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From: mgs15@comcast.net [mailto:mgs15@comcast.net]
Sent: Wednesday, May 03, 2006 6:14 PM
To: AB93Comments; Clarke, Robert
Subject: Submission of Comments on Proposed Rule Changes

Hi,

Attached is a PDF of my comments on the proposed rule changes.

Thank you for your consideration.

Mark Sandbaken

May 3, 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandra, VA 22313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims"
71 Fed. Reg. 48 (January 3, 2006)

Attn: Robert A. Clark
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Practice for the Examination of Claims in Patent Applications"
71 Fed. Reg. 61 (January 3, 2006)

Dear Under Secretary Dudas:

I appreciate the opportunity to offer comments regarding the U.S. Patent and Trademark Office ("PTO") proposed rules directed to changes to practice for continuing applications and the proposed rules directed to changes in examination of claims. For the reasons discussed below, the proposed rules would severely and disparately impact small entities[1], and thus should not be implemented in their current form.

[1] The undersigned agrees with the comments submitted by the SBA Office of Advocacy, dated April 27, 2006, noting the PTO has miscalculated the impact on small businesses and recommended further evaluation of the proposed rules prior to implementation.

Summary:

The proposed rules, if adopted, will disproportionately affect small entities, particularly small businesses.[2] Small businesses necessarily have limited operating capital. If implemented, the proposed rules will force small entities into a Hobson's choice of narrow patent coverage or spending disproportionate amounts of capital to preserve the option of obtaining patent protection for inventions. In contrast, larger companies have the necessary resources to better absorb the dramatically increased filing and prosecution costs that will be needed if the rules are implemented. Small businesses will also be disproportionately harmed because they are dependent on private and public capital. The ability of small businesses to raise capital for research and development is heavily dependent upon their patent estates. By restricting the ability of small businesses to thoroughly prosecute patent applications, small businesses will be less able to raise capital, which will further impede their ability to build patent estates. The proposed rules, therefore, represent a fundamental threat to the survival of small businesses, particularly biotechnology businesses, and to the health of all small businesses for which patents are important assets.

Background:

In practice before the PTO, I have represented many small entities, including small business concerns (such as university spin-offs), non-profit organizations, such as universities, and independent inventors. I am currently in-house counsel for a small biotech company dedicated to developing monoclonal antibody (mAb)-based therapeutics for cancer and immunologic diseases. The company currently has three product candidates in six clinical trials, and has additional lead preclinical candidates in development. The company was founded in 1997 and currently has about 140 employees.

It is no secret that biotechnology research is complex and takes many years to yield profitable results. For example, Immunex Corporation (now a part of Amgen Corporation) was founded in 1981 but did not become profitable until 1999, after 18 years of research and development. The profitability was due to the launch of a blockbuster drug that revolutionized the treatment of rheumatoid arthritis. That success was due, in no small part, to a robust patent estate covering that product.

Similarly, investors and potential partners for small biotech companies require robust patent estates around the inventive proprietary technology. Due diligence by potential investors and partners routinely includes a review of the company's patent estate for the scope of patent protection that might be obtained around the company's proprietary technology. The prospect of receiving patents that cover both potential

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[2] As used herein, "small entity" refers to small business concern, non-profit organization and individual who would quality as a small entity under 37 CFR § 1.27, but without regard to whether any rights in any invention have been licensed to a large entity.

products and technology for out-licensing is an essential part of obtaining investment dollars.

It is with this background that the following comments on the two sets of proposed rules are submitted.

Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48 (January 3, 2006)

The proposed rules will place strict limits on continuation practice that will greatly impede thorough examination of biotechnology patent applications. Biotechnology patent applications are necessarily large and complex. The examination of patent applications constitutes a dialogue between the applicants and examiners. In that dialogue, applicants educate the examiner about the new invention and negotiate the issues around the patentability of claimed invention. Based on my experience in recent cases before the PTO, most applications in Group 1600 require at least three or four *non-final* office actions on the merits (i.e., excluding restrictions requirements) and responses for a set of pending claims in an application to be thoroughly examined and a proper decision of patentability obtained. This is due in large part to the complexity of biotechnology inventions.[3]

The proposed rules, if adopted, will prematurely end the dialogue between the examiner and the applicant. Current office practices typically generate one non-final office action, followed by a final office action, per application or request for continued examination. (Because final office actions are reviewed under a different standard than non-final actions, applicants and examiners have fewer opportunities to respond to patentability issues.) The changes to continuation and RCE practice will force applicants into a Hobson's choice of accepting narrower claims than those to which the applicants would entitled on the merits or appealing each second (and subsequent) rejection of the pending claims. The former choice will undermine patent estates, discourage investment and may well create easy opportunities for designing around issued claims. The latter choice will result in more appeals and, most likely, significant delays in patent prosecution. Appeals to the Board of Patent Appeals and Interferences (Board), and to the Federal Circuit, are considerably more expensive than continued prosecution practice. Currently, appeals are filed when issues are ripe for appeal and/or as a tool of last resort when it becomes apparent that an impasse has been reached with the examiner. Under the proposed rules, appeals will likely become a regular part of the examination process for each application when agreement on appropriate scope of claims has not been reached. Each appeal brief will likely contain more issues, many of which may not be ripe for appeal. This result will be markedly increased cost of patent prosecution and substantial increases, not decreases, in application pendency, due in part to backlogs in

