----Original Message-----

From: Robert J. Yarbrough [mailto:robert@yarbroughlaw.com]

Sent: Friday, April 28, 2006 3:46 PM

To: AB93Comments

Subject: Comments to proposed rulemaking, "Changes to Practice for

Continuing Applications...," Docket No. 2005-P-066

Sirs:

Attached are comments to the following rulemaking by the Pennsylvania IP Forum in .pdf format:

Notice of Proposed Rulemaking, Changes to Practice for Continuing Applications...

71 Fed. Reg. 48 (January 3, 2006)
Docket No. 2005-P-066
If the file format is not suitable, please advise me.

Robert J. Yarbrough, Attorney at Law www.yarbroughlaw.com phone (610) 891-0668 fax (610) 891-0655

201 North Jackson Street • Media • Pennsylvania • 19063 Phone: (610) 891-0668 • Fax: (610) 891-0655 email: ipforum@yarbroughlaw.com

April 28, 2006
Mail Stop Comments - Patents
Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Notice of Proposed Rulemaking,
"Changes to Practice for Continuing Applications..."
71 Fed. Reg. 48 (January 3, 2006)
Docket No. 2005-P-066

Dear Mr. Commissioner:

In the above Federal Register Notice dated January 3, 2006, the U.S. Patent and Trademark Office requested public comment regarding the above Notice of Proposed Rulemaking. This letter presents the comments of the Pennsylvania Intellectual Property Forum ("Pennsylvania IP Forum"). The Pennsylvania IP Forum is an organization of patent practitioners and intellectual property attorneys located principally in Southeastern Pennsylvania. While some of us represent large entities, all of us represent individual inventors and small entities. Large entities already have significant advocates in Washington. Our purpose in making these comments is to provide a voice to individual inventors and small entities that otherwise would not be heard.

The Pennsylvania IP Forum appreciates the opportunity to offer comments on the rule and practice changes proposed by the Office. We believe that the proposed changes would adversely affect the patent prosecution process in terms of time and cost, particularly for small business. We are concerned by the continuing shift in burden during prosecution from the Office to applicants having limited resources. We are specifically concerned that the proposed rules will have unintended consequences to small business.

The value of small business entities to the US economy cannot be overstated. The publication entitled "A Guide for Governmental Agencies: How to Comply with the Regulatory Flexibility Act" ("RFA Guide"), promulgated by the Small Business Administration, sets forth Federal agency data on small businesses. In its description of how important small businesses are to the US economy, the RFA Guide indicates that small businesses represent more than 99.7 percent of all

employers. Moreover, on p.99 of the RFA Guide, the research set forth indicates that "small firms produce 13 to 14 times more patents per employee than large patenting firms. Those patents are twice as likely as large firm patents to be among the one (1) percent most cited." It is thus a matter of public record and, indeed, a finding of the Federal government, that the patent activities of our country's small business entities are crucial to the U.S. economy.

INCORPORATION OF COMMENTS BY REFERENCE

The Pennsylvania IP Forum agrees with and adopts as its own the comments of Robert A. Vanderhye. Mr. Vanderhye's comments are incorporated herein by reference and a copy of those comments is enclosed as Attachment 1.

ADDITIONAL COMMENTS RELATING TO THE REGULATORY FLEXIBILITY ACT

a. The Office has failed to comply with the Regulatory Flexibility Act

The PTO has failed to adequately consider the effect of the above pending rulemaking on the small business community as required by the Regulatory Flexibility Act, 5 U.S.C. §§601-612 (hereinafter "RFA"). The rulemaking package in question is crucial to small businesses and a full regulatory flexibility analysis is required. We request that you direct the PTO staff to fully comply with the requirements of the RFA, and that the rulemaking package be republished for public comment after that compliance and prior to final promulgation. We believe that if the PTO fails to perform a full regulatory analysis in compliance with the terms of the RFA, the rulemaking package will be invalid and vulnerable to challenge under 5 U.S.C. §611(a)(4).

