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To: AB93Comments

Subject: Comments on Proposed Rules Relating to Continuation Practice (71 Fed. Reg. 48 (Jan.

3, 2006)) and Examination Practice (71 Fed. Reg. 61 (Jan. 3, 2006))

Please find attached comments on the Proposed Rules:

"Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims", 71 Fed. Reg. 48 (Jan. 3, 2006); and

"Changes to Practice for the Examination of Claims in Patent Applications", 71 Fed. Reg. 61 (Jan. 3, 2006)

These comments are submitted on behalf of Bozicevic, Field & Francis, LLP.

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May 2, 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
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Dear Under Secretary Dudas:

We are grateful for the opportunity to comment on the proposed rule changes regarding continuation application practice (71 Fed. Reg. 48 (January 3, 2006)) and examination practice (71 Fed. Reg. 61 (January 3, 2006)) (the "Proposed Rules"). Our comments are provided *probono* and are independent of the direction of any client.

We are opposed to the enactment of the Proposed Rules in their present form.

The proposed rules to change continuation application practice and the proposed rules to change examination practice, either alone or combined, raise several serious concerns. We have outlined our concerns below.

In addition, we provide several alternative options for accomplishing the goals of the Proposed Rules. We believe that the implementation of one or more of these alternative options could achieve the Office's stated goals to provide meaningful improvements in the system while mitigating the severe adverse impact on applicants that will result from implementation of the Proposed Rules.

COMMENTS ON THE PROPOSED RULES

THE PROPOSED RULES, ESPECIALLY WHEN COMBINED WITH CURRENT CASE LAW, EFFECTIVELY PAINT APPLICANTS INTO A FINANCIAL AND LEGAL CORNER.

Severely restricting the ability to file a continuation application as a matter of right and limiting the number of claims that can be examined in a single application as set out in the Proposed Rules would have severe adverse impacts on many applicants, both financially and legally. We provide some examples of this below.

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Continuation applications allow applicants to delay significant costs of pursuing claims of broader scope to which they are entitled.

The current continuation practice allows applicants to compromise on the scope of claims that pass to issue from the first-filed application, with the goal of obtaining broader patent coverage in a later-filed continuation application. This practice is not borne of a desire to abuse the process, but rather is borne of the financial realities applicants face every day.

Small companies, particularly startups, and academic and other non-profit institutions, must make decisions on how best to spend their limited patent budgets. Every dollar a small company must spend on pursuing patent protection is a dollar that is not spent on research and development activities. At the same time, small companies need to attract investors who, in turn, are more inclined to invest in companies that have patents. The ability to obtain issued claims of narrower scope, while maintaining a pending application to pursue the broader claims when financial resources become available, is key to balancing an applicant's financial constraints with the applicant's need to develop a viable patent portfolio and to attract potential investors.

Academic institutions provide a wealth of technological innovations and advancements. These institutions have limited resources for pursuing patent protection and for marketing their inventions to identify licensees who will cover patent prosecution costs and develop the Until a licensee is identified, the academic technologies for commercial applications. institution must pay for prosecution costs from a severely limited budget. The challenge for academic institutions can be compounded where the invention is a cutting edge technology. The market often simply does not recognize the value of truly innovative advances until long after patent applications on the technology must be filed. As a result, academic institutions require both time and flexibility in prosecution of their patent applications. In addition, once a licensee is identified, the licensee may have needs for particular claim coverage that the academic institution could not predict from the outset. Often, having an issued claim -- even if it is narrower in scope that the claim to which the academic institutions are rightfully entitled -and maintaining a pending application is an effective tool in attracting a licensee and achieving the ultimate goal of moving the technology from the bench to the commercial market. This meets the basic constitutional goal of promoting the useful arts.

If the Proposed Rules are implemented in their current form, applicants will be denied the tools critical to achieving a balance between the rights to which they are entitled and the financial realities they face daily. Patent rights will be lost simply because the applicants' budgets are limited.

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Continuation applications allow applicants to craft claims that are best suited for a later-developed product or activity.

Development of a client's commercial activities over time reveals the subject matter that is the most critical to their business. This is particularly true in technologies such as biotechnology, where lead times for development of a product and FDA approval can take many years (e.g., 5 to 10 years). However, under the Proposed Rules, by the time the details of the final commercial product and/or activities are known, applicants will not be able to obtain the ultimate "picture claim" to protect their interests. This opportunity will no longer be available if the Proposed Rules are enacted because the deadline for filing a continuation application will have long ago lapsed.