[3] I wish to make clear my respect for the helpful, conscientious and skilled examiners, administrators and others at the PTO and to acknowledge both the difficult circumstances under which they operate and the significant initiatives the PTO has taken to improve the examination process.

Board appeals. While large companies may be able to afford these increased expenses, small businesses will not. The result will be an unjustified loss of patent rights.

The proposed changes to continuation practice will most significantly affect new startups that are most dependent on investment capital. In a due diligence review, the question asked by investors and partners will change. Instead of asking "what protection is this company likely to obtain by thorough prosecution of the patent estate?" the question will be "what protection is this company likely to obtain at the conclusion of prosecution of the first continuation application for each invention." The answer to the latter question, at least for biotechnology applications, is likely to be much narrower patent scope. The effect of this answer on the capital invested in such companies is easily imagined.

The proposed rules would also require applicants to file all divisional applications prior to the conclusion of the examination of the original application. This will be necessary to preserve the right to obtain the full scope of patent protection for each invention. Recent experience with biotechnology applications is that most restriction requirements divide pending claims in an original application into two, more typically at least five, and up to over 4,000 allegedly different inventions.[4]

To require small businesses to file all divisional applications prior to the conclusion of examination of the original application simply may not be economically feasible. Small businesses by nature have limited resources. Assuming *arguendo* an average of a five-way restriction requirement per original application, the proposed rules will require a four-fold increase patent application filings simply to preserve the opportunity to seek protection for each group of claims.[5] This rule will again force applicants into a Hobson's choice, either for go patent protection for certain groups of claims or markedly increase the costs of maintaining a patent estate. In the latter case, it is easily imagined that patent prosecution costs would rapidly escalate by at least three- to five-fold over current levels. And again, both choices will have a disparate effect on small businesses, which necessarily have limited budgets for prosecution costs.

The proponents of the proposed rules state that continuation practice is abused. To the contrary, the decision to file a request for continued examination ("RCE") or a continuation application is based in large part on the status of examination when prosecution is closed. Filing an RCE or continuation application is an appropriate vehicle when an applicant believes, for example, that a prior communication has not been fully considered, there is an honest disagreement over the scope of claims, there is

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[4] In the last case, the patent examiner said he wished to divide the claims into more groups, but said he was precluded for so doing by unity of invention practice under the PCT.

[5] Some of these filings may be redundant, if method claims are later rejoined with composition claims. The proposed rules, however, would require applicants to file divisional applications with method claims as a precautionary measure to preserve the option of examination of such claims, if rejoinder had not already occurred.

disagreement over the PTO's interpretation of a cited reference(s) and/or when new arguments have been raised in an office action,. To this point, the undersigned agrees with the comments of the AIPLA (dated April 24, 2006, "Deliberate Prosecution is Not an Abuse", page 4).

In contrast, when an office action presents an objectively complete and accurate argument against patentability of certain claims, applicants, particularly small businesses, are unlikely to continue prosecution. There is no objective benefit to prosecuting an application for which there is no reasonable argument for obtaining a patent.

To the extent the PTO alleges that a "small minority of applicants have misused continued examination practice," the PTO has adequate remedies to address such practices, namely prosecution laches (MPEP § 2190) and finding an amendment not fully responsive (MPEP § 714.02). Further, because the notice of proposed rule making does not provide any statistics on the fraction of applications or responses that might be viewed as "abusive," the PTO has not demonstrated sufficient need to justify the draconian effect of the proposed rules, rather than simply enforcing existing PTO regulations.

The proponents of the proposed rules further state that "finality" needs to come sooner to patent estates. The proposed remedy, to terminate prosecution at the conclusion of prosecution of the first continuation application, or conclusion of prosecution after the first RCE, absent undefined extenuating circumstance, probably effects this PTO goal. The finality is achieved, however, by unfairly denying patent protection for small businesses, particularly in the biotechnology field.

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The proposed rules on examination of claims will have a similar disproportionate impact on small businesses. To obtain an appropriate scope of patent coverage for an invention in the biotechnology area, a patent applicant must often submit ten or more independent claims, which then usually are subject to restriction requirements. The proposed rules would require such an applicant to conduct a pre-examination art search and then prepare and submit a complex examination support document if applicant wishes to have more than ten claims examined.