The Small Business Administration ("SBA") has determined that the PTO should conduct a full RFA analysis of the pending rulemaking. See enclosed Attachment 2, a letter of April 27, 2006 to Undersecretary Jon W. Dudas of the PTO from Thomas M. Sullivan, Chief Counsel for Advocacy and Carrol L. Barnes, Assistant Chief Counsel for Advocacy of the SBA.

b. The RFA requires the PTO to adequately analyze the effect of rulemakings on small business

When an agency issues a rulemaking proposal, the RFA requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis (IRFA)" which will "describe the impact of the proposed rule on small entities." 5 U.S.C. §603(a); Northwest Mining Association v. Babbitt, 5 F. Supp.2d 9 (D.D.C. 1998). Before a proposed regulation is published in the Federal

Register, the RFA requires the promulgating agency to identify the entities to be regulated by size and number, estimate the economic impact by size category and determine which size categories will be impacted. The promulgating agency must then ask the following question, "Will the rule changes have a significant economic impact on a substantial number of small entities?" 5 U.S.C. §605(b). If the answer to that query is positive, an initial regulatory flexibility analysis must be performed. If the answer to this question is negative, the head of the agency may then certify that the rule will not have a significant impact. Such a certification must include a statement providing the factual basis for this determination.

The Office of Advocacy of the Small Business Administration is required by Section 612 of the RFA to monitor agency compliance and disseminated the RFA Guide to inform agency action. The RFA Guide provides that the statement accompanying a certification of no impact, at a minimum, must include (a) a description of the affected entities, and (b) the facts that clearly justify the certification that there will be no significant impact. The agency's reasoning and assumptions underlying the certification must be explicit in order to obtain public comment and thus, receive information that would be used to re-evaluate the certification. See <u>Guide</u>, at pp. 8-9. The decision to certify must be based upon a sound threshold analysis to support a finding of no significant impact and the record an agency builds to support a decision to certify is subject to judicial review under 5 U.S.C. §611(a).

c. The PTO certifications do not meet the RFA requirements because proper credible facts to support the certifications are lacking.

The PTO failed to provide facts that clearly justify the certification of no significant impact. The proposed rule change seeks to revise the rules of practice by requiring an applicant, among other things, to pay a large fee and file a petition with a showing "to the satisfaction of the Director" as to why any second or subsequent continuation applications or requests for continued examination should be accepted for filing. The PTO has certified that "the changes proposed in this notice will not affect a substantial number of small entities". This conclusion is incorrect because the PTO has not adequately examined the facts surrounding the proposed regulation and misperceives the effect of the proposed rulemaking.

The proposal increases risk, cost and uncertainty for small businesses. To meet enablement and best mode requirements, the prudent patent applicant discloses in the application a great deal of information about his or her invention. If the proposed regulation is finally promulgated, every applicant must claim all of the aspects of an invention that are disclosed or risk never being able to claim the disclosed invention, whether the applicant understands all of those aspects at the

time of filing or not. When a small business invents a technology having multiple applications, the small business likely will not know until the technology is fully developed which of those applications, if any, will have value and therefore are worthy of an investment in patent protection.

If the regulation is finally promulgated, the small business will be presented with an expensive and risky dilemma: at great and wasteful cost, the small business can keep its options open by pursuing patent protection for all of the aspects of the technology that the small business can foresee; alternatively, the small business can risk that it has guessed correctly and that the patent for which it has applied will provide the applicant with adequate protection. If the small business guesses wrong, then the mistake is costly and valuable aspects of its invention are not protected. The proposed rulemaking does not address the increased cost to small business of attempting to protect all aspects of an invention and does not address the cost associated with increased risk to small business.

The rulemaking misperceives the effect of the regulation and overstates any benefit from the reduction in the number of applications. First, many applicants will keep their options open by submitting multiple claims addressing multiple patentably distinct inventions in the same application, knowing that the claims likely will draw a restriction from the examiner and require divisional applications. Second, other applicants will submit multiple applications addressed to different aspects of the invention at the earliest stages of the patent process. Either approach will result in an increase in cost to small businesses and an increase in the number of patent applications that must be reviewed by the PTO. The PTO will find itself reviewing claims for many dead end and blind alley applications that would not have been filed but for the proposed regulation.

As disclosed by the RFA Guide, small businesses engage in proportionately more patenting activity than large businesses. Restrictions on patenting therefore disproportionately affect small businesses. Contrary to the PTO's assertions, these changes will have a significant economic impact on a great number of small entities.

d. The proposed rulemaking does not comply with the RFA because the PTO does not evaluate alternatives.

