such as those discussed below. The proposal of

Heritage Woods, Inc.

May 2, 2006

Mail Stop Comments—Patents
Attn: Robert W. Bahr and Robert A. Clarke
Commissioner for Patents
P.O. Box 1450
Alexandria, VA, 22313–1450

Comments on

"Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" (71 Fed. Reg. 48, January 3, 2006) and

"Changes to Practice for the Examination of Claims in Patent Applications" (71 Fed. Reg. 61, January 3, 2006)

Heritage Woods, Inc. appreciates the opportunity to comment on the two proposed rule packages published in January 2006.

Heritage Woods is a small business that relies on its patents to protect its product line from larger competitors. This letter also expresses concerns of other small businesses who rely on their patents.

The two proposed rule packages noted above have been brought to our attention by patent counsel. While there are a few good ideas in the two rule packages, and Heritage Woods appreciates the PTO's effort to correct a perceived problem, the packages as a whole will cause and aggravate more problems than they solve. They will remarkably increase the cost of the patent system as a whole – the costs of obtaining a patent will go up by a large factor, and the costs of litigation will go up even more.

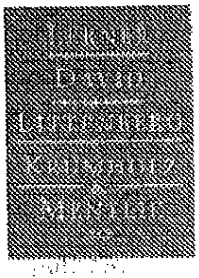
Ironically, both packages will have the most negative effect on the most important inventions and applications. The "Examination of Claims" rule package (71 Fed. Reg. 61) explicitly embodies a view that large applications are "bad" and should be penalized.. However, from both a commercial point of view and from a patent public policy point of view, large applications are good: they are the applications that are directed to economically-important inventions, and they provide the greatest disclosure of ideas to the public – which is, after all, the main public good of the patent system. They are immensely cost-effective to the patent system – a patent that has many claims is a much more efficient dispute-resolution document than a short imprecise patent that needs to rely heavily on fuzzy notions of "equivalents." A patent is analogous to a commercial contract – a contract this is fully negotiated, and that expressly spells

Jones, Eugenia

From: Anderson, Barbara [BAnderson@ldlkm.com] on behalf of Millet, Marcus J [mmillet@ldlkm.com]
Sent: Tuesday, May 02, 2006 5:29 PM
To: AB94Comments
Subject: RIN 0651-AB94 - Comments
Importance: High

Please see our comments attached.

Marcus J. Millet
Lerner, David, Littenberg, Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, NJ 07090
Tel. (908) 518-6450; Fax (908) 654-7866
mmillet@ldlkm.com



600 South Avenue West · Westfield, New Jersey 07090
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Patents, Trademarks, Copyrights & Unfair Competition

Marcus J. Millet
908.518.6450
mmillet@ldlkm.com

May 2, 2006

AB94Comments@uspto.gov.

Re: Comments Concerning Notice Of Proposed Rule Making
Docket No.: 2005–P–067
RIN 0651–AB94
Changes To Practice For The Examination Of Claims In Patent Applications

Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("LDLKM") respectfully submits the comments below with respect to the above-referenced Notice of Proposed Rule Making (hereinafter the "Examination Notice"). The Continuation Notice is accompanied by a separate Notice of Proposed Rule Making, Docket No.: 2005-P-066, RIN 0651-AB93 Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims (hereinafter the "Continuation Notice"). As addressed below, certain aspects of these two notices interact with one another, and should be considered together.

LDLKM is the largest intellectual property law firm in New Jersey. LDLKM includes over sixty lawyers, the vast majority of whom are registered to practice before the United States Patent and Trademark Office (the "Office"). LDLKM represents diverse clients ranging from individual inventors to some of the largest corporations in the world, both before the Office and in the courts, and represents both patentees and parties accused of infringement. LDLKM, therefore, is cognizant of the interests of parties with diverse interests in the patent system. However, the present comments are offered solely on behalf of LDLKM and are should not be construed as reflecting the views of any client of LDLKM.

LDLKM shares the concerns raised by the comments submitted by the American Intellectual Property Law Association (AIPLA) and offers the following additional comments.

The Examination Notice imposes severe penalties on an applicant who files 10 or more independent claims, either in a single application or in a set of related applications. One part of the Examination Notice sets up what appears to be a sensible, beneficial procedure, namely, that the applicant must designate representative claims for initial examination, and that the examiner will confine his or her work to those initial claims until the application is otherwise in condition for allowance. Proposed 37 C.F.R. § 1.75(b). Under the proposed rule, however, all independent claims are automatically designated as claims for initial examination. If the applicant designates more than 10 claims, he or she must submit an "examination support

-----Original Message-----
From: Anderson, Barbara [mailto:BAnderson@ldlkm.com]**On Behalf Of** Millet, Marcus J
Sent: Tuesday, May 02, 2006 5:28 PM
To: AB93Comments
Subject: RIN 0651-AB93 - Comments
Importance: High

Please note our comments attached.

