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To: AB93Comments
Cc:
Subject: Comments on Proposed Rules - Continutation Practice

Attached in pdf format are my comments on the proposed rules.

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May 1, 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
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Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

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

Dear Under Secretary Dudas:

The following comments are submitted in response to the U.S. Patent and Trademark Office proposed rules directed to changes to practice for continuing applications, requests for continued examination practice, and applications containing patentably indistinct claims that were published on January 3, 2006.[1]

I am a partner in the intellectual property law firm of Birch, Stewart, Kolasch and Birch, LLP. For the last three years the firm has been ranked 3rd in the nation in terms of the number of patents granted for our clients.[2] That is relevant here because it means that the attorneys in the firm are extremely experienced with prosecution before the USPTO. I personally have 25 years of experience as a patent agent/patent attorney during which I have been involved in the prosecution of thousands of applications, particularly in the chemical, pharmaceutical and biotechnology fields. The following comments, therefore, are based on a large amount of experience with precisely the issues addressed by the proposed new rules. These comments should be considered my personal comments, and not those of the firm.

[1] See, 71 Fed. Reg. 48.
[2] Source – *Intellectual Property Today*

SUMMARY

The proposed rules should not be implemented because:

1. The fundamental basis and reasoning for the proposed rules is flawed.
2. The USPTO does not have the legal authority to make the proposed changes by means of rule making procedures.
3. The limitations on the number of continuation applications and requests for continued examination will be particularly detrimental to chemical/biotechnology companies.
4. The limitation on divisional applications is particularly egregious in view of the USPTO restriction requirement practice, and will actually have a counterproductive effect.
5. The retroactive effect of the proposed rules is particularly inappropriate and damaging.
6. Other less drastic options are available to deal with the true problems in the patent system.

DETAILED COMMENTS

1. The Fundamental Basis for the Proposed Rules is Flawed.

The USPTO has repeatedly stated that these proposed changes are necessary to deal with a backlog of pending applications, which the PTO in part blames on an increasing number of continuing applications. The PTO, in essence, complains that there are too many patent applications for it to handle, and that the Office cannot "hire its way out" of the problem.

The Constitutional purpose of the patent system, which the USPTO is to fulfill, is "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".[3] An increasing number of patent applications are a positive development and evidence of active technology innovation. The USPTO should be seeking to grant patents to those innovators, not seeking ways to simply reduce the number of patents. So at the most fundamental level, the PTO proposals are flawed, because the PTO has not in any way even attempted to explain how these proposals will "promote the progress of science and useful arts".

Seeking to limit the number of patent applications to deal with what may be a practical problem for the PTO beaurocracy is simply illogical, particularly if one were to apply this type of solution to other government functions. Imagine that the U.S. Postal Service thought that timely delivery of the mail was becoming difficult because of the large volume of mail, so the Postal Service proposed that companies be limited to only five letters per day, no letter could be more than three pages long and more than that would not be delivered by the Postal Service

[3] Art. I, Section 8, U.S. Constitution

unless the mailer filed a petition showing good cause for increased mailing. What would the public think of such a proposal? Everyone would of course think such a proposal was outrageous and would suggest that the Postal Service needs to hire more people, buy bigger trucks, or utilize technology to increase efficiency. But the USPTO apparently believes that its purposes are primary and can best be serviced by placing limits on the innovators in U.S. technology.

2. The USPTO Lacks Legal Authority to Make the Proposed Changes Through Rulemaking Procedures

I fully support the comments submitted on April 24, 2006 by the American Intellectual Property Law Association (AIPLA) on this issue, as well as all other issues addressed by the AIPLA. Other commentators have also explained why the USPTO lacks statutory authority to place limits on filing of continuing applications, so I will not repeat those arguments. But, suffice to say, if the USPTO proceeds to issue the proposals as final rules, legal challenges to the rules will surely be made, with the best result (for the USPTO) being a significant period of confusion and uncertainty and, the worst case (for the USPTO) being a striking down of the rules which would result in the USPTO somehow reversing its interim actions. Neither result is desirable for the USPTO nor applicants.

