PENNSYLVANIA INTELLECTUAL PROPERTY FORUM
201 NORTH JACKSON STREET • MEDIA • PENNSYLVANIA • 19063
PHONE: (610) 891-0668 • FAX: (610) 891-0655
EMAIL: IPFORUM@YARBROUGHLAW.CO

FAX COVER SHEET: 15 PAGES, INCLUDING THIS PAGE

April 6, 2004

RE: PATENT OFFICE'S NONCOMPLIANCE WITH REGULATORY FLEXIBILITY ACT

TO THE CHAIRMAN AND ALL MEMBERS OF THE SENATE COMMITTEE
ON SMALL BUSINESS & ENTREPRENEURSHIP

Patent and Trademark Office ("PTO") Management has ignored its duty to comply with the Regulatory Flexibility Act, 5 U.S. C. 601 et seq. ("RFA"), in proposing massive sets of PTO rules without giving any consideration to the impact of those rules upon small businesses and small organizations. Our forum protested the proposed rules on behalf of our small business client-inventors and for our own part, as we are entitled to RFA protection as a small organization.

In response to a detailed RFA letter of March 17, 2004 (copy attached) to Honorable Jon W. Dudas, Acting Under Secretary and Acting Director of the PTO, Mr. Knight, PTO's RFA Counsel, placed a teleconference call to members of our Forum, including the undersigned, on March 23, 2004 and followed that up with a fax letter on March 24, 2004, (copy attached).

We were stunned by the crude inaccuracies contained in Mr. Knight's letter. We had no choice, lest silence be construed as acquiesce, other than to respond by faxing the enclosed letter of April 5, 2004 to Mr. Knight, Secretary Evans, Acting Under Secretary Dudas, as well as to each of you to set the record straight.

The purpose of the enclosed is to ask that each of you do everything in your power to protect our Nation's small businesses and small organizations from the extraordinarily adverse impact of the PTO's proposed rules. In current years, in keeping with the History of our Country, inventions made by our small business and solo inventors have been crucial drivers of powerful new technologies which have increased productivity and have advanced science and technology.

Small businesses employ more than 90% of Americans. Many rely on their innovations to keep them competitive. We ask only that the Patent Office be constrained from impeding this tremendously vital source of American enterprise. If nothing else, the Patent Office, by its proposed rules, should follow the RFA to ensure, as is the first rule in Medicine, that they "Do No harm" --to our small-inventor clients.

Thank you for your consideration. May God Bless America.

Respectfully,
Pennsylvania Intellectual Property Forum

Robert J. Yarbrough, Chairman

PENNSYLVANIA INTELLECTUAL PROPERTY FORUM
201 NORTH JACKSON STREET • MEDIA • PENNSYLVANIA • 19063
PHONE: (610) 891-0668 • FAX: (610) 891-0655
EMAIL: IPFORUM@YARBROUGHLAW.CO

April 5, 2004

BY FAX: 703-305-5907
Bernard J. Knight, Jr., Esquire
Deputy General Counsel for General Law
United States Patent & Trademark Office
P. O. BOX 1450
Alexandria, VA 22313-1450

Re: Failure of the Patent and Trademark Office (PTO) to comply with the Regulatory Flexibility Act relating to four recent rulemakings

Dear Mr. Knight:

This letter is in response to your letter of March 24, 2004. For the record, you initiated a telephone call to our office on March 23, 2004. The following persons participated in the telephone conference for the PTO: Bernard Knight, Steve Kunin, Bob Barr, Harry Moatz, Administrative Patent Judge Richard Tortzen and Jennifer Simmons. The following persons participated for the Pennsylvania IP Forum: Stuart S. Bowie, Deborah Logan, Robert J. Yarbrough, Gerry J. Elman, and Robert S. Lipton.

We disagree with your letter of March 24 and with the positions that you argued during the telephone conference on March 23. The areas of disagreement are as follows:

I. MR. KNIGHT, IN HIS CAPACITY AS DEPUTY GENERAL COUNSEL OF THE PTO, MADE STATEMENTS THAT ARE FACTUALLY INCORRECT.

A. SBA personnel have no recollection of memoranda from the PTO.

1. During the telephone call, we asked you whether the PTO performed analyses and collected facts to support its certifications that the four rulemakings in question would have no significant effect on small business under the Regulatory Flexibility Act (5 U.S.C. 601 et seq., hereinafter "Flex Act" or "RFA"). You responded that prior to publication of each of the four certifications, the PTO submitted memoranda to the SBA Office of Advocacy documenting the PTO's conclusions of no significant effect. You further stated that the SBA Office of Advocacy did not object to the PTO's memoranda or conclusions. You implied that the SBA's failure to object amounted to approval of the PTO's certifications of no significant effect and that the SBA's approval demonstrated compliance with the RFA. You stated that the PTO did not conduct any other analyses or collect any additional facts to support the certifications of no significant effect.

