April 18, 2006

Jon W. Dudas, Director
John J. Doll, Commissioner for Patents
U.S. Patent and Trademark Office
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RE: Proposed New Rules for "Continued Examination Practice"[i]

Dear Director Dudas and Commissioner Doll:

The Patent Office is to be commended for seeking creative approaches to reducing the backlog of unexamined patent applications and improving the quality of patents. However, the changes proposed by the Office in connection with continuation practice are ill-conceived. If implemented, the proposed new rules will weaken the patent system and result in insufficient protection for new and valuable inventions. The biotechnology industry in particular will be burdened by increased prosecution costs and reduced protection. These detrimental effects will be unaccompanied by any proportionate reduction in the burden on the Office.

I. Executive Summary

In proposing rules that fundamentally change the patent system, the Office should provide reasoning and evidence the rules are needed and that implementing them will have the intended results. The Office has not done this. Instead, the arguments made by the Office in support of the new rules are characterized by unsupported conclusions, flawed reasoning, unwarranted assumptions, and misleading statistics. Each of five justifications provided by the Office for the proposed rules is addressed (Section II and Section V).

The problems the proposed new rules are intended to solve can be more effectively addressed through changes in Office practice and implementation of new rules that alter both Applicant and Office obligations. Several such changes are proposed (Section III).

The Office does not have authority to implement the proposed rules. As drafted, the rules are inconsistent with statute (35 USC § 120) and case law (*In re Henriksen* CCPA 1968) (Section IV).

If the Office is determined to implement the proposed changes to continuation and RCE practice, the rules should be modified and clarified (Section VI and Section VII).

II. Given the extraordinary scope of the proposed new rules, it is incumbent on the Office to justify them with clear reasoning and clear evidence. The Office has not done so.

Applicants, especially in the biotechnology community, believe that if the proposed changes to continuation and RCE practice are implemented, meaningful patent protection will not be available for many inventions, and the cost of obtaining those patent rights that remain available will increase significantly. Even though the Office[ii] does not now share this view, respect for the rights and views of patent applicants demands that the Office should at least support the proposed rules with clear reasoning and evidence showing the rules are necessary and would accomplish the goals intended by the Office. Instead the Office relies on murky reasoning, unsupported conclusions, and artificial categories to justify the proposed changes.

The Office asserts the proposed rules changing continuation and RCE practice are needed because:

1) Current continuation and RCE practice are not good uses of Office resources;[iii]

2) Implementation of the proposed rules is required to reduce the backlog of pending applications at the PTO; [iv]

3) Implementation of the proposed rules will reduce attorney incompetence or inattention, and will combat abuse of the patent system; [v]

4) Under the new rules the public will have earlier and better notice about which inventions disclosed in a patent application may be removed from the public domain as granted claims; [vi]

5) Implementation of the rules will result in better patents. [vii]

The following Sections 1-5 explain the arguments made by the Office are unsupported and incorrect and/or the rules offered by the Office do not solve, or are not appropriately tailored to, genuine problems of the patent system.

1. **The Office's assertion that current continuation and RCE practice are inferior uses of Office resources is unsupported by any evidence or meaningful analysis, and is incorrect in at least the biotechnology arts.**

The Office asserts that implementation of the proposed changes to continuation and RCE practice would "**focus the Office's limited examining resources on new applications disclosing "new" inventions instead of on "reworking" continued examination filings**" (quotation marks in original).[viii]

While the Office does not explain what it means by "reworking," the clear implication is that prosecution following an RCE or in a continuation application is largely a rehash of issues that could and should have been resolved earlier.[ix] If the Office has *any* evidence that current prosecution of continuations or RCEs is, to any significant extent, unproductive "reworking," the Office should present the evidence for discussion.

What *is* apparent is that so-called reworking is much more common in the biotechnology art units than in other fields. According to Office statistics, in Group 1600 more that 42% of first actions on the merits in 2005 were in continuing or RCE applications, a proportion substantially higher than in other technologies (the next highest being 28.5% in Group 3600).[x]

There is no indication the Office has conducted any serious analysis of how or why RCEs and continuation applications are used by Applicants in the biotechnology arts, or in any other field, in the prosecution. A suitable analysis to support the Office contention that continuation and RCE practice are unproductive (or evidence to the contrary) would involve review of prosecution histories of patents that have matured from continuation applications and/or applications prosecuted using RCE practice. In such an analysis, the Office should determine whether the subject patents *could* have issued if the proposed new rules were in place. Exemplary patents issuing from continuation applications that likely could *not* have been filed or examined under the proposed new rules include:[xi]