Under 5 U.S.C. §603(c), the keystone of an initial regulatory flexibility analysis is the description of any significant alternatives to the proposed rule that accomplish the stated objectives and that minimize the rule's economic impact on small entities. There are no viable alternatives suggested within this rulemaking to provide regulatory relief to small entities as required.

PENNSYLVANIA INTELLECTUAL PROPERTY FORUM

There are several alternatives that the PTO should evaluate that would efficiently and effectively achieve the PTO's stated goals without unduly burdening small entities or stifling innovation. The first alternative is to exempt small entities. Since, as the PTO alleges, only a small percentage of applications by small entity applicants will be affected, one manner in which to avoid the further scrutiny under the RFA is to exempt small entity applicants from compliance with this proposed rule.

e. The PTO should conduct the required analyses of impact on small business and republish the proposed regulations for comment.

In making public comment to the proposed rulemaking, the public is entitled to review any and all credible information the PTO relied upon in making its decision to certify that the proposed rule changes will not have a significant effect under the RFA. The PTO has presented no such credible information in the proposed rulemaking. The PTO also has provided us with no such credible information in response to a Freedom of Information Act request from one of our members. We are left to infer that no such credible information exists.

We believe that the proposed rule change will have a significant impact on a substantial number of small entities both in terms of out of pocket costs as well as in valuable time. The PTO should perform a full regulatory flexibility analysis and should republish for public comment the proposed regulation, including the regulatory flexibility analysis. If the PTO does not comply with these requirements of the RFA, the regulation packages will not be effectively promulgated and will be vulnerable to challenge under 5 U.S.C. §611.

The members of the Pennsylvania IP Forum appreciate the opportunity to comment on the proposed rules and would be pleased to further assist the Office in any manner necessary to consideration of the issues discussed above.

Very truly yours,

Robert J. Yarbrough PTO Reg. No. 42,241

Chairman,

Pennsylvania Intellectual Property Forum

The following members of the Pennsylvania Intellectual Property Forum concur in the foregoing comments:

Stuart S. Bowie, Esquire, PTO Reg. No. 22,652

Brian P. Canniff, Esquire, PTO Reg. No. 43,530

Richard A. Elder, Esquire, PTO Reg. No. 30255

Gerry J. Elman, Esquire, PTO Reg. No. 24,404

Mark A. Garzia, Esquire, PTO Reg. No. 35517

David Guttman, Esquire, PTO Reg. No. 27479

Andrew T. Hawkins, Esquire, PTO Reg. No. 51791

Lawrence Husick, Esquire, PTO Reg. No. 38,374

Art Kyriazis, Esquire, PTO Reg. No. 53169

Robert S. Lipton, Esquire, PTO Reg. No. 25,403

Deborah A. Logan, Esquire, PTO Reg. No. 54,279

Nils H. Ljungman, Esquire, PTO Reg. No. 25,997

Loretta Smith, Esquire, PTO Reg. No. 45116

Ash Tankha, Esquire, PTO Reg. No. 33,802

Laurence A. Weinberger, Esquire, PTO Reg. No. 27,965

Patricia A. Wenger, Esquire, PTO Reg. No. 42,218

Arnold W. Winter, Esquire, PA Atty. ID No. 62,347

----Original Message----From: Bob Vanderhye [mailto:ravar@nixonvan.com] Sent: Monday, January 23, 2006 1:38 PM

To: AB93Comments

Subject: Comments of Robert Vanderhye on Proposed Rules

The attached provides my comments, in Word format, on the proposed new rules regarding ocntinuing applications.

ATTACHMENT 1

Comments of Robert A. Vanderhye to Proposed Rules of the Patent & Trademark Office regarding "Changes to Practice for Continuing Applications,..."; RIN 0651-AB93 [Docket No. 2005-P-066]

These comments are made by Robert A. Vanderhye, individually, as a former patent examiner [1968-1973], as a registered patent attorney [Reg. #27,076] for more than 30 years, and as an independent inventor [14 issued or pending patents]. They are not made on behalf of, and do not necessarily reflect the views of, my former law firm, Nixon & Vanderhye P. C.