3. The Limitations on the Number of Continuation Applications and Request for Continued Examination will be Particularly Detrimental to Chemical/Biotechnology Companies

3.1. A high percentage of continuing applications are required because of overly restrictive "after final" practice in the USPTO.

A key aspect of the proposed new rules is a prohibition against the filing of more than one continuation application or request for continued examination (unless the applicant can make an as yet undefined "showing to the satisfaction of the director"). Public comments by PTO officials explain that these limitations are needed to curb "abuses" of continuation practice or deal with those who are "gaming the system". But the vast majority of continuation applications and requests for continued examination (RCE's) are not filed for any abusive purposes. Rather, most continuing applications are necessitated by unreasonably strict and inflexible "after final" practice at the USPTO, which seems to have become increasingly problematic over the last several years. Under this practice, applicants actually have only one opportunity to amend the claims and submit supporting evidence because the second issued office action is almost invariably a final rejection, following which examiners routinely refuse to consider even minor amendments to the claims or any evidence in support of patentability. The egregious nature of this practice is highlighted by the numerous circumstances where an examiner refuses to consider any amendments or evidence after the final rejection, "forcing" the applicant to file a continuing application, which application is then quickly allowed. The only conclusion that practitioners around the country draw from these repeated circumstances is that the PTO examiners are "gaming the system" simply to increase their production numbers.

It is my personal experience that this practice has become increasingly frequent, and circumstances which 15 years ago would have permitted entry of an amendment after final

rejection leading to allowance of an application now invariably are forced into a continuing application scenario. Thus the restrictive after final practice of PTO examiners is an essential cause of the increasing number of continuation applications, but the proposed new rules will punish applicants for the problem mostly created by the USPTO itself.

3.2. Continuation practice is legitimately used by companies needing early granted patents.

Another common reason for applicants to file continuing applications is a desire to obtain patent protection on the most essential aspects of an invention, while accepting some delay in obtaining patent protection on the full scope of applicant's invention. This is particularly important for young, start-up biotech companies which need quick patent protection to validate their technology to investors and/or to ward off infringing competitors. Companies in such situations often accept grant of somewhat narrow claims and file continuing applications to pursue broader claims, rather than delaying the grant of all claims while fighting for perfectly proper broad claims. These actions seem to be labeled by the USPTO as an "abuse" of the system, but in fact are based on sound business strategies. The USPTO should not be implementing changes to the patent system that inhibit the growth and financing of one of the important technology industries in the United States.

4. The Limitation on Divisional Applications is Particularly Egregious in View of the USPTO Restriction Requirement Practice

In addition to limiting applicants to only one continuation application or request for continued examination, the USPTO also proposes to limit divisional applications to claim priority on only one prior application. This would, in effect, prohibit the traditional "serial" filing of divisionals, that is the filing of a divisional from a divisional application. This will require applicants to file all possible divisional applications before the initial/parent application grants, or forever forego the possibility of filing additional divisional applications.

These rules will be particularly damaging and burdensome to biotechnology companies because of the extremely strict restriction/unity of invention practice currently enforced in the USPTO. It is not uncommon for biotechnology applications to be restricted by an examiner to 10, 20 or even many more groups of claims, requiring the applicant to consider filing that many divisional applications to protect the full scope of the applicant's invention. This restriction practice is considered by applicants to be extremely unreasonable, but at least the current rules permit the applicants to file the necessary divisional applications in a step wise or serial manner, thereby defraying the filing and prosecution costs of many divisional applications, and perhaps ultimately providing time for the applicant to decline filing some divisional applications. But the PTO's proposed rules would eliminate that strategy, and force applicants to file all possible divisional applications at the same time, vastly front loading large filing and prosecution costs.

This will, in fact, actually be counterproductive to the USPTO's own stated purposes, in that, applicants will be forced to file divisional applications which they might not previously

have filed if permitted to delay the decision making while serially filing individual divisional applications.