2. Our Forum met with the SBA Office of Advocacy and has been advised that neither Mr. Sullivan nor any of his colleagues who attend to Flex Act submissions have any recollection of receiving any communication from the PTO relating to the four rulemakings in question. They have agreed to look for the submissions and send copies to us, if any can be found, and provided the documents are subject to public disclosure. As yet, we have received no such copies.

3. In light of the foregoing, we reiterate our request that you produce pursuant to the Freedom of Information Act ("FOIA") each of the memoranda to which you referred and which allegedly was provided to the SBA. We have not yet received any such memoranda from you in response to our earlier request. Your failure to supply us with those memoranda coupled with the lack of recollection of any PTO memoranda by the SBA can only cause us to infer that no such memoranda exist.

4. We hereby expand our FOIA request to include any and all documents relating to communication between the PTO and SBA and all of their agents and officers concerning the four rulemakings in question. By "documents" we mean any information in any form and whenever created relating to communications with the SBA concerning the four identified rulemakings, including without limitation electronic files resident within computer memory or recorded in any tangible form, emails, forms, reports, faxes, letters, memoranda, notes or memoranda of telephone conferences, sound recordings and all other media in any form from which information may be extracted.

5. We further expand our FOIA request to include all documents reflecting facts, information and analysis developed or performed by the PTO in reaching the decision to make the four RFA certifications in question. The four certifications in question are identified in our letter to Honorable Jon W. Dudas of March 17, 2004, which was the subject of the telephone conference of March 23, 2004, and which we hereby incorporate by reference.

6. President George W. Bush signed Executive Order 13272 on August 13, 2002 (the "EO") requiring all agencies, including the PTO, to "issue written procedures and policies, consistent with the RFA, to ensure that the potential impact of agencies' draft rules on small businesses...and small organizations are properly considered during the rulemaking process." We hereby request that you produce under FOIA and fax to the undersigned a copy of the final policies and procedures adopted by the PTO pursuant to the EO.

7. We request that you produce any and all documents relating to compliance by the PTO with its final policies and procedures adopted pursuant to the EO and relating to the four rulemakings in question.

B. The Pennsylvania IP Forum has notified the PTO of specific deficiencies in PTO compliance with the RFA.

1. Your letter states that our forum "could not outline any specific deficiencies with any of the notices." Your statement is flatly erroneous. Our letter of March 17, 2004 to Honorable Jon W. Dudas and our letter of March 17, 2004 to Senator Orrin Hatch very specifically define the "deficiencies" under the RFA. The PTO has not addressed the lengthy analysis of the deficiencies contained in those letters before, during or after the telephone conference. While some of those deficiencies are repeated in this letter, we refer you to our prior correspondence for a more complete explanation.

2. As our correspondence noted, the bald conclusions found in each of the four Federal Register notices -- to the effect the PTO had concluded that there will be no adverse impact of any of the proposed changes -- were devoid of the factual bases required by the RFA and do not comply with that Act.

II. THE PTO HAS FAILED TO DEMONSTRATE COMPLIANCE WITH THE RFA.

A. The PTO has the burden of complying with the RFA.

1. In the telephone conference and in your letter, you consistently attempt to place the burden on the public to demonstrate that the PTO must conduct an RFA analysis. Your letter ignores the undeniable rule of law pointed out in our previous correspondence: the PTO has the burden of conducting an analysis pursuant to the RFA and otherwise complying with that Act. The PTO CANNOT shift this burden to the public. It is not up to us to demonstrate to you that the PTO must comply with the law. The PTO either will comply or it will not. If it does not, then its regulations will be invalid and unenforceable.