Marcus J. Millet
Lerner, David, Littenberg, Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, NJ 07090
Tel. (908) 518-6450; Fax (908) 654-7866
mmillet@ldlkm.com

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow™

May 3, 2006

The Honorable Jon W. Dudas
Undersecretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box. 1450
Alexandria, VA 11313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

Electronically submitted to: AB93Comments@uspto.gov

Dear Under Secretary Dudas:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device industry, I appreciate the opportunity to comment on the Patent Office rules proposed by the U.S. Patent and Trademark Office ("Patent Office") on "Changes to Practice for the Examination of Claims In Patent Applications" (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and "Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims", (Fed. Reg. Vol. 71 No. 1 Page 48, Jan. 3, 2006).

We understand that several life-sciences based organizations have submitted comments in reaction to these proposed rules. The potential negative impact is very similar across our extremely research-driven disciplines: the rule changes will cause significant and costly administrative burdens on patentees, decrease the level of protection for new inventions, thereby decrease the value of new inventions, decrease the level of investments in the industry, negatively influence industry's willingness to engage in fundamental R&D and quash innovation to the extent there is a perception by industry that IP rights are more onerous and costly to obtain.

Our purpose for submitting this letter, therefore, is twofold: (1) to strongly reaffirm and support the written comments provided by BIO and others focused on life sciences research and development, and (2) to point out particular characteristics present in the medical device sector that make application of these rules particularly problematic.

-----Original Message-----
From: Mark Leahey [mailto:mleahey@medicaldevices.org]
Sent: Wednesday, May 03, 2006 2:46 PM
To: AB93Comments
Subject: "Changes to Practice for the Examination of Claims In Patent Applications" (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and "Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patenta

Mark B. Leahey, Esq.
Executive Director
Medical Device Manufacturers Association
1919 Pennsylvania Ave, NW, Ste. 660
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(202) 349-7176 fax
mleahey@medicaldevices.org

LERNER DAVID LITTENBERG KRUMHOLZ & MENTLIK LLP

600 SOUTH AVENUE WEST • WESTFIELD, NEW JERSEY 07090
908.654.5000 • FAX 908.654.7866 • WWW.LDLKM.COM

PATENTS, TRADEMARKS, COPYRIGHTS & UNFAIR COMPETITION

Marcus J. Millet
908.518.6450
mmillet@ldlkm.com

May 2, 2006

AB93Comments@uspto.gov.

Re: Comments Concerning Notice Of Proposed Rule Making
Docket No.: 2005–P–066
RIN 0651–AB93
Changes To Practice for Continuing Applications, Requests For Continued Examination Practice, and Applications Containing Patentably Indistinct Claims

Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("LDLKM") respectfully submits the comments below with respect to the above-referenced Notice of Proposed Rule Making (hereinafter the "Continuation Notice"). The Continuation Notice is accompanied by a separate Notice of Proposed Rule Making, Docket No.: 2005-P-067, RIN 0651-AB94 Changes to Practice for the Examination of Claims in Patent Applications (hereinafter the "Examination Notice"). As addressed below, certain aspects of these two notices interact with one another, and should be considered together.

LDLKM is the largest intellectual property law firm in New Jersey. LDLKM includes over sixty lawyers, the vast majority of whom are registered to practice before the United States Patent and Trademark Office (the "Office"). LDLKM represents diverse clients ranging from individual inventors to some of the largest corporations in the world, both before the Office and in the courts, and represents both patentees and parties accused of infringement. LDLKM, therefore, is cognizant of the interests of parties with diverse interests in the patent system. However, the present comments are offered solely on behalf of LDLKM and are should not be construed as reflecting the views of any client of LDLKM.

LDLKM shares the concerns raised by the comments submitted by the American Intellectual Property Law Association (AIPLA) and offers the following additional comments.

Proposed 37 C.F.R. § 1.78(d) as set forth in the Continuation Notice would bar an applicant from filing more than one continuing application or request for continued examination unless the applicant can show "to the satisfaction of the Director" that the new filing is necessary to present an "amendment, argument or evidence" which "could not have been submitted" during prosecution of the prior application.

That standard is extraordinarily strict. It ignores the substantial and legitimate reasons why an applicant might want to file more than one continuing application. For example, an

-----Original Message-----
From: Jeffrey M. Libby [mailto:jlibby@MendelBio.COM]
Sent: Wednesday, May 03, 2006 3:40 PM
To: AB93Comments
Cc: neal Gutterson; thomas.e.kelley@monsanto.com; mWard@mofo.com; jlibby@mendelbio.com
Subject: Comments on Proposed Rules, Changes to Practice for Continuing Applications

Attn: Robert W. Bahr
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

From: Mendel Biotechnology, Inc.
Jeffrey M. Libby [mailto:jlibby@mendelbio.com]
Neal I. Gutterson [mailto:neal@mendelbio.com]

Re. Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests
for Continued Examination Practice, and Applications Containing Patentably Indistinct
Claims" 71 Fed. Reg. 48 (January 3, 2006)
Dear Mr. Bahr:

Attached are the comments of Mendel Biotechnology, Inc. on the proposed rules changes to "Practice for Continuing Applications, RCE Practice, and Applications Containing Patentably Indistinct Claims." Our comments are attached as an MS Word file (our preferred format, complete with text formatting), and also embedded in the text of this message, below.