My remarks should be prefaced by stating that in the more than 30 years I have prosecuted cases before the PTO I recall only two instances in which I filed more than one continuation application. My normal procedure, in the literally thousands of patent applications I have prosecuted, is to get the case to allowance or appeal as soon as possible. That has no bearing on the propriety of filing more than one, however, or the expense or trouble one should have to go through to file more than one continuation.

Summary of Comments:

- (1) The entire reasoning of the PTO regarding the adverse effects continuations have on examination is erroneous.
- (2) The PTO does not have authority to make the changes suggested under the rule making provisions of 35 USC §2(b)(2) since they are inconsistent with law.

Detailed Comments:

(1) The entire reasoning of the PTO regarding the adverse effects continuations have on examination is erroneous

The PTO suggests on page 50, 1st column, of the Federal Register notice [hereafter "FR"] that about 30% of the new applications filed in fiscal year 2005 were some sort of continuing application, and concludes from that 30% of the patenting examining resources must be applied to examining reworked earlier applications. There is no basis in logic or fact for this assumption.

Applications examined for the first time require reading at least the claims (and hopefully the entire specification though many examiners do not do that) of the application, a search, and an original analysis of the patentability of the claims and compliance of the application with formalities. None of these exist for continuation applications (although they may for continuation-in-part or divisional applications). When I was an examiner I was able to examine a continuation application in between 5-40% (I would say on average 15-20%) of the time it took me to examine a new application. I see no reason why the same isn't as true today. If the PTO is having trouble examining all the applications that are filed it should hire more examiners.

Further, the attempt to lump CIP applications with regular continuation applications (or requests for continued prosecution) is misguided. I am aware of no one that files a CIP application unless the inventor came up with something new. CIPs by their very nature include something that was not disclosed before. Therefore requiring

someone to pay a petition fee, and increase prosecution costs, by having to prepare and submit a petition is unjust, no matter how many continuations or requests for continued prosecution have been filed.

The PTO has also failed to consider the costs to the inventors and assignees for the new procedures. The filing fees the PTO now receives for continuations and requests for continued prosecution is "gravy" since the PTO likely expends only about 20% of the resources necessary for examining an original application to examine a continuation, yet gets just as much money. If the continuation practice is greatly reduced this will mean that fees for everyone – now subsidized by those (unlike me) who drag out prosecution for one reason or the other – will go up faster than they otherwise would, or the PTO will have a shortfall. I don't want either of these – increased fees or a shortfall – to occur. People like me who expeditiously prosecute will, however, in those rare instances when more than one continuing application is necessary, end up having to pay more for petitions fees and preparation of petition papers than we do now.

In summary, the PTO cannot justify its proposed new rules on increasing efficiency of examining new applications, and the new rules will result in increased patent fees for everyone.

(2) The PTO does not have authority to make the changes suggested under the rule making provisions of 35 USC §2(b)(2) since they are inconsistent with law

Under 35 USC §2(b)(2), the PTO "may establish regulations, not inconsistent with law". The proposal to arbitrarily limit the number of continuations that may be filed absent the payment of an additional petition fee is inconsistent with statutory and case law on the subject.

- a) Nowhere in 35 USC §120 is there any support for the proposed new rules. Rather the statutory language is clear it says "An application..." (i. e. ANY application) "shall have the same effect..." (not "may, if the PTO wants it to, applying criteria nowhere set forth in the rest of the statute or case law, have the same effect").
- b) Further, not only does *In re Bogese*, 303 F.3d 1362, 64 USPQ2d 1448 (Fed Cir 2002) not support the PTO's proposed rulemaking authority here (as alleged on page 50, third column, of the FR), it fact it says that the PTO does not have such authority.