The undersigned agrees with the objections to this set of rule proposals, as discussed in the AIPLA comment letter of April 24, 2006. In addition, however, it is important for the PTO to realize that these rules will impose a crushing financial burden on small businesses. Small businesses will not be able to afford the costs of pre-examination prior art searches and the added expense of preparing the examination support document. Most small businesses cannot afford to have in-house patent attorneys or agents. Thus, such searches will be performed by outside patent counsel. The PTO appears to have dramatically underestimated the costs of such searches. Instead, the cost estimate stated in the SBA Office of Advocacy Letter, dated April 27, 2006, of about $25,000-$30,000 per examination support document, is believed to be more accurate than

the PTO's estimate of $2,500. While $2,500 may reflect the cost of a preliminary patent search, the cost of a reasonable search is estimated to be $5,000 to $10,000, or more depending on the complexity of the invention(s). Further, the PTO estimate does not include the cost of preparing, *inter alia*, "a detailed explanation of how each of the independent claims and designated dependent claims are patentable over the references cited" in the examination support document. The cost of preparing such a detailed explanation, assuming a minimum of fifteen references and ten claims under examination, might be roughly estimated at about 3-4 hours per reference, or a minimum of about 45-60 hours. At an hourly rate of $250 per hour (clearly a bargain), a minimum of an additional $11,250-$15,000 in legal fees would be required.

Such a dramatic increase in prosecution costs would, once again, have a disparate impact on small businesses, as compared with large companies. Small businesses would again be forced into the Hobson's choice of forgoing patent protection to which they would otherwise be entitled or investing a disproportionate amount of capital in their patent estates. Neither choice would benefit small businesses or the public.

The PTO is respectfully requested to consider the following alternatives to the proposed rules.

General Suggestions:

1. The PTO needs more resources for examination of pending and newly filed applications. Increasing examiner retention, salaries and time for examination of all patent applications should be the first priority of the PTO.

2. The PTO should institute a deferred examination system. Most biotechnology patent applications disclose patentable inventions, but many are of uncertain commercial value. If examination of these applications could be deferred, many applications would be abandoned prior to substantive examination. Because such applications would not be maintained in the active docket of the examiners, the result would be a reduced number of applications pending for substantive examination. Applicants would have every incentive to abandon applications that do not have commercial value. Applicants would also have every incentive to start examination of valuable applications as soon as possible, given the loss of effective patent rights that occurs under the twenty-year term.

3. Restriction practice should be reformed under a unity of invention standard.

Specific Comments:

1. Proposed Rule 1.75. This proposed rule should not be adopted. The implementation of this rule change will have a disparate affect on small entities.

2. Proposed Rule 1.78(d). This proposed rule should not be adopted. The implementation of this rule change will have a disparate affect on small entities, as discussed above.

3. Proposed Rule 1.78(e). This proposed rule should not be adopted. The implementation of this rule change will have a disparate affect on small entities, as discussed above.

4. Proposed Rule 1.78(f)(1). The proposed rule should not be adopted because it is duplicative with Rule 1.56. If implemented, the rule should be amended to require identification of such related applications in an IDS submitted not later than four months after mailing of the filing receipt. This change will avoid requiring citation of applications before application numbers have been assigned and avoid citation of applications that are abandoned soon after filing.

5. Proposed Rule 1.78(f)(2). This proposed rule should not be adopted. See AIPLA comments (dated April 24, 2006, "Double patenting presumption without considering claims" (pages 6-7) and "Flawed Assumptions of Proposed Rules 5" (pages 9-10)).

6. Proposed Rule 1.78(g). This proposed rule should not be adopted, as written. Instead, if adopted, this subsection should be amended to require that in response to a statutory or obviousness type double patenting rejection, the Office may require the assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and if not indicate which named inventor(s) is/are the prior inventor, unless Applicant traverses the rejection. In the latter case, the request to identify the prior inventor should be held in abeyance, pending a final decision on the double patenting rejection.

7. Proposed Rule 1.104. This proposed rule should not be adopted. The implementation of this rule change will have a disparate affect on small entities, as discussed above.

8. Proposed Rule 1.114(f). This proposed rule should not be adopted, for the reasons set forth above.

9. Proposed Rule 1.261. This proposed rule should not be adopted. The implementation of this rule change will have a disparate affect on small entities, as discussed above.

Conclusion

While the PTO's goal to improve patent examination quality and pendancy are to be applauded and encouraged, I strenuously object to both sets of proposed rules. If

enacted, they will force some small businesses out of business by cutting off investment capital and severely limiting the ability of small businesses to obtain U.S. patents protecting proprietary technologies, particularly in biotechnology. In essence, they will deal a fatal blow to many small businesses that are in complex fields of technology where patent rights are essential.

Respectfully submitted,

Mark Sandbaken

Mark Sandbaken, Reg. No. 39,354

The views expressed here are mine and not to be attributed to any other person or entity.