Please confirm receipt of this communication.
Sincerely,

Jeffrey M. Libby, Ph.D.
Senior Patent Agent
Mendel Biotechnology, Inc.

Neal I. Gutterson, Ph.D.
President and Chief Operating Officer
Mendel Biotechnology, Inc.

May 3, 2006

The Honorable Jon Dudas

-----Original Message-----
From: LSMT (Len Smith) [mailto:LSMT@novonordisk.com]
Sent: Wednesday, May 03, 2006 6:29 PM
To: AB93Comments
Cc: REZG (Reza Green); LAKE (Lars Kellberg); JCSH (Jim Shehan); CPOR (Chris Porter)
Subject: Comments of Novo Nordisk, Inc. (regarding 71FR48 - proposed limitations on continuing application practice)

To Whom It May Concern:

Please accept the attached comments from Novo Nordisk, Inc., in response to 71 FR 48, published on January 3, 2006.

Please contact us if you have questions or concerns associated with this message.

_____

Len S. Smith
Senior Patent Counsel
Novo Nordisk Inc.
100 College Road West
Princeton, NJ (USA) 08540
609-919-7760 (direct)
609-933-8578 (mobile)
609-580-2459 (direct fax)
609-919-7741 (department fax)
lsmt@novonordisk.com

May 3, 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments on the *Federal Register* Notice Entitled "Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims"

Dear Under Secretary Dudas:

Novo Nordisk, Inc. appreciates the opportunity to present our views, on behalf of Novo Nordisk, Inc., Novo Nordisk A/S, and affiliates, on the proposed rule changes published in the Federal Register at 71 Fed. Reg. 48 (January 3, 2006) on behalf of Novo Nordisk A/S and all of its affiliates ("Novo Nordisk").

As detailed below, Novo Nordisk opposes the proposed rules because we believe

(1) the immediate effect of the proposed rules would be an *increased* burden on the United States Patent and Trademark Office ("PTO") and US legal system, resulting in an *increase* in the pendency of many important patent applications (particularly in respect of pharmaceutical and biotechnology-related inventions) and

(2) the larger effect of the proposed rules would be to (a) discourage sharing of scientific information, (b) reduce investment in new technologies, and (c) generally inhibit innovation and, therefore, to negatively impact the US economy, and

Novo Nordisk Inc.
100 College Road, West
Princeton, New Jersey 08540
USA
Telephone:
609-987-5800
Direct Telephone:
609-987-5931
Fax:
609-919-7741
E-mail:
REZG@novonordisk.com
Internet:
www.novonordisk-us.com

-----Original Message-----
From: Derek Freyberg [mailto:dfreyberg@telik.com]
Sent: Wednesday, May 03, 2006 4:46 PM
To: AB93Comments; AB94Comments
Subject: Comments of Telik, Inc. on the Notices of Proposed Rulemaking at 71 FR 48 and 71 FR 61

Enclosed is a letter from Michael M. Wick, MD PhD; Chairman, CEO & President of Telik, Inc.;
with Telik's comments in response to the Notices of Proposed Rulemaking at 71 FR 48 and 71 FR 61.

-----Original Message-----
From: JENJ (Jennifer Johnson) [mailto:johnsonj@zgi.com]
Sent: Friday, April 28, 2006 7:41 PM
To: AB93Comments
Subject: ZymoGenetics' 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).

Please note that these Comments are sent in addition to comments sent earlier by ZymoGenetics' CEO, Bruce Carter.

Sincerely,

Jennifer K. Johnson

Jennifer K. Johnson
Associate General Counsel, Patents
ZymoGenetics, Inc.
1201 Eastlake Ave. E.
Seattle WA 98102
(206) 442-6676 (direct)
(206) 442-6678 (FAX)

TELIK

3 May 2006

By e-mail

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments
P. O. Box 1450
Alexandria, VA 22313-1450

Re: Comments on Proposed Rules:
"Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims", 71 Fed. Reg. 48; and
"Changes to Practice for the Examination of Claims in Patent Applications", 71 Fed. Reg. 61

Dear Under Secretary Dudas:

I am writing on behalf of Telik, Inc. to comment on the U.S. Patent & Trademark Office ("PTO") proposed rules.

Telik is a biopharmaceutical company of 180 employees in Palo Alto, California, developing drugs to treat cancer. Information about Telik can be found at its website at www.telik.com. Like all other biopharmaceutical companies, Telik relies very heavily on patents to protect its intellectual property.

I have been made aware of the proposed rule changes by Telik's Patent Counsel, who suggested that Telik provide input to the PTO in its decision making process. I believe the two letters dated 24 April 2006 to you from the American Intellectual Property Law Association and the letter of 27 April 2006 from the Office of Advocacy of the U.S. Small Business Administration reasonably present Telik's concerns regarding the proposed changes; and Telik agrees in general with the observations and recommendations of those letters.

Telik's opposition to the changes in these proposed rules is based on economic policy issues that relate to the financing of research and development in the biopharmaceutical industry.