2. Your also assert that you offered to delay the final rules by seven days to permit the Pennsylvania IP Forum to present "any additional comments." Please consider our letter of March 17, 2004 to Honorable Jon W. Dudas, our letter of March 17, 2004 to Senator Orrin Hatch and this letter to be "additional comments" to each of the four rulemaking packages pursuant to your offer. Our letters sufficiently set forth PTO's violations of the Regulatory Flexibility Act and no additional comments are in order. Frankly, we believe your private offer to delay rulemaking extended to a single group is wrong. We repeatedly requested and still request that the PTO suspend the proposals and publish a full Regulatory Flexibility Act analysis, as that Act requires. The opportunity to make informed comment should be extended to ALL members of the public, including the Pennsylvania IP Forum.

3. We make the same response to your statement that we "refused" to submit additional information. As stated, our Forum has already made its position clear in prior correspondence. Specific comments, evidence, data and a demand that the PTO adhere to the Regulatory Flexibility Act are contained in our letters to Honorable Jon W. Dudas and Senator Orrin Hatch of March 17, 2004 and in our rulemaking comment letter of December 18, 2003. To the extent this assertion by the PTO was an attempt to persuade our Forum to accept the burden of "proving" anything, we reject the assertion because the burden of the Regulatory Flexibility Act is upon the PTO and not upon our Forum or any other member of the public.

4. We wish to make it clear that our letters demanding compliance by the PTO pursuant to the RFA are for the purpose of determining the impact not only upon our small business clients but also upon our organization of small firm and solo patent attorneys. As to the latter, we are a protected "small organization" and each of our members runs a protected small business. We are entitled to have the PTO assess the impact upon our businesses and our incomes, which will be caused by the proposed rules.[1]

5. We note your statement in your letter that the PTO will "proceed with publication of the final rules and will address those concerns that have been received." We construe that to mean the PTO will ignore Regulatory Flexibility Act "concerns" -- including ours -- on the grounds that our Forum's letters are not "comments" which must be addressed by the PTO. If that is what you mean, then your statement is unlawful and we object. The PTO either will comply with the RFA or it will not. Whether the PTO has received RFA-specific "comments" is irrelevant to that compliance. If the PTO fails to comply, its regulations will be invalid and unenforceable.

B. The PTO has failed to meet its burden of compliance with the RFA.

1. Your letter refers to a "disagreement as to the general requirements of the Regulatory Flexibility Act with respect to certifications." You recite a view that is not consonant with the Act and the Executive Order. We disagree with your position. Our position is contained in our letters relating to the Regulatory Flexibility Act and we stand by our position as stated in the letters.

2. Your letter asserts the PTO made "good faith" statements that these rules "do not require Regulatory Flexibility Act analyses to be performed." Whatever the faith demonstrated by the PTO in the initial certifications, it certainly knows now that the rules require RFA analyses or development of factual bases to support certifications of no effect. The PTO can

[1] We note for the record that S. 818 "A bill to ensure the independence and nonpartisan operation of the Office of Advocacy of the Small Business Administration" was introduced by Senator Snowe on 4/8/2003 and is now in Committee.

correct the deficiencies now, in good faith and prior to final promulgation, by conducting full RFA analyses, publishing the analyses, and reopening the rulemaking packages for comment in light of those analyses.

3. Since you have introduced motive, we hereby extend our FOIA request. We request that you produce all documents or other information that relate to your assertion that the PTO acted in "good faith". Candidly, we view the "good faith" assertion as an attempt to excuse the PTO's non-compliance in the event that there is litigation. The good faith of an agency is irrelevant to RFA compliance. Either the PTO will comply or it will not. We do not accept the conclusion that RFA analyses were not required based on the "good faith" of the PTO.

III. DIFFICULTY OF COMPLIANCE IS NOT AN EXCUSE FOR IGNORING THE RFA.

1. In your effort to shift the burden to the public to demonstrate that the PTO must comply with the RFA, you make the statement that "without any additional input...it is difficult—if not impossible—for the Agency to specifically address your concerns." In response, the burden is on the Agency—the PTO—to adhere to the Regulatory Flexibility Act. Our "concern" is that the PTO has evaded the Act. The PTO can fully address our concerns by conducting full RFA analyses of the four rulemaking packages in question, publishing the analyses and reopening those rulemakings for public comment so that small businesses can make an informed decision whether to submit comments to the rulemaking packages.

