



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).¹ 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.² 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 document⁶ 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*,⁸ 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.⁹ 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.¹¹ 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, 2005.¹² Out of that number, 866 small entity applications (out of 2,522) had more than ten independent claims.¹³ 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.¹⁴ 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.¹⁵

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.¹⁶ 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,

Thomas M. Sullivan
Chief Counsel for Advocacy

Carrol L. Barnes
Assistant Chief Counsel 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