You are probably aware of the complexities of developing a new drug. For small companies like Telik, funding the development of such a drug often comes in stages of financing. A major asset that financiers, whether venture capitalists, angels, partners, or stockholders, evaluate is the patent portfolio. Any opportunities to maximize the value of a company's patent portfolio aids in the fund-raising process and, thus, the development of new drugs. Telik is concerned that the proposed rules will have the effect of reducing this opportunity for drug development, thereby reducing competition in the biopharmaceutical field and harming the public interest.

ZYMOGENETICS

April 28, 2006

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

RE: 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).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to offer comments concerning the 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). We respectfully request consideration of the following comments.

A. The Proposed Rules Are Against The Public Interest As They Disparately Impact The Biotechnological Arts

The Proposed Rules limiting continuing applications are particularly harmful with respect to the biotechnological arts where the inventions are complex and there are practical considerations in bringing a product to market that necessitate the need for multiple continuation and divisional applications. Product development times for therapeutic biotechnology products are long; the average time to advance a new drug from discovery to FDA approval is 10 to 15 years. See, Tufts Center for the Study of Drug Development reported in November 2001. During this long product development cycle, complex experiments are often required to determine the commercial embodiment of an invention and to address patentability issues arising during prosecution. The final commercial product may be a single embodiment among a number of embodiments in a patent application that discloses it, and that embodiment may not be known for years after the filing date.

Limits on continuing application practice will have a detrimental effect on U.S. biotechnology businesses. 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. Biotechnology companies often need to obtain issued patents quickly, e.g., on narrow

1201 Eastlake Avenue East Seattle, Washington 98102 (206) 442-6600 Fax (206) 442-6608 www.zymogenetics.com

-----Original Message-----
From: JENJ (Jennifer Johnson) [mailto:johnsonj@zgi.com]
Sent: Wednesday, May 03, 2006 5:36 PM
To: AB94Comments
Subject: ZymoGenetics' Comments to Proposed Rules on Claim Practice
Importance: High

Attn: Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Deputy Director Clarke,

Please post the attached .pdf on the Comments Regarding Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006).

Sincerely,

Jennifer K. Johnson

Jennifer K. Johnson
Associate General Counsel, Patents
ZymoGenetics, Inc.
1201 Eastlake Ave. E.
Seattle WA 98102
(206) 442-6676 (direct)
(206) 442-6678 (FAX)

ZYMOGENETICS

May 3, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments Regarding Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to offer comments concerning the Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006). We respectfully request consideration of the following comments.

A. The Financial Cost of Preparing Support Documents Would Adversely Impact Small and Mid-sized Biotechnology Companies.

The Small Business Administration (SBA) Office of Advocacy, in its comments to the Proposed Rule, states "Contrary to the PTO's estimates…completion of an examination support document could cost from $25,000 to $30,000 – a significant outlay." SBA Comments to 71 F.R. 61, page 3 (April 28, 2006). The costs to prepare a pre-Examination Support Document (hereinafter "Support Document") will be quite large in the biotechnology arts. Because of the numerous independent embodiments typically seen in a biotechnology application, and the complexity of the biotechnology arts, we would estimate that $30,000 would be a *minimum* cost for a Support Document. The level of involvement and potential liability risk for an outside firm (based on inequitable conduct concerns) could make compilation of a meaningful Support Document comparable to a full-blown legal opinion which typically runs between $50,000 and $100,000 per biotechnology opinion. For an innovative small- to mid-sized biotechnology company, such as ZymoGenetics Inc., the costs related to Support Documents could quickly escalate into several hundred thousand dollars or more per year. This is a cost that we simply cannot afford to have on a regular basis.

In our experience, our biotechnology applications often require more than ten representative claims to fairly encompass the entire scope of the invention. Prior to a restriction requirement, our biotechnology applications routinely provide numerous independent embodiments of an invention in a single application: e.g., polynucleotides, polypeptides, active fragments thereof, fusion proteins, antibodies, antibody derivatives, methods of making, methods

1201 Eastlake Avenue East Seattle, Washington 98102 (206) 442-6600 Fax (206) 442-6608 www.zymogenetics.com

-----Original Message-----
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
ZymoGenetics, Inc.
1201 Eastlake Ave. E.
Seattle WA 98102
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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

Attachment B

The Draft Rules are "Economically Significant" under Executive Order 12,866

USPTO has represented to OMB that these draft final rules are significant under Executive Order 12,866, but not economically significant. These draft rules[4] should be considered a package because they have important interactive effects: complex patent applications are simultaneously more likely to contain more than 10 independent claims and benefit from continued examination practice to carefully refine the scope of those claims, and the two rules impose burdens and requirements that conflict with each other. They meet the test for being economically significant because:

- They may have an annual effect on the economy of $100 million or more
- They may adversely affect in a material way the economy, and in particular, those sectors of the economy that are the engines of technical innovation

I. Reasonably Expected Economic Effects

The Continuations Rule would sharply limit patent applicants' statutory right to file continuing applications and to request continued examination (collectively referred to here as a "continuation" but involving different procedures and circumstances). The proposed rule would allow only a single continuation unless the applicant could "show[] to the satisfaction of the Director [of the Patent Officer] that the amendment, argument, or evidence [contained in the continuation] could not have been submitted during the prosecution of the prior-filed application" or "prior to close of prosecution in the application".[5] The preamble is silent concerning what criteria the Director considers sufficient. For analytical purposes, it is appropriate to assume that the Director's criteria would be stringent because otherwise the rule would be superfluous.