The law of the doctrine of equivalents and the financial constraints faced by applicants may result in applicants not obtaining a claim scope to which they are rightfully entitled.

The current trend in the law tends toward limiting the circumstances under which patent claims will be construed under the doctrine of equivalents to encompass more than their literal scope. If applicants do not have the financial resources to pursue broad claims in the first-filed application through appeal, and if they are also under pressure to have even a narrow claim issued (as exemplified above), they often choose to take the narrow claim and pursue the broader claim in a continuation application.

Because the broader claims involve issues of greater legal complexity, applicants are often again faced with a decision as to whether to file a Request for Continued Examination (RCE) or appeal. At the same time, the financial pressures of applicants (such as those exemplified above) may not be relieved in the time it takes the Office to examine the first continuation application. Often in these circumstances, the applicants need the flexibility to file an RCE to avoid the costs of the appeal process.

If applicants cannot afford the appeal process and are also not given the full opportunity to pursue broad claims in a continuation application and/or to use RCEs freely in the examination process, then applicants may be forced to live with the narrower claims issued from the earlier-filed application. These narrower claims will be subject to a narrow interpretation under the doctrine of equivalents, with the end result being that applicants will never obtain claims of a scope to which they are rightfully entitled.

¹ See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002), as well as the Federal Circuit's decision on remand at 344 F.3d 1359 (Fed. Cir. 2003) (en banc).

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The Proposed Rules place applicants at an increased risk of allegations of inequitable conduct.

Many of the Proposed Rules place a heavy burden on applicants in the prosecution process. Whenever applicants are required to assume more of the examination functions normally carried out by the Office, the risk that applicants will be accused of inequitable conduct increases. Some examples of how the Proposed Rules can cause this effect are provided below.

Examination of more than ten claims under the Proposed Rules will be both inordinately expensive and fraught with risks of a finding of inequitable conduct on litigation.

For example, in order to obtain examination of more than ten claims, the Proposed Rules provide for submission of an Examination Support Document (ESD). This again places the applicant in a difficult position both legally and financially. If they need examination of more than ten claims in a single application, they must bear the cost of what will likely be an inordinately expensive document.

This assumes, of course, that applicants would ever undertake the filing of an ESD. The ESD as set out in the Proposed Rules essentially delegates the entire examination process to the applicant, including identification of all relevant art, discussion of the relevant portions of each reference and identification of claim limitations disclosed by each reference, as well as a discussion of how the claims meet the requirements of utility and written description. The risks that an ESD would be fodder for assertions of inequitable conduct during post-issuance litigation are so high as to be a certainty.

In addition to the risk of a charge of inequitable conduct, an applicant has to consider how his or her comments made in an ESD may be construed, particularly in the context of litigation. As the ESD requirement delegates the majority of the examination process to the applicant, the applicant is placed in the precarious position of competing objectives: providing as much information and advocacy as possible to support the patentability of the claimed invention and avoiding statements that can be too easily manipulated by litigious opponents.

Limiting the number of requests for continued examination prevents applicants from submitting prior art for consideration by the office.

If the Office implements the Proposed Rules in their current form, and applicants discover a reference late in prosecution (e.g., after the filing of the first continuation or RCE), applicants may find they have no recourse for consideration of the reference. For example, if the pending application is already under a Final Office Action and is either the first continuation application or already contains a Request for Continued Examination, applicants are left without apparent recourse.

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References are often identified late in the course of prosecuting a U.S. application. One contributing scenario is where an Examiner from a foreign patent office identifies a reference as relevant to patentability during examination of a foreign counterpart application. Even if these references are arguably cumulative to the references already of record in the pending U.S. application, if the reference is not submitted for consideration by the U.S. Examiner, applicants again risk allegations of inequitable conduct in obtaining their U.S. patent rights.

In addition, removing this opportunity for applicants to submit late-discovered references for consideration will impair the Office's goal of issuing patents with valid claims, since the Office will in effect be prevented under the Proposed Rules from having access to all relevant information.

Requiring divisional applications be filed during the pendency of the first-filed application will increase the probability that patent rights will be lost simply due to a lack of funding.

Again, the Proposed Rules pose a severe financial burden that many applicants may simply not be able to bear. Requiring that all divisional applications be filed during the pendency of the first-filed application means that applicants up-front costs for pursuing protection for the patent rights to which they are entitled will *increase dramatically*. The effect will be particularly severe in biotechnology, where restriction requirements are very common and routinely have large numbers of groups of claims to be elected. In our experience, it is not unusual for a biotechnology application, especially one involving gene sequences and polypeptides, to be restricted into ten or more different groups.