Page 50, 3rd column, of the FR notice states that *Bogese* at 303 F.3d 1368, n.5, says the PTO has inherent authority to do what it is doing here. Not so. Footnote 5 of Bogese provides: "Although the PTO, both in the Board decision below and in its brief on appeal, relies on 37 C.F.R. § 1.111 as supporting its action, *Ex parte Bogese II*, slip op. at 37, n.14, Appellee's Brief at 4, 18, 38, 43, 49, and 50, that section appears to be inapplicable here. That section provides "[t]he applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application . . . to final action." 37 C.F.R. § 1.111(b) (2001) (emphasis in original). The cited section, both as it existed in 1995, and currently, applies to replies to Office actions. See 37 C.F.R. § 1.111(a) (1995) ("After the Office action, if adverse in any respect, the applicant or patent owner, if he or she persists in his or her application for a patent or reexamination proceeding, must reply thereto and may request reconsideration or further examination, with or without amendment."); 37 C.F.R. § 1.111(a)(1) (2001) ("If the Office action after

the first examination (§ 1.104) is adverse in any respect, the applicant or patent owner, if he or she persists in his or her application for a patent or reexamination proceeding, must reply and request reconsideration or further examination, with or without amendment."). Section 1.113 effectively defines a reply as including an appeal, amendment, or petition. See 37 C.F.R. § 1.113(a) (2001) ("On the second or any subsequent examination or consideration by the examiner the rejection or other action may be made final, whereupon applicant's, or . . . patent owner's reply is limited to appeal in the case of rejection of any claim (§ 1.191), or to amendment as specified in § 1.114 or § 1.116. Petition may be taken to the Commissioner in the case of objections or requirements not involved in the rejection of any claim (§ 1.181).") However, a file wrapper continuation application, governed by section 1.60 of the 1995 regulations, is not included with the definition of a reply. While section 1.111 recognizes the general requirement of good faith in prosecution, its terms are not directly applicable to file wrapper continuation applications." As the underlined portion makes clear, note 5 does not suggest the PTO has authority to limit continuation applications, but rather suggests it does not.

The following portion of the dissent in *Bogese* more clearly sets for the law, and was not disagreed with by the majority opinion (even thought the majority came to a different ultimate conclusion): "If a change in the statutory rules of prosecution is deemed appropriate, it should be processed legislatively.... The already burdensome and expensive path to a patent does not benefit from the added encumbrance of an unguided bar that can be imposed as a matter of administrative discretion. The potential abuse in the administrative process appears to far transcend the wrong to be remedied. Amid the complex procedures of patent examination, statute-based rules are preferable to the "unbounded jurisdiction" of the patent examining corps relying on personal views of "equity""... Nowhere, however, has an agency been authorized to impose, in its discretion, restrictions contrary to the statute that governs agency action."

The situation in *Bogese* was a true laches situation. It has nothing to do with the proposed rules – rather it deals with an entirely different situation, with entirely different underpinnings and reasoning. Also in *Bogese* the burden was on the PTO to demonstrate that there was laches. The new rules propose to put the burden on the applicant to prove that there is no laches in a situation where there should be no presumption of laches.

The PTO's analysis in the FR also fails to take into account case law of the Federal Circuit subsequent to *Bogese*. In *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, LP*, 422 F.3d 1378, 76 U.S.P.Q.2d 1354 (Fed Cir 2005) the Court found that there were many legitimate reasons for filing continuing applications. In part the Court held: "Filing a divisional application in response to a requirement for restriction is one such legitimate reason for refiling a patent application. Given one's entitlement to claim an invention in various ways, and the PTO's practice of limiting its examination of an application to only one of what it considers to be several inventions, it cannot, without more, be an abuse of the system to file divisional applications on various aspects that the PTO has considered to be separate and distinct from each other. See 35 U.S.C. § 121 (2000); 37 C.F.R. § 1.142 (2005); see also Manual of Patent Examining Procedure §§ 803, 818 (8th ed., rev. 2 2004). That is so even when one defers the filing of a divisional application until just before the issuance of the parent application. Such action is expressly allowed by statute. 35 U.S.C. § 121. Moreover, one might legitimately refile an application containing rejected claims in order to present

evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses, although entitlement to an earlier filing date for any claimed subject matter may of course be necessary to avoid a statutory bar created by intervening events outlined in 35 U.S.C. §§ 102 and 103. One may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive.

However, refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance can be considered an abuse of the patent system. See *Bogese*, 303 F.3d at 1368-69 (discussing *Ex parte Hull*, 191 USPQ 157 (Bd. Pat. App. & Interfs. 1975)). In particular, multiple examples of repetitive refilings that demonstrate a pattern of unjustifiably delayed prosecution may be held to constitute laches".