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[4] In its Town Hall presentations, USPTO considered a third rule on related subject matter, RIN 0651-AB95, "Changes to Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808 (July 10, 2006) to be logically related and functionally intertwined with these two rules, *see e.g.* the "Chicago Slides" in Attachment N. We agree. The IDS Rule also should be designated as economically significant.

[5] 71 Fed. Reg. 59, col. 3, and 61, col. 2.

1. Annual Economic Value of Patent Rights Foregone Likely Exceeds $100 Million

USPTO reports that approximately 317,000 patent applications were filed in FY 2005, with 62,870 of them being continuing applications and 52,000 being Requests for Continued Examination (RCEs).[6] Of the 62,870 continuing applications, 44,500 were designated as continuation/continuation-in-part (CIP) applications and about 18,500 were designated as divisional applications.[7] Thus, 21,800 patent applications would have been affected in FY 2005 if the proposed Continuations Rule had been in place. The $100 million threshold for an economically significant rule would have been exceeded by this NPRM alone if the average social value foregone from each of these 21,800 applications is just $4,587.

Anecdotal (but reliable) data suggest that this threshold is easily exceeded. The value of additional patent protection sought by filing the continuation must at least equal, and almost certainly exceeds, the cost to applicants of preparing and filing such applications. These typically exceed $5,000.[8]

Turning now to the proposed Limits on Claims Rule, it would limit to 10 the number of claims that USPTO will initially examine without submission by the applicant of an Examination Support Document (ESD). In the preamble to the NPRM, USPTO estimated that 1.2% of patent applications would be affected by the rule. In public presentations, USPTO presented data that suggest approximately 1.5% of patent applications contained more than 10 independent claims.[9] Using the lower value, the $100 million threshold would have been exceeded by this NPRM alone if the average social value of the additional claims made in approximately 3,800 (1.2% × 315,000) such applications is greater than about $26,000.

The data provided by USPTO understates the number of applications affected by the proposed Limits on Claims Rule, however. In addition to limiting the number of independent claims that USPTO will examine without an ESD, the Limits on Claims Rule also changes the definition of how claims are classified.[10] Under the proposed rule, many claims that are currently regarded as dependent will be reclassified as independent. Accordingly, historical data provide a downwardly biased estimate of the scope of applications affected by the proposed rule.

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[6] 71 Fed. Reg. 50, col. 1.

[7] 71 Fed. Reg. 50, col. 2 ("About 11,800 of the continuation/CIP applications were second or subsequent continuation/CIP applications. Of the over 52,000 requests for continued examination filed in fiscal year 2005, just under 10,000 were second or subsequent requests for continued examination.")

[8] The filing fee alone for a continuation application is $1,000 and for a continued examination is $790 (halved for small entities). The market value of patent attorney time exceeds $300 per hour.

[9] See Attachment N, slide 57 of the Chicago Town Hall slides.

[10] We explain this flaw more fully in Attachment H, at Section II.2.

Even if the draft final rule under review by OMB has different cut-off values for independent and dependent claims, estimates of regulatory scope based on historical data are still downwardly biased as long as the draft rule reclassifies some dependent claims as independent.

2. Economic Value of Deciding Disputes, and Delay Due to Overloading of Senior USPTO Adjudication Capacity

As a first approximation, we've assumed that patent applicants don't change their behavior in response to these rules. Of course, applicants will change their behavior. For example, a predictable effect of the Continuations Rule is a significant increase in the number of appeals to the Board of Patent Appeals and Interferences (BPAI). In the last several years, USPTO has been able to reduce the number of appeals to BPAI (and the number of appeals it loses) by affording applicants the ability to request a pre-Appeal Brief review by senior examiners and requiring high-level staff review after the appeal brief has been filed. These reforms have succeeded in identifying and rectifying some of the worst examiner mistakes. But if USPTO limits the number of continuations and examiners issue Final Rejections as they do now, senior USPTO management will be inundated by new demands for supervisory review prior to appeal.[11]

As noted above, the proposed Continuations Rule did not specify what criteria USPTO would use to determine whether a further continuation would be permitted, leaving that decision to the discretion of the Director of USPTO (or his designee). With no reliable prospective standard by which applicants can predict how USPTO will exercise this discretion, uncertainty alone will raise the cost of resolving disputes. It is reasonable to expect that the number of contests within USPTO, plus civil suits against USPTO in federal district court, will rise monotonically with the number of denials. These predictable costs would contribute to exceeding the $100 million threshold.

