**SIGNATORIES**

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

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

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

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

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

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

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

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

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

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

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

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

Joe Kiani
Chairman and CEO
Masimo Corp.
Irvine, CA

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

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

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

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

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

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

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

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

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

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

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

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
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

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
Telik, Inc.
3165 Porter Drive, Palo Alto CA 94304-1213
Tel: +1 650 845 7720
Fax: +1 650 845 7800
E-mail: dfreyberg@telik.com

-----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

Order Entry: P.O. Box 888215, Grand Rapids, Michigan 49588-8215
Corporate Office: 6543 Thornapple River Drive SE, Alto, Michigan 49302-9765
Phone: (616) 698-9644 • (800) 809-9644

## 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

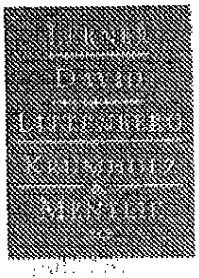
Please see our comments attached.

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





PAGE 1/5 * RCVD AT 10/10/2006 2:45:22 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/15 * DNIS:2737719 * CSID:12345678901234567890 * DURATION (mm-ss):03-18



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

*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**
**Washington, D.C. 20006**
**(202) 349-7174**
**(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.

Telik, Inc., 3165 Porter Drive, Palo Alto, CA 94304 TEL 650-845-7700 FAX 650-845-7800 www.telik.com

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
(206) 442-6676 (direct)
(206) 442-6678 (FAX)

# 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.

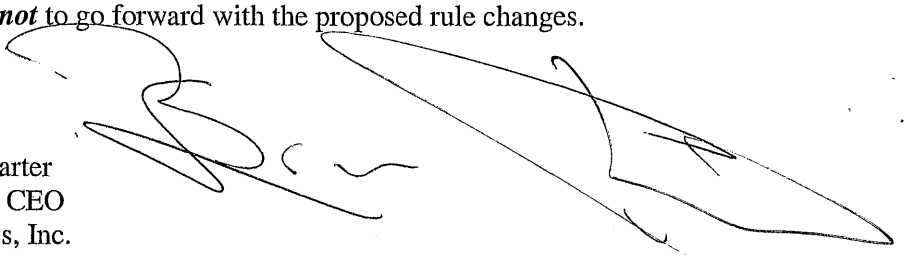
Historically, biotechnology companies like ZymoGenetics have used multiple continuing applications to obtain a meaningful scope of drug patents that both narrowly cover a drug itself and that more broadly cover an area of protection surrounding the drug. Multiple applications allow us the opportunity 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