- US 4,237,224 [Recombinant DNA technology (Cohen-Boyer patent)]
- US 6,387,371 [Treatment of breast cancer with anti-HER2 antibody]
- US 5,333,675 [PCR thermocycler]
- US 5,955,422 [Recombinant erythropoietin]
- US 6,180,399 [Ribozymes]
- US 5,744,305 [DNA array]

If analysis reveals that these or other patents would or might *not* have issued under the new rules, the Office should then explain how such a loss of rights is consistent

with the goals of the patent system, and how the reduced protection would encourage innovation and investment or otherwise benefit the U.S. economy.

A similar retrospective analysis can be carried out using other patents that could not have been filed or would not have been examined under the proposed rules. These include any patent from a family in which more than one round of RCE occurred during prosecution, in which more than one continuation was filed, or in which both an RCE and a continuation were filed. In any case in which the Office determines that the patent that issued under the current rules would not have issued if prosecuted under the new rules, the Office should be prepared to defend this outcome.[xii]

Such an analysis would have collateral benefits. Understanding why specific continuation applications and/or RCEs were filed, what arguments were made by the Office and applicants, and how the issued claims differed from those in ancestor applications (continuations) or presented earlier in prosecution (RCEs), would allow the Office to identify *practice changes* that would likely reduce the need for so-called "continued examination filings."

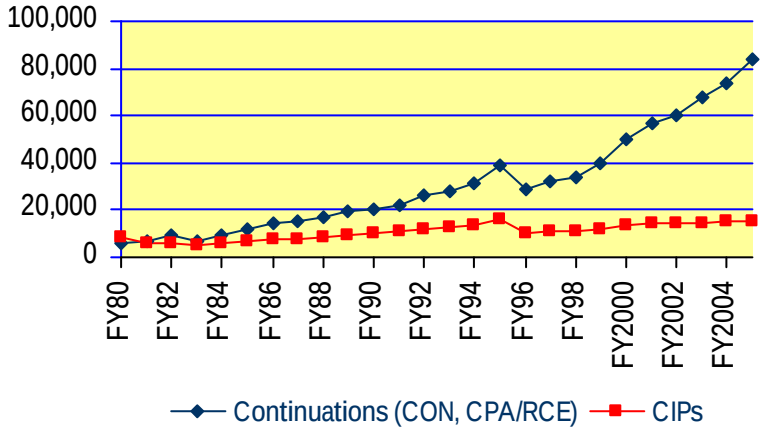
The Office has also asserted "**In such a string of continued examination filings, the exchange between examiners and applicants becomes less beneficial and suffers from diminishing returns.**"[xiii]

Again, the Office has provided absolutely no evidence for this assertion. I submit that in prosecution of inventions in complex technologies it sometimes takes several rounds of prosecution to establish to the satisfaction of the Office what the bounds of patentable subject matter are. In this case, contrary to the Office assertion of "diminishing returns" the later portions of examination may be considerably *more* fruitful and productive than a first Office Action.

On the other hand, if the Office's assertion that the quality of the exchange deteriorates in continuation or RCE prosecution is correct, an *appropriate* response by the Office would be to determine why this is the case and determine whether the proposed rules are the best remedy, or whether steps to improve examination efficiency should be adopted.

2. The assertion that implementation of the proposed rules is necessary to reduce workload is based on bundling Rule 53 continuation applications and RCEs. By not distinguishing between an *application* and a *request* the Office presents misleading statistics, and misconstrues the problem to be solved. Having mischaracterized the problem, the Office provides an inappropriate "solution."

The principal justification given by the Office for adopting the proposed new rules is that they would result, the Office contends, in a reduction in workload for overburdened examiners.[xiv] The Office has presented the graph below to demonstrate that a dramatic increase in continuation filings requires the rule change.[xv]



However, because this graph bundles continuation applications ("Cons") and requests for continued examination ("RCEs") it is misleading. Continuation applications and RCEs are governed by different statutes and rules, and differ from each other in function and effect. For example:

- RCEs extend examination of a pending application and particular claim set; continuations are new applications in which claims of a different category may be prosecuted;
- Each continuation can give rise to a different patent; this is not the case with RCEs;
- RCEs must be filed with a substantive response to the most recent Office Action; continuation applications are not filed with a response;
- A continuation application is generally not reviewed by an examiner until at least a year after filing; arguments accompanying an RCE are considered in the course of ongoing prosecution as any other amendment would be.