II. Adverse Effects on the Economy, and on Innovation

These two NPRMs radically change the patent application and examination process. For them not to have adverse effects on innovation, it must be true that (a) second and subsequent

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[11] USPTO's own evidence suggests that this is already occurring. For example, the backlog of 882 appeals reported at 71 Fed. Reg. 51, col. 2, was a 20-year low. Since then, the Board's backlog has more than doubled, to 2,071 appeals at the date of this writing. Compare http://www.uspto.gov/web/offices/dcom/bpai/docs/process/fy2007.htm and …/fy2005.htm. Similarly, the backlog in the Office of Petitions, which has historically been 2-4 months, is now over a year for issues such as the "Premature Final Rejection" petition that USPTO proposes as the best remedy for harshness of the Continuations rule. *E.g.*, in application serial no. 09/385,394, a Petition for Review of Premature Final Rejection filed April 10, 2006 remains on the docket for consideration by Brian Hearn in the Office of Petitions as of June 4, 2007.

continuations have no net social value and (b) any independent claims in a patent application over the tenth independent claim, or some other arbitrarily set limit, have no net social value.

Both propositions conflict with both logic and our experience, and USPTO has provided no support for either of them. Logically, there is nothing special about continuation practice suggesting that a single continuation is the socially optimal number. Nor is there any logical basis for believing that the socially optimal number of independent claims is 10 or fewer.[12]

Our experience has been that continuation practice is essential for properly defining the scope of intellectual property rights for complex inventions. The examination and prosecution process is inherently iterative, and each side in the negotiation has generally appropriate substantive incentives.[13] Applicants seek the broadest defensible scope for their intellectual property, and examiners deny claims that are either unclear (*i.e.*, "vague and indefinite"), not supported by the technical disclosure, or overbroad because they cover the prior inventions of others (*i.e.*, "prior art"). When the process begins, particularly with complex inventions, neither applicants nor examiners can predict the scope of the patent that will be finally approved. This discovery and sharing of information drives the process, which leads to more investigation and information discovery, and neither examiner nor applicant can perceive that an outcome is fair until the process has run its course. Price competition among patent attorneys requires them to find the value-maximizing balance between the least-costly path to allowance and the broadest claims that are legally patentable, to the degree this balance can be predicted *a priori*, and to pursue the most-efficient path to it at every step.

The proposed rules assume that these uncertainties do not exist and denies the social value of iterative negotiation to clearly define the scope of an applicant's legitimate claims. USPTO falsely assumes that, very early in the process, applicants have near perfect knowledge about (1) all aspects of what was discovered, (2) which aspects of what they have discovered are most valuable, (3) everything relevant to patentability that others invented that preceded their own discovery, and (4) the precise contour of what claims they will eventually be able to legitimately call their own. Perhaps most perplexingly, USPTO assumes that applicants have perfect knowledge about how an unknown patent examiner of unknown skill, training, and experience will (5) understand the technology related to a complex invention, (6) evaluate his application and (7) the prior art, (8) apply the patent law and guidance to the invention, and (9) that the examiner and applicant will, during examination, find and consider all prior art that all

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[12] Because of its decades of experience implementing the Paperwork Reduction Act, OMB surely is familiar with the arbitrary nature of such thresholds, and the extent to which they induce strategic behavior (e.g., agencies propensity to discover that the optimal number of persons from whom to collect information is nine).

[13] In Attachment F, we explain why examiners' financial incentives are not compatible with expeditious procedure.

future potential licensees, litigants, and other challengers to the patent will ever be able to find.[14] Neither preamble analyzes the practicality of any alternative to this iterative dialog or the effect of cutting it off or limiting it, especially in the context of a complex invention.

USPTO's proposed rules would damage innovation in at least two other important ways. First, by raising the cost of filing patent applications the Office will discourage inventors at the margin from submitting them and divert resources from other innovative activities. To the extent that innovation is financially motivated, reduced patent applications must translate into reduced protection for intellectual property, a diminished incentive to innovate, and less future intellectual property. These social costs may be impossible to quantify, but nevertheless they are very real.

Second, the proposed rules create vast new uncertainty about whether intellectual property will be adequately protected in the United States. Uncertainty diminishes economic actors' willingness to invest and take risks, and thus will reduce innovation by an unknown but significant amount.[15]

III. Other Costs

USPTO claims that these rules will reduce paperwork burden. For the Limits on Claims rule, this appears to reflect USPTO's expectation that no applicant will actually submit the extremely burdensome Examination Support Document (ESD) that the Office would require for applications designating more than 10 claims for initial examination. For the Continuations Rule, USPTO appears to assume that either the circumstances that lead to continued examination will disappear or applicants will simply abandon affected applications.

In Attachment M we show that USPTO has seriously underestimated the existing paperwork burden it imposes on the public, and why its estimates of burden reduction are invalid and unreliable.

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[14] Patent prosecution is akin to a contract negotiation in which applicant and examiner work to reach a consensus decision. The Continuations Rule would allow one side (USPTO) to impose on the other (patent applicants) the restriction that their negotiation shall have no more than two rounds.