2. The PTO cannot know if a Regulatory Flexibility Act analysis is "difficult –if not impossible" until it tries to perform such an analysis. Your statement is nothing more than an unsubstantiated sweeping generalization. Specifically, your position that adhering to the Act and the EO might be "difficult-if not impossible" without having tried to comply, and then using that presumed "difficulty" or "impossibility "as an excuse for not complying with the Act and the EO is the worst sort of boot-strapping argument. The RFA does not relieve the PTO of the duty to conduct an evaluation of the burden on small business because the evaluation is difficult. The RFA requires an evaluation regardless of the difficulty.

IV. THE FOUR RULEMAKING PACKAGES ARE SUBSTANTIVE.

1. You argue that RFA compliance was not required for the four rulemaking packages because "interpretative rules, general statements of policy and rules of agency organization, procedure and practice' are exempt from the Regulatory Flexibility Act." Your arguments are not credible and are not supported by the cases that you cited.

2. The argument is not credible because you admitted during the telephone conference that at least some of the rulemakings are substantive and not procedural. You did not identify the rulemakings to which you referred. You therefore admit that at least some of the rulemakings require RFA compliance.

3. The argument is not credible because the PTO published defective RFA certifications of no effect for each of the four rulemakings. The PTO therefore admitted that the RFA applies to each of the four rulemakings.

4. The argument is not credible because you expressly stated that the PTO made submissions to the SBA (which we have not yet seen) in an effort to demonstrate RFA compliance.

5. The argument is not credible because several of the proposed rules will have a substantial effect on both large and small business. The proposed rules, such as proposed 37 CFR §1.105, cannot be swept under the rug as "procedural." Our comments to specific rules are contained in our letter to the Commissioner for Patents of December 18, 2003, hereby incorporated by reference herein.

6. The Pennsylvania IP Forum is not the only organization that believes these rules to be substantive. The IPO, American Intellectual Property Law Association and the American Bar Association all have submitted comments including objections to many of the proposed rules. In many cases, these groups asserted that the rules they objected to would be burdensome to their clients. The IPO—to take one example—represents the largest corporations in the United States. If those large corporations (which have abundant resources including ample support staff and huge budgets) assert that the rules proposed would burden them, then we assert that, ipso facto, those rules will burden small businesses, individual inventors and our Forum .

7. Your letter demonstrates that the PTO does not understand the Regulatory Flexibility Act. In short, once an agency proposes rules that may impact small business, it must perform the Regulatory Flexibility Act analysis and cannot escape doing so by conveniently labeling the rule as "procedural." The cases cited in your letter make very clear the inability of an agency to avoid its obligations under the Act. The ability of the PTO to avoid its obligations under the RFA is further restricted by Executive Order 13272.

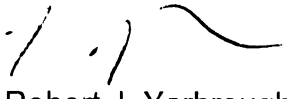
8. If you desire numbers to support our contention that a significant number of individuals and small business will be affected, consider these: from the PTO website, between 1977 and 2001 a total of 1,435,712 patents were issued to applicants from the United States. Of that total, 445,872 patents were issued to individuals from the United States; that is, persons who did not assign their rights in the patent to others. During that period, individual

U.S. inventors therefore accounted for 31% of the total patents issued to U.S. inventors. The number of patents obtained by small businesses that are not individuals is undoubtedly even higher. Small business and individuals therefore account for a significant portion of the patent business before the PTO. To ignore the effect of PTO rulemakings on such a major constituency is a significant mistake and contrary to the RFA.

9. The data collected by the PTO and published on the PTO's website does not separately address patents granted to "Small Entities" (SE) as defined by the Small Business Administration. Since the PTO assesses different fees for SEs and maintains records for at least 17 years for maintenance notification purposes for all grantees, we ask: (a) Does the PTO have data showing or reflecting the number of SE patents granted during 1977-2001 or during any other period over the last thirty years? (b) If PTO has such SE data, we ask that the PTO produce it to us voluntarily by return fax, since such data would decisively enumerate the number of SE patents. If the PTO refuses to provide us with that data, please consider this as a FOIA request for such data.

The Pennsylvania IP Forum looks forward to the PTO's response. We respectfully demand that the PTO suspend promulgation of the proposed rules and perform the required Regulatory Flexibility Act analyses, publish the analyses and reopen the rulemakings for comment so that the public can make comments informed by the analyses.