Thus, the Federal Circuit has clearly stated that only if there is laches may the PTO deny one the benefit of the filing of multiple continuation applications, and the burden is on the PTO to demonstrate laches by a "pattern", etc.. No pattern can occur upon the filing of two continuation applications. Further, the PTO cannot impose by regulation a burden of proof different than that required by the statute and case law.

c) Also the standard set forth in the proposed new rules for allowing second or further continuations, namely "a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application", is unduly harsh and arbitrary. The whole purpose of filing continuations is so that one cannot or does not have to make this showing in the previous application. Thus, in practice this standard will put a definitive, arbitrary, limit of one continuation application for each new application filed. Thus in practice there will be the *per se* limit on continuations that the PTO itself recognizes is prohibited by *In re Hogan*, 559 F.2d 595, 603-5 (CCPA 1977) and *In re Henrikson*, 399 F.2d 253, 262 (CCPA 1968) [see page 50, 3rd column of the FR].

In summary, if the new rules are adopted, they will be challenged in Court, and the PTO will lose. Any action taken by the PTO in the interim will be null and void, and the result will be a greatly enhanced burden on the PTO, which will slow down examination of new applications much more than the examination will allegedly be enhanced by the adoption of the new rules. Therefore I urge the PTO to withdraw the proposed new rules relating to continuing applications.

Sincerely,

Robert A. Vanderhye Reg. No. 27,076 801 Ridge Dr. McLean, VA 22101-1625 703-442-0422 ravar@nixonvan.com



Advocacy: the voice of small business in government

April 27, 2006

The Honorable Jon W. Dudas
Undersecretary of Commerce for
Intellectual Property and Director of the
U.S. Patent and Trademark Office
600 Dulany Street
Madison West
Suite 10D44
Alexandria, VA 22314

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

The Office of Advocacy (Advocacy) of the U.S. Small Business Administration (SBA) submits this comment in response to the U.S. Patent and Trademark Office's (PTO) notices of proposed rulemaking referenced above. The proposed regulations would limit to ten the number of representative claims contained in an initial examination of a patent application as well as restrict an applicant to one continuation application as of right. Current rules of practice neither limit the number of claims that are reviewed on initial examination nor the number of permissible continuation applications. In the two proposals, the PTO concluded that the changes to the patent application and examination process would not have a significant economic impact on a substantial number of small entities.

Advocacy's comment relays concerns expressed by small entities about the proposed regulations. Advocacy believes that as written, the proposals are likely to have a significant economic impact on a substantial number of small entities, including small businesses and small independent inventors. Advocacy recommends that the PTO conduct a supplemental Initial Regulatory Flexibility Analysis (IRFA) before publishing the final regulations.

Background on the Office of Advocacy

The Office of Advocacy, created in 1976, monitors and reports on agency compliance with the Regulatory Flexibility Act of 1980 (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The RFA requires federal agencies

¹ Pub. L. No. 96-354, 94 Stat. 1164 (1980), (codified as amended at 5 U.S.C. §§ 601-612).

to determine a rule's economic impact on small entities and consider significant regulatory alternatives that achieve the agency's objectives while minimizing the impact on small entities. Because it is an independent office within the SBA, the views expressed by the Office of Advocacy do not necessarily reflect the views of the SBA or the Administration.

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring federal agencies to implement policies protecting small businesses when writing new rules and regulations. In accordance with Executive Order 13272, Advocacy may provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget. Executive Order 13272 requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.³

Background on the Proposed Rules

The PTO proposed two regulations changing the rules of practice in order to reduce pendency and accelerate the patent examination process. The first proposal, *Changes to Practice for the Examination of Claims in Patent Applications*⁴ would require that only representative claims designated by the applicant would be reviewed in the initial examination. The agency defines representative claims as all of the independent claims and the dependent claims that are expressly designated by the applicant for examination.⁵ Applicants who designate more than ten representative claims will be asked to provide the PTO with an examination support document discussing all of the representative claims. The agency asserts that preparation of the examination support document should cost about \$2,500.⁷ However, small entities argue that completing an examination support document will be more costly, time consuming and restrict their ability to prosecute patents vigorously.