[15] USPTO may allege that applicants "game the system" by overfiling in various ways. Despite years of experience, patent attorneys are always uncertain about patent examiners will review and respond to similar claims, and how it will apply the Manual on Patent Examination Practice (MPEP). In addition to deterring some applications for patentable inventions from being filed at all, uncertainty about USPTO behavior logically causes defensive overfiling if (as in the case of patent applications) a failure to advance a claim means that it is permanently lost. See Office of Management and Budget, Economic Analysis Under Executive Order 12866 ("For risk-averse individuals, the certainty equivalent of [an uncertain] net benefit stream would be smaller than the expected value of those net benefits, because risk intrinsically has a negative value")

Attachment C

The Draft Rules Are Not Required by Patent Law or Necessary to Implement Patent Law

The most fundamental requirement of Executive Order 12,866 may be the stated regulatory philosophy:

> **Section 1**. *Statement of Regulatory Philosophy and Principles.* (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

We examine these circumstances justifying regulation in a logical order that is somewhat different from the text.

I. Does the statute require another regulatory approach?

USPTO's rulemaking authority and obligation to examine patent applications are governed by federal patent law, most notably, 35 U.S.C. §§ 2, 3, 131 and 132 (see Attachment O). Nothing in any statute directs USPTO to restrict inventors' access to continuations, nor does the law direct USPTO to arbitrarily limit the number of claims that will be initially examined in a single patent application.[16] Furthermore, nothing in the law directs USPTO not to maximize net

[16] USPTO may assert that the Limit on Claims Rule does not set an absolute limit on the number of claims that will be examined because applicants who want to have more than 10 claims initially examined are always free to submit the Examination Support Document (ESD). In Attachment M, Sec. II.2, we note that senior USPTO officials have made public statements indicating that they do not expect applicants to actually utilize this "safe harbor" because it is overly burdensome.

social benefits from the issuance of patents. Thus, the regulatory philosophy in Executive Order 12,866 unambiguously applies to these two draft final rules.

II. Are these rules required by law or to interpret the law?

USPTO was required to issue certain regulations implementing new provisions in the American Inventors Protection Act of 1999 (AIPA).[17] These two draft rules are neither required by this law nor needed to interpret any provision of it. Congress has amended the Patent Act several times in recent decades, but never to limit the opportunities of inventors in any way analogous to the proposed rules, or to suggest that USPTO should do so. For example, the AIPA made continued examinations easier, not harder, by adding a new "request for continued examination" provision as a lower-cost, easier alternative to older mechanisms for continuations. It also extended patent term for some classes of continuation applications, and asked USPTO to study ways to encourage inventors to participate in the patent system, not to restrict participation.[18]

III. Is there a material failure of private markets that would justify these regulations?

The patent process is somewhat unusual insofar as it is a user fee based service the federal government provides to utilize market forces (intellectual property rights) in the furtherance of delivering a public good (stimulating innovation). The protection of intellectual property is precisely the kind of function that only governments can provide. Congress having acted to provide this public good, it has delegated to USPTO the authority to provide structure, process and predictability to this process, not to make policy concerning how much of the public good to provide.

As we discuss in Attachment F, a strong case can be made that the problems USPTO is seeking to remedy through regulation are the result of "government failure."[19] Unfortunately, instead of addressing governmental failure directly, USPTO appears to have chosen to further regulate the inventors and innovators who are the customers who pay user fees for its services. USPTO is a monopoly provider of these services. One of its problems is overcoming the natural

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[17] *E.g.*, 65 Fed. Reg. 50092, "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule" and 65 Fed. Reg. 56365, "Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term; Final Rule."

[18] 35 U.S.C. § 132(b); 35 U.S.C. § 154(b) (providing for term extension for certain continuation applications filed under § 120 but not RCE's under § 132(b)); 113 Stat. 1501 § 4204 (instructing USPTO to "conduct a study of alternative fee structures that could be adopted … to encourage maximum participation by the inventor community").

[19] For a lengthy description and analysis of government failure, see Charles Wolf Jr., Markets or Governments? Choosing Between Imperfect Alternatives. MIT Press, 1988. *See also* Susan E. Dudley, Primer on Regulation, Mercatus Policy Series, Policy Resource No. 1, Mercatus Center, 2005.

characteristics of monopolists – producing less than the optimal quantity at a higher than optimal price.[20]

IV. Has USPTO decided whether and how to regulate based on an assessment of all costs and benefits of available regulatory alternatives, including the alternative of not regulating?

USPTO has disclosed only the results of certain forecasts of changes in backlog ("patent pendency"). These results are found in the Chicago Town Hall slides.[21] None of the results reported concern social benefits or social costs. Thus, if USPTO has performed any analysis of social benefits and costs, it has not disclosed it. In May 2006, one of the signatories of this letter informally asked USPTO Deputy Director Office of Patent Legal Administration Robert Clarke if there were any other supporting data besides the limited information contained in the preambles to the Notices of Proposed Rulemaking. Mr. Clarke replied via email:

> We do not have a complete package of supporting information that is available for public inspection. The study for these packages was substantiated in a series of pre-decisional electronic communications that has not been made available to the public.[22]

In September 2006, another signatory filed a formal Freedom of Information Act (FOIA) request. In October 2006, USPTO FOIA Officer Robert Fawcett replied that USPTO had "identified 114 pages of documents that are responsive to [the] request and are releasable."23 Mr. Fawcett did not acknowledge the existence of pre-decisional materials exempt from FOIA disclosure or explain why they were exempt, and none of the 114 pages released contain readily analyzable data that adhere to OMB's (or USPTO's) principles for information quality, most notably, the principles of transparency, reproducibility, and objectivity.