Respectfully,
Pennsylvania IP Forum



Robert J. Yarbrough
Chairman

Copies of this letter and Mr. Knight's letter of March 24, 2004 by fax to:

Senate & House Judiciary Committee Members
Senate Small Business & Entrepreneurship Committee Members
Senator Arlen Specter—Philadelphia Office
House Small Business Committee-Majority Office
House Small Business Committee-Democratic Office
Thomas Sydnor, Esquire

Hon. Donald Evans, Secretary
US Department of Commerce
Hon. Jon W. Dudas, Acting Under Secretary
US Department of Commerce
SBA Office of Advocacy

UNITED STATES PATENT AND TRADEMARK OFFICE

GENERAL COUNSEL

MAR 2 4 2004

BY FACSIMILE and FIRST CLASS MAIL

Robert J. Yarbrough, Esq.
Pennsylvania Intellectual Property Forum
201 North Jackson Street
Media, PA 19063

Re: Regulatory Flexibility Act Compliance

Dear Mr. Yarbrough:

Thank you for assembling several members of the Pennsylvania Intellectual Property Forum for the telephone conference call yesterday. Jon Dudas, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office, referred your March 17, 2004 letter to me and asked me to respond for the Agency. Your letter raises concerns with the Regulatory Flexibility Act certifications in four notices of proposed rulemakings: Changes to Support Implementation of the USPTO 21st Century Strategic Plan, Rules of Practice Before the Board of Patent Appeals and Interferences, Revision of Patent Term Extension and Patent Term Adjustment Provisions Related to Decisions by the Board of Patent Appeals Interferences and Changes to Representation of Others Before the United States Patent and Trademark Office.

I suggested to you in a telephone call on March 19, 2004 that we meet, at your convenience, to discuss your concerns with the certifications in each of these notices of proposed rulemaking. You agreed and we held the telephonic meeting on Tuesday, March 23, 2004 with you and several other members.

During our conference call, I asked for the Forum's specific concerns with the certification in each of these four proposed rulemakings. The Forum could not outline any specific deficiencies with any of the notices. Instead, we disagreed as to the general requirements of the Regulatory Flexibility Act with respect to certifications. I also offered to consider any additional comments that the Forum may desire to submit, in writing, and offered to delay the publication of the final rules for seven days to allow you to submit specific concerns with each of the certifications. The Forum declined our offer, refusing to submit any specific comments, evidence or data to refute the agency's good faith statements that these rules do not require Regulatory Flexibility Act analyses to be performed. Without any additional input either during the telephone conference call or by later submission, it is difficult – if not impossible – for the Agency to specifically address your concerns. Consequently, we will proceed with publication of the final rules and will address those comments that have been received.

As you noted in your letter, the Regulatory Flexibility Act requires federal agencies to perform a regulatory flexibility analysis unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. §605(b). The Regulatory Flexibility Act also requires the agency to provide a statement of the "factual basis" for the certification at the time of publication and to the Chief Counsel for Advocacy of the Small Business Administration. See id.

However, the Regulatory Flexibility Act only applies to proposed and final rules that require publication under the notice and comment process set forth at 5 U.S.C. §553. See 5 U.S.C. §603(a), 5 U.S.C. §604(a). Thus, rules that are exempt from notice and comment, such as interpretive rules, general statements of policy and rules of agency organization, procedure and practice, are also exempt from the requirements of the Regulatory Flexibility Act.[1] See id.

I would like to assure you that the USPTO complies with all federal requirements in promulgating rules and regulations. In fact, the USPTO exceeds the mandates of federal law by seeking comment from the public on proposed rulemakings where the solicitation of comments is not required by 5 U.S.C. § 553. The Regulatory Flexibility Act is one such area where the USPTO believes that user input is beneficial to the decision-making process. Accordingly, in many instances, the USPTO has voluntarily complied with the Regulatory Flexibility Act even though, by law, the agency may not be required to do so.

Again, we thank you for arranging the telephone conference call. We received your March 23, 2004, Freedom of Information Act request regarding the USPTO's certifications to the Small Business Administration. That request will be promptly processed, in accordance with routine FOIA procedures. You will receive separate correspondence in response to your FOIA request.

Sincerely,

Bernard J. Knight, Jr.
Deputy General Counsel for General Law

[1] Most USPTO rules are procedural or interpretive in nature, and therefore, are not subject to the Regulatory Flexibility Act. See Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed.Cir. 1996); see also Eli Lilly & Co. v. Board of Regents of the University of Washington, 334 F.3d 1264, 1269 n.1 (Fed.Cir. 2003); Fressola v. Manbeck, 36 U.S.P.Q.2d 1211, slip op. at 12 (D.D.C. 1995).