5. The Retroactive Effect of the Proposed Rules is Particularly Inappropriate and Damaging.

5.1. Companies will not be able to afford the sudden need to file all possible divisional applications.

As proposed, the PTO rules will have a retroactive effect because the limitations on continuing applications are intended to apply to "any application filed on or after the effective date of the final rule", meaning that any currently pending applications will fall under the new rules upon the filing of any continuation, divisional or RCE. Company patent filing strategies which have been developed and implemented for a number of years under the current rules would thereby suddenly be prosecuted in the USPTO under the new proposed rules. This again will be particularly burdensome and damaging to biotechnology companies that have developed filing strategies with the expectation of filing divisional applications in a serial or stepwise manner. For example, applications which contain tens, hundreds or thousands of amino acid or nucleotide sequences have been filed with the expectation that the applicants could file necessary divisional applications over time as resources permitted the applicant to seek protection for important sequences. But the proposed rules would force such applicants to suddenly file large numbers of divisional applications. The patent budgets of young biotechnology companies will simply not sustain the sudden filing of so many divisional applications, which will essentially result in the dedication to the public of discoveries that applicants could have protected, but for the unfair retroactive application of new rules.

5.2. *The rules will create sudden prior art bars to patent protection.*

Another egregiously negative result of the retroactive effect of the proposed rules will be somewhat hidden prior art bars that will suddenly arise. These problems will arise when an applicant is prohibited from claiming priority to more than one prior application and there has already been an earlier publication of the invention. The following rather typical scenarios exemplify the problems that will arise.

Scenario Number 1 – Typical Problems with Continuation Applications:

- A priority application is filed at month 0.
- A PCT application is filed at month 12.
- A US national phase application is filed at month 30 (Appln. #1).
- During prosecution of the US application, it becomes necessary to file a continuation application (Appln. #2) (either before or after implementation of the new rules)
- After implementation of the new rules, the continuation application (Appln. #2) is allowed, and the Applicant files a divisional or continuation application (Appln. #3) to pursue other claims. [4]

[4] Note that under the proposed rules, the Applicant would not even be able to file Appln. #3 unless the PTO granted a petition showing good cause, and this would be the case whether Appln. #2 was filed before or after implementation of the new rules.

What is the consequence of the new rules? The newly filed Divisional/Continuation Appln. #3 will be barred/anticipated/lack novelty over the prior published PCT application. This would be the result because Appln. #3 can only claim priority to one prior application (namely Appln. #2), but the filing date of Appln. #2 is more than one year after the PCT publication date.

Scenario Number 2 – Problem with "Serial" Filing of Divisionals

- A priority application is filed at month 0.
- A PCT application is filed at month 12.
- A US national phase application is filed at month 30 (Appln. #1).
- During prosecution of the US application (Appln. #1) a restriction requirement was issued with three or more groups of claims, and the applicant pursued claims in Group 1.
- Appln. #1 is allowed, and the Applicant files a divisional (Appln. #2) to pursue the claims of Group 2 (either before or after implementation of the new rules).
- Appln. #2 is allowed, and after implementation of the new rules, Divisional Appln. #3 is filed to pursue the claims of Group 3 from the restriction requirement.[5]

What is the consequence of the new rules? The newly filed Divisional Appln. #3 will be barred/anticipated/lack novelty over the prior published PCT application. This would be the result because Appln. #3 can only claim priority to one prior application (namely Appln. #2), but the filing date of Appln. #2 is more than one year after the PCT publication date. To avoid this problem, it would be necessary to file all possible divisional applications before Appln. #1 grants as a patent.

The retroactive effect of these proposed rules is, therefore, an unconscionable action on the part of the USPTO that will have severe consequences to applicants with patent filing strategies that were developed with an expectation that the "rules of the game" would continue in place. Changing the rules "in the middle of the game" will in these circumstances deprive applicants of their ability to effectively protect their intellectual property.

6. Other Less Drastic Options are Available to Deal with the True Problems in the Patent System

Most parties, including the many submitting comments against the PTO's rules, recognize that the USPTO is facing some true and significant struggles. But there are other steps that could be taken which would more effectively address the true root causes of the problems, without damaging applicants.