We again refer you to the plight of the small company and the academic institution. Small companies must choose between dollars spent on patents and dollars spent on research and development. Academic institutions have very limited budgets, and particularly so when they have not identified a licensee for the technology. Simply put -- implementation of this rule means that the *patent rights will be lost simply due to a lack of funding at outset*.

In addition, applicants will be forced into filing divisional applications for all identified groups, which can be numerous. The unintended result may be an enormous increase in the number of applications being filed and concomitant increase in the backlog of unexamined applications, which is contrary to the stated goals of the Proposed Rules.

The Proposed Rules could not only lead to an *increase* in the number of applications filed, but may also result in the filing of many "thinner" patent applications.

Because continuations of any sort would become a precious tool, applicants will be motivated to file "thinner" applications, claiming subject matter that differs only incrementally from application to application. This activity could create a situation of "patent flooding", with

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an even greater myriad of patent rights minefields to be negotiated. In short, a patent system subject to the Proposed Rules would not be less complex by any means. Indeed, because these "thinner" applications would be filed independently, there would be an increase in complexity since fewer applications will be associated by priority claim, and thus will be more difficult to identify when conducting freedom to operate searches.

Continuation applications filed for the consideration of a new reference should be allowed as a matter of right.

The Proposed Rules indicate that any second continuation application must be accompanied by a petition and a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application. The Proposed Rules do not clearly set out whether the types of showing the Office will deem acceptable would include continuation applications filed in order to ensure consideration of late-discovered art.

As discussed above, particular problems arise when foreign patent offices identify art that was not identified by the U.S. Examiner. If these references are not made of record in the U.S. counterpart application, they can serve as a source of allegations for inequitable conduct.

We urge the Office to accept the submission of a reference not previously of record as acceptable grounds for filing of a continuation application, such as an RCE. Allowing a continuation application to provide for consideration of a reference can only serve to improve the quality of any patent that ultimately issues from the application.

RCEs should be excluded from the definition of continuation applications.

During prosecution, applicants will often find themselves at a procedural crossroads in which they must either appeal a final rejection or file an RCE in order to further prosecute the claims of the application with the Examiner. As it can be difficult to come to agreement with an Examiner during a first round of prosecution, an RCE can be a cost-effective tool to allow for further discussion with the Examiner about the claims and to come to an agreement.

Under the Proposed Rules, RCEs will be treated no differently than other continuation applications. The Office will then force applicants at a procedural crossroads to prematurely appeal the rejection (particularly when a Final Rejection is issued on a first continuation application), when in fact the case could more efficiently and effectively be prosecuted to completion by filing an RCE. By excluding RCEs from the definition of continuation applications, the Office will preserve this prosecution tool for both applicants and Examiners. Abuse of RCEs could be addressed through a system of escalating fees, as discussed below.

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QUESTIONS SURROUNDING THE OFFICE'S STATUTORY AUTHORITY TO IMPLEMENT THE PROPOSED RULES WILL CREATE GREAT UNCERTAINTY AND CONFUSION.

Serious questions have been raised about whether the Office has the statutory authority to implement the Proposed Rules, particularly as they relate to limiting the ability to obtain priority benefit under 35 U.S.C. § 120. Others, including the American Intellectual Property Law Association (AIPLA), have submitted detailed comments and analysis of this issue.

Should the Office proceed with the Proposed Rules in their present form, it is evident that there are parties prepared to challenge these rules in court. If this happens -- as it seems likely it will -- applicants will be left in limbo for years to come while awaiting a decision. If the decision is adverse to the Office in whole or even in part, the work required to undo the harm to applicants who had applications pending during this time of uncertainty will only result in an even more enormous backlog of work at the Office.

There has been a substantial amount of legislative activity to address the need for patent reform. Last year, the Patent Reform Act of 2005 (H.R. 2795) was debated in Congress. This bill included modification of the statute to provide the Office with the authority to promulgate rules to limit the circumstances under which certain patent applications would be entitled to benefit under 35 U.S.C. § 120.² This legislation was not passed. Regardless, it is apparent that Congress is aware of the public policy issues raised by the Office in the context of the Proposed Rules.

The Office has continued to take an active role in expressing its views on patent reform legislation, which has continued this year with the recent introduction of the Patent Depends on Quality (PDQ) Act (H.R. 5096).