PENNSYLVANIA INTELLECTUAL PROPERTY FORUM
201 NORTH JACKSON STREET • MEDIA • PENNSYLVANIA • 19063
PHONE: (610) 891-0668 • FAX: (610) 891-0655
EMAIL: IPFORUM@YARBROUGHLAW.COM

March 17, 2004

Hon. Jon W. Dudas
Acting Under Secretary and Acting Director
United States Patent And Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Noncompliance with Regulatory Flexibility Act

Dear Acting Under Secretary and Acting Director Dudas:

This correspondence is directed to you on behalf 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. Our purpose is to provide a voice to individual inventors and small entities that otherwise would not be heard.

A. The PTO has failed to comply with the Regulatory Flexibility Act with respect to four pending rulemakings.

We wish to bring to your attention that the PTO has failed adequately to consider the effect of four pending rulemakings on the small business community as required by the Regulatory Flexibility Act, 5 U.S.C. § 601-612 (hereinafter "RFA"). The rulemaking packages in question are crucial to small business. We request that you direct the PTO staff to fully comply with the requirements of the RFA, as described below, and that the rulemaking packages be republished for public comment after that compliance and prior to final promulgation. If the PTO fails to comply with the RFA, the four rulemaking packages will be void and unenforceable.

The four rulemaking packages with which we are concerned are the following:

1. "Changes to Support Implementation of the USPTO 21st Century Strategic Plan", 68 Fed. Reg. 53816, et seq. (Sept. 12, 2003);
2. "Rules of Practice Before the Board of Patent Appeals and Interferences", 68 Fed. Reg. 66647, et seq. (Nov. 26, 2003);

3. "Revision of Patent Term Extension and Patent term Adjustment Provisions Related to Decisions by the Board of Patent Appeals and Interferences", 68 Fed. Reg. 67818,et seq. ; and

4. "Changes to Representation of Others Before the United States Patent and Trademark Office", 68 Fed. Reg. 69441, et seq. (Dec. 12, 2003) (with related "Notice of Extension of Comment Period, 69 Fed. Reg. 4269 [Jan. 29, 2004]).

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

Congress established the Office of Advocacy of the U.S. Small Business Administration (SBA) under Pub. L. No. 94-305 to represent the views of small business before Federal agencies and Congress. The Office of Advocacy is also required by Section 612 of the RFA to monitor agency compliance. In 1996, Congress further enacted the Small Business Regulatory Enforcement Fairness Act which made a number of significant changes to the Regulatory Flexibility Act, the most significant of these amendments are provisions allowing judicial review of agencies' compliance with RFA provisions and requirements for more detailed and substantive regulatory flexibility analyses. 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 the regulation by size and number, estimate the economic impact by size category, determine which size categories will be impacted. The promulgating agency 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 this question is positive, an initial regulatory flexibility analysis must be performed. If the answer to this query is negative, the head of the agency may then certify that the rule will not have a significant impact. 5 U.S.C. §605(b). **Such a certification must include a statement providing the factual basis for this determination.**

The Office of Advocacy has disseminated a publication entitled "A Guide for Governmental Agencies: How to comply with the Regulatory Flexibility Act", which sets forth that the accompanying statement, 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 Guide, 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. 5 U.S.C. §611(a).

C. In each of the rulemakings, the PTO certified that there would be no significant effect on small business.

In EACH of the above proposed changes, the PTO certified that the proposed regulation will not have a significant economic impact on a substantial number of small entities. The language inserted by the PTO in the regulation preambles is instructive and two examples are quoted at length in Appendix A.

The certifications by the PTO of no effect on small business do not comply with the requirements of the RFA because each lacks the requisite factual basis. Merely stating that a proposed rule will not significantly impact any businesses does not meet the requirements of the RFA. The agency's blanket statement is not a factual basis--it is a mere assertion. The regulation preambles provide no information about the basis of the conclusions or facts to support those conclusions.

The certifications by the PTO do not meet the requirements of the RFA because (1) facts required by the RFA to support the conclusions are entirely lacking, and (2) the conclusions are not credible.