6.1 Dealing with True "Abusers" of Continuation Practice

The PTO publicly states that one reason for changing the rules regarding continuation practice is to deal with applicants who abuse the system by filing a long string of continuation applications and continuously redraft claims in an attempt to cover developing industries,

[5] Note that under the proposed rules, the Applicant would not even be able to file Appln. #3 unless the PTO granted a petition showing good cause, and this would be the case whether Appln. #2 was filed before or after implementation of the new rules.

thereby depriving the public of fair notice. The most egregious of these situations have already been addressed by limiting the term of U.S. patents to 20 years from the earliest effective filing date. This prevents applicants from filing a never ending chain of continuation applications while an industry develops over many years. But even the less egregious, though still abusive, situations could be addressed in a much more focused manner without adversely affecting the "non-abusers".

The essential aspect of the abuse criticized by the USPTO is that applicants could file an application with one set of claims and then over a series of continuation applications redraft and broaden those claims to cover subject matter not initially considered to be the applicant's invention. The focused solution to that problem is to simply prohibit applicants from broadening claims beyond the scope of the originally described invention. This is precisely the effect of the limitations in the European patent system.[6] The United States already has a similar law – 35 U.S.C. 112, first paragraph. Reasonable enforcement of the written description requirement would avoid the abuse complained of by the USPTO. Further "gaming of the system" would thereby be prohibited but legitimate use of continuation practice would still be possible.

6.2 Increased Flexibility of After Final Practice Will Inherently Reduce the Number of Continuation Applications

As explained above, a significant number of continuing applications are required because examiners refuse to consider amendments or evidence submitted after issuance of a final rejection. Examiners, for their part, feel pressured into this practice because they do not receive "credit" for time spent reviewing such submissions by applicants, but instead are driven by the "count" system which effectively rewards examiners for forcing applicants to abandon the existing application (giving the examiner one count) and filing a continuation application in which the examiner can issue another first office action and ultimately grant the patent (giving the examiner two more counts). The solution to this problem seems readily apparent – namely, the USPTO needs to alter its examiner production review system to provide examiners with credit and incentives for reviewing submissions after final rejection.

It may be instructive to again take some lessons from the European Patent Office. True continuation applications are not permitted in the EPO. But the filing of continuations is not deemed as necessary by applicants in the EPO because European practice does not have restrictive "after final" practice. In fact, applicants in the EPO can submit amended claims and evidence throughout the appeal process and even during opposition proceedings, of course with some reasonable time limitations to provide fair notice to participating parties. Adoption by the USPTO of a more flexible examination system would drastically reduce the need for applicants to file continuing applications. The initial, long ago reasons for the USPTO instituting final rejections and so-called "compact prosecution" to prevent examiners from issuing a continuing stream of rejections has been completely turned around to the current situation where the USPTO now complains that it is applicants who file a long string of continuation applications. Some better balance and flexibility in the system is necessary to bring prosecution to a close within a reasonable period of time, but without unduly restricting applicant's right to amend the claims and submit supporting evidence.

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[6] See, Article 123(3) EPC

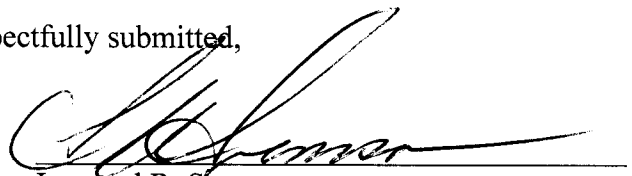
6.3 Focus on Retaining Experienced Examiners

The USPTO complains that it cannot "hire its way" out of the current situation with a backlog of applications and undesirably high pendency times. But the true cause of that problem is not applicants abusing continuation practice, but rather the PTO's inability to retain experienced and, therefore, efficient examiners. The remedy is not to punish applicants, but rather to find ways to reward good examiners who will stay at the PTO.

CONCLUSIONS

The new rules on continuing applications, as currently proposed by the USPTO, would be severely damaging and prejudicial to applicants, particularly biotech and pharmaceutical companies, effectively depriving those important industries of the ability to adequately protect their innovations. These truly draconian and heavy-handed proposals will not help either the USPTO or applicants. Instead, the USPTO should listen to the overwhelming negative reaction to these proposals, recognize that they truly do have the potential to seriously damage important industries, and then initiate a truly constructive dialogue with patent applicants, including open hearings, to seek realistic and balanced solutions to the actual problems in the US patent system.

Respectfully submitted,

By 

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