SEC. 8. CONTINUATION APPLICATIONS.

(a) In general.—Chapter 11 is amended by adding at the end the following:

"§ 123. Limitations on continuation applications

(emphasis added)

² H.R. 2795 ("The Patent Reform Act of 2005") was introduced to the House on June 8, 2005 (see http://thomas.loc.gov/cgi-bin/query/F?c109:1:./temp/~c1093lhVrk:e47844) included a provision as follows:

[&]quot;The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application. No such regulation may deny applicants an adequate opportunity to obtain claims for any invention disclosed in an application for patent."

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We urge the Office to consider the serious impact uncertainty will have for applicants in the wake of a challenge to the Office's authority to implement the Proposed Rules. We further urge the Office to continue its activities in providing its insight and expertise as Congress shapes legislation to address the need for patent reform.

ALTERNATIVE APPROACHES

We believe that the goals of decreasing pendency of applications and improving efficiency and quality of examination can and should be achieved through less draconian and severe measures than those set out in the Proposed Rules.

None of the Proposed Rules address quality of examination. Instead, the rules attempt to simply reduce the overall number of patent applications to be examined, without providing additional resources or tools to encourage an improvement in examination quality. We are not aware of any change in internal policy at the Office that would address the latter issue.

We respectfully submit the following alternative approaches to addressing the problems identified by the Office.

<u>Provide incentives to Examiners to facilitate examination of original applications.</u>

The Proposed Rules make it apparent that the Office intends to increase examination efficiency by modifying applicants' behavior. However, we are not aware of any efforts at the Office to address Examiners' motivations and behavior, or to reduce the heavy burden on Examiners.

If the Proposed Rules are implemented, Examiners will still be required to meet the same performance goals in the same amount of time, but now with the expectation that Examiners will meet these same goals by examination of more original applications (i.e., a first-filed non-provisional application or national phase application). There is no apparent recognition by the Office that it simply takes more time to pick up an original application with which the Examiner has no familiarity to conduct a quality search of the prior art and to provide a cogent first Office Action on the merits.

We believe the Office's goal in reduction of pendency times for new patent applications and improving examination quality cannot be achieved without changing internal policies and incentives under which Examiners currently operate. Some exemplary proposals are provided below.

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Encourage examination of original applications by modifying the "counts" system for Examiners.

At least one measure of an Examiner's performance is based on the number of "counts" an Examiner accumulates over a given time period. Examiners are credited the same number of possible "counts" for examination of an original application as they are for a continuation application. This system completely ignores the reality that examining an original application necessarily requires more time and is more complex than examining a continuing application with which the Examiner may already be familiar.³

Modification of this system to provide an increased number of possible counts for an original application compared to a continuation application would further the Office's goals in decreasing pendency of original applications. For example, the system could be modified so that an Examiner receives more credit for a first Office Action on the merits for an original application (e.g., 1.5 counts) than for a continuation application in which the subject matter claimed is the same as in the parent application (e.g., 1 count).

The system could also be modified so that Examiners receive a certain number of counts in a given performance period for Examiner-initiated interviews with applicants. Often we find that when an Office Action is not clear or the issues are particularly complex, a telephonic or in-person interview provides a much better understanding of the Examiner's position. The opposite must also be true -- while applicants and their counsel endeavor to make themselves clear, there must be occasions when Examiners find the arguments unclear or recognize that applicants have not understood the Examiner's position. Improving communication by encouraging Examiners to contact applicants for clarification, combined with an Interview Summary prepared by applicants, would both increase efficiency of examination and provide a clear record.

Under a modified count system, Examiners in need of counts to meet their requirements for a given time period would be more likely to pick up an original application in their queue than to pick up a continuation application. This, combined with flexibility to take an original application out of turn in the examination queue relative to a continuation application (see below) could result in an increased number of Office Actions on original applications. Examiners would also be encouraged to initiate interviews with applicants in order to dispose of applications, again serving to decrease pendency and provide for more efficient communication between Examiners and applicants.

³ This, of course, assumes that the Examiner who examines the original application will also examine any continuations of that new application. In our experience, this is usually the situation.

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Modify the examination queue through assignment of dates for action by Examiners and/or implement a Deferred Examination practice.

We are not aware of any internal policy changes at the Office that would provide any incentive for an Examiner to examine an original application instead of a continuation application. As we understand it, applications are taken roughly in order by filing date with no incentive to an Examiner to pick up an original application for examination over a continuation application.