In order to discuss continuations and RCEs *as if* they were similar, the Office has *invented* the new category of "**continued examination filings**."[xvi] I submit it is

unhelpful, in a frank discussion of the merits and deficiencies of the rules proposed by the Office, to ignore the fundamental differences of continuations and RCEs. When continuation applications and RCEs are appropriately distinguished in the filing rate data, two important points emerge. First, it is clear that the increase in "continuation filing rates" identified by the Office is due primarily to increases in RCE filings. The increase in continuation applications filings is comparatively modest, and there is a slight decrease in CIP filings relative to the total activity at the PTO (a consequence of patent publication and twenty-year term, and a trend likely to continue).[xvii]

FY	Continuation Applications Filed (% of total applications filed)	CIPs Filed	RCEs/CPAs/ R129s Filed
2001	21,467 (6.6%)	13,842 (4.3%)	35,051 (10.8%)
2002	25,618 (7.7%)	14,586 (4.4%)	34,773 (10.5%)
2003	26,145 (7.9%)	14,468 (4.4%)	41,985 (12.7%)
2004	27,995 (7.9%)	14,512 (4.1%)	45,990 (13.0%)
2005	30,767 (8.1%)	14,863 (3.9%)	54,495 (14.3%)

Limiting the ability of applicants to file *continuation applications* would not substantially reduce work load, especially because an unknown number of the continuations would still be examined under the proposed rules. However, reducing reliance on RCEs could significantly ease the burden on the Office. The need for filing RCEs can be reduced by implementing practice changes that promote early and complete resolution of patentability issues during the examination process. By inappropriately bundling RCEs and continuation applications, and failing to fully analyze actual prosecution practice, the Office has misidentified the workload/backlog problem as being a result of too many so-called "continuing application filings," rather than a consequence of rules and practices that prolong prosecution and increase the need for filing continuation applications and RCEs.

Moreover, even if the new rules were imposed to limit Applicants' ability to file continuations and RCEs, the Office's prediction of a reduction in Office work load is naive and almost certainly wrong. Instead, implementation of the rules will result in an increase in Office burden due to substantial changes in petition and appeal practice (see Section V below). In addition, under the proposed rules there will be a steep rise in the number of divisional applications filed.[xviii] Approximately 20,000 divisional applications are filed each year.[xix] If this number were to rise even by a factor of three, the increased burden on the Office would exceed decrease in burden the Office supposes would result from restricting continuations and RCEs.

3. The proposed rules are an inappropriate mechanism for combating attorney incompetence and misfeasance or for combating abuse of the patent system.

The Office comments are suffused with the assumption that applicant incompetence, misfeasance and misconduct are chief contributing factors to examination backlog, and that discouraging such incompetence, misfeasance and misconduct are justifications for the proposed rules. For example, one rationale provided by the Office for the proposed rules relates to poor quality specifications and claims:

> The Office also notes that not every applicant comes to the Office prepared to particularly point out and distinctly claim what the applicant regards as his invention, for example, where the applicant's attorney or agent has not adequately reviewed or revised the application documents (often a literal translation) received from the applicant. In these situations examination of what applicants actually regard as their invention may not begin until after one or more continued examination filings. Applicants should not rely on an unlimited number of continued examination filings to correct deficiencies in the claims and disclosure that applicant or applicant's representative have not adequately reviewed.[xx]

To the extent poorly translated applications present a problem, there are better remedies than the proposed rules. For example, poorly translated applications could be deemed informal and correction required. As to cases in which "one or more continued examination filings" are required to settle on allowable claims, it is the nature of prosecution of new and innovative inventions that claims are refined prior to issuance. As the Office itself has observed, continued examination practice “allows applicants to craft their claims in light of the examiner's evidence and arguments, which in turn may lead to well-designed claims that give the public notice of precisely what the applicant regards as his or her invention."[xxi] As to supposed cases in which an applicant or attorney goes through several rounds of prosecution without understanding the invention, my only comment is that such a situation must be a relatively rare occurrence, not warranting the global rule changes now proposed.