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

The RFA requires administrative agencies to consider the effect of their actions on small entities, including small businesses, small non-profit enterprises, and small local governments. 5 U.S.C. §§ 601, et. seq.; Northwest Mining Association v. Babbitt, 5 F. Supp. 2d 9, (D.D.C. 1998). 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); Id.

The law clearly states that an IRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all Federal rules that may duplicate, overlap or conflict with the proposed rule. The agency

must also provide a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. 5 U.S.C. § 603(c).

Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an IRFA, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities. **If the head of the agency makes such a certification, the agency shall publish such a certification in the Federal Register at the time of the publication of the general notice of proposed rulemaking along with a statement providing the factual basis for the certification.**

The certification as to each of the proposed rule changes above clearly violates the RFA because each lacks the requisite factual basis. Merely stating that the rule will not significantly impact any businesses DOES NOT meet the requirements of the RFA. The agency's statement is not a factual basis--it is a mere assertion. There is no information about the basis of that conclusion or facts to support that conclusion. Since no factual information is provided to support the certifications, public comment cannot properly be made.

E. The certification of no significant effect on small business by the PTO is not credible.

The four proposed rule packages total more than 195 pages and involve changes to greater than 396 rules, many of which have a significant economic impact upon a substantial number of small business entities. Many of these proposed changes set forth unduly restrictive rule changes that will prolong the examination process, which in turn will increase the burden and economic costs on applicants. See, for example, proposed changes to rules 37 C.F.R. 1.4 (signature requirements), 37 C.F.R. 1.19 (imposition of additional document supply fees), 37 C.F.R. 1.57 (incorporation by reference), 37 C.F.R. 1.105 (increased prosecution costs for applicants to respond to interrogatories and written stipulations propounded by examiners), 37 C.F.R. 1.111 (supplemental replies), and 37 C.F.R. 1.213 (non-publication requests), all set forth within "Changes to Support Implementation of the USPTO 21st Century Strategic Plan", 68 Fed. Reg. 53816, et seq. Even more blatant within this set of referenced rule changes are the additional petition fees proposed in 37 C.F.R. 1.53, for which there is presented no reduction for small entities and which represent MORE than the entire filing fee for a patent application in a small entity amount.

Fee increases are not the only impact that the proposed rulemakings will have on small entities. See the comments submitted by the Pennsylvania IP Forum

to the Changes to Support Implementation of the USPTO 21st Century Strategic Plan, copy attached as Appendix B.

Likewise, "Changes to Representation of Others Before the United States Patent and Trademark Office", 68 Fed. Reg. 69441, et seq., contains more than 100 pages and more than 128 proposed rule changes pertaining to, among other things, the recognition to practice before the USPTO, practitioner recertification, annual fees and mandatory continuing training, all presented without a substantial justification or basis. The implementation of these rule changes will create an enormous economic burden on small and solo patent practitioners, a burden which will ultimately be passed on to their clients, most of whom are also small business entities.

All business entities that apply for patents, including both large and small entities, will be significantly affected by the proposed rulemakings. As such, all of the proposed rule changes set forth above have a significant effect on small business entitles. The USPTO should have considered the impact those proposals will have on small businesses prior to making the blanket certifications.

F. 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 four proposed regulation packages, and in deciding whether to make a public comment, the public was entitled to review the factual 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. If the PTO made the above certifications without the required factual basis, the PTO should perform a threshold analysis to determine if the conclusions of no significant impact are accurate as to each of the proposed rulemakings. If the threshold analysis supports the conclusions of no impact on small business, the RFA requires that the PTO republish the proposed regulations along with the factual basis and allow time for the public to comment on the proposed rules.

If the threshold analysis indicates that the rule will have a significant economic impact on a substantial number of small entities, the PTO must perform an IRFA and publish the IRFA for public comment prior to the finalization of the rule. The information provided in the current proposals indicates that the proposals will have such an adverse impact on small businesses. If the PTO does not comply with these requirements of the RFA, the regulation packages will not be effectively promulgated and will be unenforceable.

The value of small business entities to the US economy cannot be overstated. The RFA Guide promulgated by the Small Business Administration sets forth much Federal Agency data on small businesses. In its description of how important small businesses are to the US economy, research shows that they represent more than 99.7 percent of all employers. Moreover, on p.99 of the 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 SBA, that the patent activities of our country's small business entities are tremendously important to the U.S. economy. Accordingly, since each of the proposed rules will significantly increase the expense of filing and prosecuting U. S. patent applications, the PTO has a mandate to follow the law and comply with the provisions of the Regulatory Flexibility Act. These rules must NOT become final until the USPTO comes into compliance, fully considering the economic impact of each on small entities and releasing the factual basis for such consideration for public comment, and if necessary, setting forth alternatives to reduce such adverse impact.

