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May 21, 2007

By U.S. Mail

David Rostker, Policy Analyst The Office of Management and Budget 725 17<sup>th</sup> Street, NW Washington, DC 20503

Re: RIN 0651-AB93

Dear Mr. Rostker:

I am concerned that the Patent and Trademark Office ("PTO") may have ignored certain legal requirements in connection with its attempt to finalize the subject rule. Accordingly, I submit this to you to assist you in ensuring that the PTO complies with requirements designed to protect small business.

## **Background**

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. The PTO's definition of small entities excludes any

<sup>&</sup>lt;sup>1</sup> 5 U.S.C. § 605(b).

<sup>&</sup>lt;sup>2</sup> 71 Fed. Reg. at 66.

 $<sup>^3</sup>$  Id

<sup>&</sup>lt;sup>4</sup> 71 Fed. Reg. at 56.

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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.<sup>5</sup>

## **Procedural Failures**

We believe that the United States Patent and Trademark Office (Office) has failed to comply with certain procedural requirements generally applicable to rulemaking. Specifically, this proposal is insufficient as to requirements of the Regulatory Flexibility Act (5 U.S.C 601 et seq.) Although the Office has certified that this proposal will not have a significant impact on a substantial number of small entities pursuant to 5 U.S.C. 605(b), and accordingly has not performed the initial regulatory flexibility analysis otherwise required under 5 U.S.C. 603, we do not agree that the factual basis for the certification supports its conclusion. Among other things, because the PTO's certification did not address the impact on small businesses, as defined and required under the Regulatory Flexibility Act of 1980 (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), the PTO's certification did not comply with SBFRA. Therefore, this deficiency requires the PTO, at a minimum, to make a new certification that related to the required group and more appropriately, should conduct a supplemental Initial Regulatory Flexibility Analysis (IRFA) before publishing the final regulations.

We note that such a failure has resulted in at least one court holding that failure to use this definition resulted in a failure to comply with the Regulatory Flexibility Act. In view of the serious nature of this matter, we urge that OMB insists the PTO comply with the law.

The PTO estimates that 4,470 small entities making a second or subsequent continuation application and 1,796 small entities making a second request for continued examination will be affected by this proposal. Although we do not necessarily agree that this is not a substantial number of small entities, we strongly disagree with basis of the assertion that the impact on small entities will not be significant. The Office states that the impact amounts to the \$400 petition fee for each applicant. However, the Office also acknowledges that "the primary impact of this change would be to require applicants to make a bona fide attempt to advance the application to final agency action by submitting any desired amendment, argument, or evidence prior to the close of prosecution after a single continuation application or a single request for continued examination ..." This statement suggests that the Office has failed to account for the cost of either performing additional work up front, or later making a showing as to why amendments, arguments, or evidence presented could not have been presented earlier. In either case, additional costs would be incurred by small entities as additional professional fees, and those fees may be significant. The certification made by the Office also fails to acknowledge the

<sup>&</sup>lt;sup>5</sup> Manual of Patent Examining Procedure § 509.02 (October 2005).

<sup>&</sup>lt;sup>6</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1980), (codified as amended at 5 U.S.C. §§ 601-612).

<sup>&</sup>lt;sup>7</sup> Nw Mining Ass'n v. Babbitt, 5 F. Supp. 2d9 (D.D.C. 1998).

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potential differential impact on small entities that would arise from the payment of such professional fees. It is possible that while small entities will need to make financial outlays, large entities have access to internal resources they may draw on in lieu of payment for services.

We therefore believe the certification is unjustified, and that an initial regulatory flexibility analysis is required to address these matters. We encourage the Office to consider in its analysis alternatives for small entities that would accomplish stated goals, as required by 5 U.S.C. 603(c). One such alternative would be to except small entities from these requirements in their entirety. Given that the Office estimates that the proposal would affect so few small entities, it is difficult to envision how this small number contributes in any significant way to the backlog of unexamined claims this proposal is intended to address.

## **Conclusion**

The procedural flaws in the PTO's proposed rules would most easily be addressed by exempting small entities from its application. This is also the preferred approach from our perspective and we urge that OMB requires the PTO to act in a legal manner by making a new certification or by exempting small entities from the application of the rule.

Sincerely

Marcia S. Wagner

Thank you for your attention to this matter.