A more reasonable argument by the Office is the new rules would discourage applicants from delaying prosecution as a technology advances, and then amending claims to cover a competitor's product developed after, and without reliance on, the Applicant's invention:

> "In addition, a small minority of applicants have misused continued examination practice with multiple continued examination filings in order to simply delay the conclusion of examination. This skirts applicant's duty to make a bona fide attempt to advance the application to final agency action and impairs the ability of the Office to examine new and existing applications. It also prejudices the public by permitting applicants to keep applications in pending status while awaiting

> developments in similar or parallel technology and then later amending the pending application to cover the developments."[xxii]

This "gaming" of the patent system appears to be an issue primarily in the computer and high tech arenas. Without intending to minimize what some believe is a significant issue, the proposed new rules are not the best way to address this problem. First, it makes no sense to make a major change to the entire patent system to address a practice by "a small minority of applicants" and largely limited in a particular technology. Second, a better tailored modification of the patent system would be to limit the types of claims that can be filed in a continuation application (for example, to limit broadening claims in continuations) or to limit the time-frame in which claims can be presented or prosecuted. Finally, rare abuses of the patent system may be have been and are properly addressed by the Courts and Congress (e.g., through the doctrine of prosecution laches or creation of prior use rights for parties developing technology covered by a claim broadened in a late-filed continuation application).

4. The Office asserts implementation of the new rules will improve the public notice function of patent claims.

The Office also argues:

> ". . . current practice allows an applicant to generate an unlimited string of continued examination filings from an initial application. . . . Moreover, the possible issuance of multiple patents arising from such a process tends to defeat the public notice function of patent claims in the initial application."[xxiii]

As an initial observation, the Office comments are peppered with references to strings of continuations that are "unrestricted," "unlimited," "unfettered," and the like. The Office comments thus create a straw man argument rather than focus on the real issues and consequences. Unlimited and unwarranted filings of continuation applications, if intended to abuse the system, can surely be addressed with more tailored and effective rules than those proposed by the Office (such as those mentioned above).

As to the concerns about the "possible issuance of multiple patents," this obviously is not relevant to RCEs, which do not result in multiple patents, and thus is no justification for the proposed new rules.

Moreover, the proposed rules do not preclude multiple patents issuing from the same application: they will continue to be issued from divisional applications. An Applicant inclined to defer the filing of, or extend the pendency of, a divisional application will not be prevented from doing so under the rules proposed by the Office. Thus, to the extent to which the proposed rules are intended to provide better public notice of possible claims,

they are largely ineffective. To the extent they are effective, this is a remedy that causes more damage than the problem it is intended to solve.

Finally, in crafting policy, the alleged notice benefit of issuing a single application should be balanced with the rights of the applicant to adequate protection of her invention. Patent prosecution can take several years, and appeal can take several more. I submit there is nothing nefarious if a small biotechnology company, for example, issues a first patent with claims to a commercially valuable embodiment of an invention and pursues generic claims in a continuation application. This is a rational and reasonable response to impediments in prosecution beyond the applicant's control. Further, given that in this scenario both the parent and continuation might issue in a shorter time than would be required to take a single application through the appeal process, the notice function of the patents is better served under the present system. There are numerous other legitimate, rational, and economically desirable reasons continuation applications are filed, none of which are discussed by the Office.

5. The Office assertion that implementation of the proposed rules will improve the prosecution process is based on false assumptions.

The Office states "**It is expected that these rules will make the exchange between examiners and applicants more effective and efficient. The revised rules should also improve the quality of issued patents.**"[xxiv]

Nothing in the discussion by the Office suggests that the rules would require any changes at the Patent Offices that might make the exchange between examiners and applicants more effective. Instead, **the new rules are premised on the notion that it is *Applicants* who impede efficient prosecution, unintentionally, through inattention and incompetence, or intentionally. Consequently the Office has concluded that compelling Applicants to "shape up" will reduce burden on the Office.**

Incredibly, in proposing a fundamental and destructive change to the patent system, the Office contends

> "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 or continuation-in-part application or single request for continued examination." [xxv]

This contention makes sense only if the Office believes a substantial proportion of RCEs and continuation applications are filed by Applicants *not* making a *bona fide* attempt to advance the application. The basis for such a belief is unclear.

More critically, it is clear from this and other[xxvi] comments by the Office that the implementation and effect of the new rules has not been clearly or completely considered. Assuming, as I do, that the Office comment about "primary impact" is sincerely intended, the Office should understand that **"a *bona fide* attempt to advance prosecution" is not synonymous with the standard under the proposed rule of "showing as to why the amendment, argument, or evidence presented could not have been previously submitted."** If the Office wishes to prevent applicants from maintaining applications in which no *bona fide* attempt is made to advance prosecution, the Office should propose rules to that effect.