Very Truly Yours,

Robert J. Yarbrough
Chairman
Pennsylvania Intellectual
Property Forum

cc: Senate Judiciary Committee
Thomas Sydnor, Counsel
Senate Judiciary Committee
Thomas M. Sullivan, Esquire
Chief Counsel for Advocacy, SBA
Susan Howe
Director, Office of Interagency Affairs
Office of Advocacy, SBA

APPENDIX A

1. "Changes to Support Implementation of the USPTO 21st Century Strategic Plan", 68 Fed. Reg. 53816, et seq. (Sept. 12, 2003)

"Regulatory Flexibility Act: The Deputy General Counsel for General Law, United States Patent and Trademark Office certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes proposed in this notice (if adopted) would not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The primary impact of the changes proposed in this notice are to: (1) Permit electronic signatures on a number of patent-related submissions; (2) streamline the requirements for incorporation by reference of prior-filed applications; and (3) clarify the qualifications for claiming small entity status for purposes of paying reduced patent fees. These changes to the rules of practice (if adopted) will simplify the patent application, and as such, will benefit all patent applicants (including small entities). The Office is also proposing to adjust certain petition fees that are set under the Office's authority under 35 U.S.C. 41(d) to adjust these petition fees to be in alignment with the actual average costs of deciding such petitions. There are approximately 7,500 petitions filed each year of the type that would be affected by the proposed patent fee changes. Since the Office received over 400,000 applications (provisional and nonprovisional) in fiscal year 2002, this proposed change would impact relatively few (less than 2% of) patent applicants. In addition, the petition fee amounts proposed by the Office for petitions whose fees are set under the authority in 35 U.S.C. 41(d) are comparable or lower than the petition fee amounts for petitions whose fees are set by statute in 35 U.S.C. 41(a) ($110.00 to $1,970.00 for extension of time petitions (35 U.S.C. 41(a)(8)), or $1,300.00 to revive an unintentionally abandoned application (35 U.S.C. 41(a)(7))." (at p. 58344)

2. "Changes to Representation of Others Before the United States Patent and Trademark Office", 68 Fed. Reg. 69441, et seq. (Dec. 12, 2003)

"Regulatory Flexibility Act The Deputy General Counsel, United States Patent and Trademark Office certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes in this notice of proposed rule making will not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The provisions of the Regulatory Flexibility Act relating to the preparation of an initial flexibility analysis are not applicable to this rulemaking because the rules will not have a significant economic impact on a substantial number of small entities. The primary purpose of the rule is to codify enrollment procedures and bring the USPTO's disciplinary rules for practitioners into line with the American Bar Association Model Rules, which have been adopted

by most states. This will ease both the procedures for processing registration applications and practitioners' burden in learning and complying with USPTO regulations. The rule establishes a new annual registration fee of $100 per year for practitioners. The average salary of a practitioner is over $100,000, and an annual fee of less than one tenth of one percent of that amount will not have a significant economic impact on a substantial number of practitioners. The rule also establishes a fee of $130 for petitions to the Director of the Office of Enrollment and Discipline. As with the annual fee, this fee is insignificant. Further, the rule requires registered practitioners to complete a computer-based continuing legal education (CLE) program once every one to three years. The program, which will consist primarily of a review of recent changes to patent statutes, regulations and policies, will take one to two hours to complete. This dedication of a small amount of time for CLE every one to three years will not have a significant impact on practitioners. Further, the CLE will substitute for or reinforce practitioners' independent efforts to keep their knowledge of relevant provisions current and avoid time-consuming and costly errors. The rule imposes a $1600 fee for a petition for reinstatement for a suspended or excluded practitioner and removes the $1500 cap on disciplinary proceeding costs that can be assessed against such a practitioner as a condition of reinstatement. [[Page 69511]] Approximately 5 of the 28,000 practitioners petition for reinstatement each year, and approximately 2 of these petitions occur under circumstances where disciplinary proceeding costs may be assessed. These changes therefore will not affect a substantial number of practitioners." (At pp. 69510-69511)