The second proposal, Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, is intended to help make the patent examination process more efficient by facilitating examiners review of new applications, improve the quality of patents, and expedite the issuance of patents. Continuing applications allow applicants to amend a patent application after it is rejected as well as obtain examination of the amended application. Continued examination practice allows additional examination of a patent application and helps advance an application to final agency action. Instead of permitting an unlimited number of continuing application and continued examination filings, the proposed regulation revises the rules to allow only one continuation

² E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.

³ Id. at § 3(c), 67 Fed. Reg. at 53,461.

⁴ 71 Fed. Reg. 61 (January 3, 2006).

⁵ Id. at 62.

⁶ Id. at 65.

⁷ Id. at 66.

⁸ 71 Fed. Reg. 48 (January 3, 2006).

⁹ *Id*.

application and one continued examination as of right. The proposal also requires that second and subsequent requests for continuation applications and continued examinations should include a petition explaining why the new information could not have been submitted in a prior filing. A fee of \$400 would be required for each petition.¹⁰

The PTO certified that the proposed rules would not have a significant economic impact on a substantial number of small entities in accordance with Section 605(b) of the RFA. The agency's certification was based on data obtained from its Patent Application Locating and Monitoring System (PALM) which showed that about 65,785 "small entities patent applications" were filed (out of a total 216,327 applications) from January 1, 2005 to October 13, 2005. Out of that number, 866 small entity applications (out of 2,522) had more than ten independent claims. PALM also showed that in Fiscal Year 2005, 19,700 (out of 62,870) small entity patent applications were continuing applications and the PTO received 8,970 (out of 52,750) new requests for continued examination from small entities. Advocacy notes that the PTO's definition of small entities excludes any application from a small business that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status.

The PTO Should Conduct an Initial Regulatory Flexibility Analysis (IRFA)

On March 8, 2006, the Office of Advocacy hosted a roundtable to discuss the potential economic impacts of the two proposed regulations. Present at the roundtable were independent inventors, patent attorneys, trade association representatives, PTO staff, and Advocacy staff. PTO personnel gave a presentation on the two proposals, listened and participated in the discussion.

At the roundtable, and through subsequent discussions, Advocacy was informed by those representing small business interests that the proposed rules would have a significant economic impact on small entities seeking patents. Small entities asserted that taken together, the two regulations would increase the cost of application preparation and hinder the patent prosecution process. Moreover, they raised concerns that the regulations will significantly impact the most valuable and commercially viable patents, because those types of patents typically involved a higher number of continuations.

Small entity representatives indicated that limiting applicants to ten representative claims would make it very difficult to properly identify a potential patent, could create future liability concerns, and would weaken potential patents. Contrary to the PTO's estimates, they stated that completion of an examination support document could cost from \$25,000 to \$30,000 - a significant outlay. Further, small entities argued that limiting continuation applications and examinations would inhibit their ability to enhance their applications, significantly increase costs

¹⁰ 71 Fed. Reg. at 56-57.

¹¹ 5 U.S.C. § 605(b).

¹² 71 Fed. Reg. at 66.

¹³ *Id*.

¹⁴ 71 Fed. Reg. at 56.

¹⁵ Manual of Patent Examining Procedure § 509.02 (October 2005).

through new fees, and force small entities to seek review through the very expensive appeals process. Some small entities also stressed that continuation applications are used frequently by small businesses to secure the most commercially successful inventions. Therefore, limiting the number of continuations could severely weaken small entities' ability to protect their patents.

Advocacy believes that the rule will affect a substantial number of small entities. The two proposed changes to the rules reshape the basic rights of any small entity that files a patent application. In addition, the definition of small entity that the PTO uses in its certification is for calculating filing fees and excludes any small entity that has a contractual arrangement involving the invention with a larger company. Small business size standards for RFA purposes don't include this restriction so the number of small businesses affected is likely to be larger than stated in the certification.

Given the issues outlined by regulated small entities and the far reaching impact on many small businesses, Advocacy urges the PTO to complete an IRFA prior to publication of the final rule. The IRFA would allow the agency to examine the impacts of the proposed rule changes on affected small entities more closely. It would permit the agency to evaluate the issues discussed above as well as encourage small entities to comment on the additional information provided in the IRFA. Including an IRFA would also help identify viable regulatory alternatives to the proposed rules and demonstrate agency compliance with the RFA.