The Office could promote earlier examination of original applications by giving continuation applications a lower priority in the examination queue compared to original applications. For example, an original application which has had no Office Action on the merits would be assigned an earlier due date for substantive action on an Examiner's docket than a continuation application.

If the Office does not have the authority to direct that applications be examined out of order, or if the Office is concerned it will be criticized for delaying examination of an application, the Office could seek implementation of a Deferred Examination practice for continuation applications. Under a Deferred Examination practice, applicants would be put on notice that a second continuation (including an RCE) would receive a lower priority for examination than original applications or first-time continuation applications. Applicants could be given the opportunity to petition to expedite prosecution of continuation applications subject to Deferred Examination. The grounds for such petitions could be similar to those for a Petition to Make Special.

The Office could also allow applicants to request Deferred Examination of a second continuation application. Deferred Examination would be disadvantageous to applicants since the patent term for these applications would still be running, but would be advantageous in that costs of prosecution could be delayed.

Decrease multiple continuation applications through escalating fees.

The Office has identified the filing of multiple continuation applications as a source of extra work for Examiners which adds to the Office's backlog. The Office has also suggested that many of these applications result from abuse of the system. To the point -- the Office has implied that many of these continuation applications are not filed out of serious and immediate need by applicants, but rather are a tool of "patent trolls" who maintain a pending continuation application until it is apparent whether and if the market finds a commercially feasible and financially rewarding application of the technology claimed.

The Office has also implied that applicants are not motivated to move an application along to a final decision (either allowance or rejection) because applicants have the "out" of filing a continuation application.

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We believe that these asserted problems could be alleviated through a system of escalating fees for filing continuation applications. Under this system, the first continuation application would require payment of fees according to the current fee schedule. However, the second continuation application would require payment of higher fees, the third continuation even higher fees, and so forth. These fees could be dictated by either the number of continuation applications in the series and/or the number of months from the mailing date of the first Office Action on the merits in the original application.

Escalating fees would require applicants to very seriously weigh the costs and benefits of filing multiple continuation applications. Abuse of continuation practice would be discouraged since the cost of doing so increases dramatically with time. Applicants who have an insufficient stake in the outcome of examination of a continuation application, such as the patent trolls who simply await the emergence of a commercially viable technology to seriously prosecute their applications, would find it increasingly expensive to pursue such patent applications. Meanwhile, the Office would receive more money in filing fees in order to better serve applicants' needs. These additional funds would allow the Office to respond by hiring more Examiners and provide more resources to improve examination quality and efficiency.

A similar system of escalating fees in European practice has, in our experience, effectively limited the number of filings. European practice allows for filing "divisional" applications, which are similar in many ways to a "straight" continuation application under U.S. practice. However, filing a divisional application in the European Patent Office (EPO) requires payment of back annuities, which can make these applications prohibitively expensive. As a result, very few "divisional" applications are filed in the EPO. In general, European "divisional applications" are only filed when the patent rights are of critical importance, or where applicants are concerned the original application may be opposed by a third party.⁴

Establish remote branches of the Office to increase the pool of applicants for hiring and retaining qualified Examiners.

The Office has asserted that it can not "hire its way out" of the examination backlog. We acknowledge that hiring qualified personnel and training them to be competent Examiners would be a difficult task.

In addition to the difficulties in finding and hiring those unique individuals who have the requisite technical expertise, who are able to quickly learn patent law and the examination process, and who can effectively and efficiently communicate in writing and orally to applicants, the Office has the additional challenge in that these individuals must be willing to

⁴ We acknowledge that the number of "divisional" applications might be greater if these applications were subject to prosecution history estoppel as in the U.S.

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live and work in a single geographic location. This is a serious limitation on the pool of applicants from which the Office can draw.

The Office would increase the number of candidates for positions as Examiners, and would likely more successfully maintain Examiners if the Office opened remote branches located in different cities across the U.S. These remote branches could be headed by senior Examiners and officials who could serve as mentors for junior examiners. Remote access to the Office's files, already being used by Examiners in the current "hoteling" program, could be used by Examiners in remote offices. Communication tools, such as teleconferencing and videoconferencing technologies, could facilitate the engagement of these remote offices so that they are treated as a single unit within the Office. In addition, having remote locations in geographically diverse locations of the country will facilitate more personal interviews between applicants and Examiners and result in more expeditious prosecution of patent applications.

CONCLUSION

We again thank you for the opportunity to provide our comments, and for your careful consideration of the issues and concerns raised.

Very truly yours,

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