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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
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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)