Regulatory Alternatives

Advocacy appreciates the PTO's challenge in seeking to identify a reasonable solution to ever increasing caseloads and rising pendency of patent applications. Should the PTO decide to publish an IRFA prior to finalizing the proposed regulations, Advocacy suggests the following alternatives for consideration. The alternatives discussed below attempt to minimize the potential impact of the regulations on affected small entities while also meeting the agency's regulatory objectives. Not intended as an exhaustive list, the following alternatives are just a few of those suggested by the small entities affected by the rulemakings.

Examination of Claims in Patent Applications

1. The PTO Should Expand the Number of Representative Claims Included in Initial Review.

The PTO should evaluate whether increasing the number of representative claims allowed on initial review would be feasible. Small entities argued that ten representative claims would be insufficient to describe the parameters of a potential patent properly. Further, required completion of an examination support document for those applications containing more than ten

¹⁶ 5 U.S.C. § 603 (which requires an agency to publish an IRFA whenever it is required by Section 553 of the Administrative Procedure Act to publish a general notice of proposed rulemaking. As part of a IRFA, the agency must include a description of the reasons why they agency is considering the rule, a succinct statement of the objectives of the rule, the legal basis for the rule, a description and estimate of the numbers of small entities affected by the rule, a description of the projected compliance requirements, identification of Federal rules that overlap or duplicate, and a description of significant alternatives).

representative claims would be more costly than the estimates provided by the PTO and could lead to liability concerns.

2. The PTO Should Provide Expedited Review of Applications that Contain Ten or Fewer Representative Claims.

Since the agency would like to complete initial reviews more efficiently, Advocacy suggests providing an incentive for the applicants to limit the number of representative claims. Offering expedited initial review of applications with ten or fewer representative claims could persuade many applicants to reduce their claims to a lesser number voluntarily. This would help meet the agency's regulatory objectives while facilitating the initial review of patent applications.

3. The Agency Should Not Apply the Regulation Retroactively

Advocacy encourages the PTO to remove retroactive application of the ten representative claim limit to currently pending applications. This provision could be particularly costly for regulated small entities that are less able to absorb expenses associated with reviewing and revising pending applications. As a result, the proposed regulation could prevent small entities from prosecuting their pending patents.

Changes to Practice for Continuing Applications

1. The PTO Should Increase the Number of Permissible Continuation Applications.

Small entities informed Advocacy that limiting patent applicants to a single continuation would negatively impact the most commercially viable and important patents. Similarly, they assert that, in many cases, the most valuable inventions are based on continuation applications. Advocacy recommends that the PTO, at a minimum, permit two continuation applications as of right. In an IRFA, the PTO could request comment on a reasonable number of continuations. Advocacy's discussions with small entities indicate that increasing the number of permissible continuation applications could reduce the potential impact of the regulation.

2. Consider Increasing the Fees for Additional Continuation Applications.

If the agency increases the number of continuations as of right, it could increase the associated fees as well. Small entity representatives have suggested that increasing the fees for additional continuations beyond the first, could deter the filing of additional continuations. Thus, applicants would be encouraged to limit their continuation filings in order to avoid excessive fees.

3. The Agency Should Defer Review of Subsequent Continuation Applications.

Under current rules of practice, continuation applications are often reviewed in advance of many new applications. Some small entities have suggested that the PTO could institute deferred review of continuation applications. This change would permit patent examiners the

opportunity to review more initial applications, thus helping to achieve the agency's regulatory goal of reducing pendency.

Conclusion

Advocacy encourages the PTO to review the comments provided and use the information to conduct a more complete analysis of the potential impact on small entities, which appears to be significant. Advocacy recommends that the PTO release an IRFA that responds to concerns and viable alternatives presented here as well as those filed by small business commenters.

Thank you for your consideration of these issues. Should you have any questions or require additional information, please contact me or Carrol Barnes of my staff at (202) 205-6533.

Sincerely,	
/s/	
Thomas M. Sullivan	-
Chief Counsel for Adv	rocacy
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/s/	
Carrol L. Barnes	
Assistant Chief Couns	al for Advocacy

cc: Mr. Donald Arbuckle, Acting Administrator,
Office of Information and Regulatory Affairs, Office of Management and Budget
Mr. John Doll, Commissioner for Patents, U.S. Patent and Trademark Office