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[20] *See* W. Kip Viscusi, John M. Vernon, and Joseph E Harrington Jr., Economics of Regulation and Antitrust (2d ed.), MIT Press 1995.

[21] See Attachment N, slides 49-54.

[22] http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/alderucci.pdf, page 39.

[23] See Attachment N. The 114 pages are the materials found in these four web pages:
http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides.ppt
http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslidestext.html
http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html
http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/laiplabackgroundtext.html

If the responses that we received are full and accurate, USPTO did not perform any analysis of regulatory effects as required by Section 1(a) of Executive Order 12,866.[24]

V. What constitutes a "compelling public need"?

The primary stated benefit of these two draft rules is to reduce USPTO's backlog, and thereby improve various performance metrics. For example, the Office has established the reduction in backlog ("patent pendency") as a performance goal under the Government Performance and Results Act (GPRA).[25]

Unfortunately, USPTO's management goal of reduced patent pendency is, at best, a poor proxy for output. Better output measures might include:

1. Maximizing the number of patent claims issued that meet some established standard of quality, and maximizing the number of patent claims denied that fail to meet this standard; and
2. Minimizing the number of erroneous decisions, including both invalid claims issued and valid patent claims denied.

As a proxy for these output measures, patent pendency is not very helpful. Among pending patents, one cannot easily distinguish between valid and invalid patents being delayed. The social cost of delaying a valid patent is almost certainly much greater than the social cost of delaying an invalid patent, as there is no mechanism to compensate an innovator for the lack of or delay in obtaining a valid patent whereas invalid patents may be attacked or limited in several ways.

More importantly, all output measures are inherently defective because they do not take account of the outcomes that the patent examination program was created to achieve – maximizing the social value of protection provided for patentable intellectual property net of the

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[24] Public comments by senior USPTO officials also indicate that the Office did not analyze its data to ascertain whether applicants or examiners were predominantly responsible for its "rework" problem, which was the presumed cause of backlog. At one of the pubic "Town Hall" meetings, held in New York on April 7, 2007, a question was asked by a member of the audience, and answered by Commissioner Doll as follows:

> Question: Commissioner Doll, did you do any studies to identify where these rework applications are coming from? Do you have any sense for whether they're caused by the examiner screwing up or the applicant screwing up? How are you getting into that problem?
>
> Commissioner Doll: No, I didn't differentiate between whether it was an applicant error or an examiner error.

[25] United States Patent and Trademark Office, 2007-2012 Strategic Plan (http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf).

social costs of error.[26] Patent pendency is not well correlated to outcome value. For example, pendency could be lowered if applications were rushed through the examination process with a cavalier regard for patent quality, though one certainly would not correlate this decrease in pendency to an improvement in outcomes. Alternatively, USPTO could restrict access to the examination process and otherwise make the application process more cumbersome and expensive. This also would drive down pendency, but there is no basis for assuming that the quality of patents issued would improve, nor would it account for the losses associated with failing to issue patents that should have been issued but never entered examination. (Indeed, that's precisely the mechanism by which these two rules would reduce patent pendency: they would reduce the number of applications, and especially complex ones.)

USPTO's regulatory rationale for these two draft rules can be reduced to agency convenience in service of the management goal of reducing patent pendency. It is conceivable that an agency's management goal might be itself a "compelling public need." That seems highly unlikely unless the management goal is very closely aligned with the substantive policy outcomes that the agency's program is intended to achieve. Perhaps that kind of alignment exists in such extraordinary matters as national security emergencies. It does not exist in this case.

Still, it's not clear why USPTO elevates pendency and backlog over all other concerns, such as costs, incentives for investment, and disclosure, clarity and precision in the definition of the scope of property rights. Perhaps there are other nonregulatory objectives USPTO has in mind for which it has unfortunately selected a blunt regulatory tool.[27]

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[26] USPTO includes quality as one of its management goals. According to its strategic plan, USPTO measures quality three ways:

- "In-process compliance with published statutory, regulatory, and practice standards"
- "End-of-process compliance with these same standards"
- "Review of statistically significant, random samplings of examiners' work".

But there is an inevitable tradeoff between achieving these quality measures and reducing patent pendency. A proper Regulatory Impact Analysis would take account of the adverse effects on quality of regulatory efforts to reduce pendency.

[27] Reducing patent pendency is the first of three metrics listed in OMB's Program Assessment Rating Tool (PART). OMB rates USPTO performance as "adequate" ("Pendency, or the time to examine an application and issue a patent, remains high at 30 months, and approximately 500,000 patent applications await examination"). None of the three metrics is a measure of outcomes. See ExpectMore.gov at http://www.whitehouse.gov/omb/expectmore/summary/10000046.2003.html (summary) and http://www.whitehouse.gov/omb/expectmore/detail/10000046.2003.html (detailed report).