I respectfully submit that in prosecution of complex inventions it may take multiple rounds of prosecution "to craft . . . claims in light of the examiner's evidence and arguments, which in turn may lead to well-designed claims that give the public notice of precisely what the applicant regards as his or her invention."[xxvii] This process generally has little or nothing to do with whether amendments or evidence "could have" been submitted earlier by the applicant. Instead, this has to do with the reality that in new and complicated technologies it sometimes takes multiple rounds of prosecution for the examiner to fully understand the invention, for the applicant to find language acceptable to the examiner, and for complex issues of enablement and written description to be resolved. The difficulties are amplified by distortions on both sides of the examination process (for example, Office policies that retard prosecution, as discussed below, on one hand, and pressures on applicants to submit over-inclusive IDSs on the other). Seeking improvements to the prosecution process should be the common goal of Applicants and the Office. As discussed below in Section III, improving the prosecution process is the key to reducing the need for RCEs and continuation applications, and in turn lessening the burden on the Office.

III. Alternatives ways to address the problems faced by the Office.

A premise of the Office's proposed changes is that by restricting Applicants to *one* continuation *or* RCE, the number of applications filed and duration of examination will decrease, allowing more effective examination of the remaining and additional cases. As noted above, the Office does not actually explain why examination should be more effective (other than by compelling attorneys to do a better job). Instead there is every reason to believe that the burden on the Office will not be reduced, and the effect of the proposed rules will be to inject additional uncertainty and delay into the examination process.[xxviii]

Many of the problems the proposed new rules are intended to solve can be more effectively addressed through practice changes that improve the efficiency and effectiveness of examination and *thereby* result in reduced need for RCEs and reduced reliance on continuation practice. Appropriate changes would alter both Applicant and

Office obligations and in addition to reducing the burden on the Office would result in better patents at lower cost. Examples of changes I believe are appropriately tailored to the problems the proposed continuation rules are intended to (but do not) solve are provided below.[xxix]

1. Adopt Optional Unity of Invention Practice

Adoption of Unity of Invention practice could significantly reduce the number of patent applications filed. For example, a single patent application claiming a novel protein, a DNA that encodes the protein, an antibody specific for the protein, and a method for detecting the protein using the antibody, may mature into a single patent in the EPO when examined under Unity of Invention practice. In the U.S., however, four or more different applications will generally be required. Unity of Invention is in many cases a more efficient approach to examination. The Office is now evaluating possible Unity of Invention standards for claim examination.[xxx] The Office should accelerate this process, if possible. Alternatively, adoption of an interim standard based on current Section 371 practice (see M.P.E.P. § 1850) should be made available at the option of the applicant.

2. Prior to beginning examination of an application, ask the applicant to confirm intent to maintain the application

Prior to beginning examination of an application the Office should require an affirmative indication by the applicant that she wishes to prosecute the application. Amendments to the claims should be permitted at the time of affirming interest in prosecution, and payment of at least a portion of the examination fee should be paid at that time.

Although in an ideal system the originally filed claims would be in final form for examination, as the Office has noted, this is not always the case in practice.[xxxi] , Moreover, in the period between filing of the application and the beginning of examination the applicant may acquire information that allows her to sharpen or focus claims for examination. Implementation of this practice would improve the quality of prosecution and may result in some reduction in the number of first Office Actions the Office is required to prepare.

3. Require the applicant to advance prosecution

In cases in which an applicant is clearly manipulating the system to extend prosecution or is filing serial continuations without examination, the Office may require the application move to appeal (i.e., a mandatory close to examiner review). However, the *burden* in

such cases should be on the Office and implementation should require review of the prosecution history by persons other than the examiner(s) involved in prosecution.

4. Change the format of claim amendments

The Office should investigate whether adoption of the EPO approach to presenting claim amendments (i.e., presentation of a substitute claim set in which claims may be rewritten) results in better and more efficient examination than the U.S. practice of presenting marked-up claims. The U.S. practice encourages the applicant to make, to the extent possible, small, incremental changes. Although U.S. practice allows an examiner to easily identify changes in claims, it often results in awkward claim language and impedes prosecution. Although applicants would still be burdened by *Festo* considerations, flexibility in claim presentation could improve both examination and notice.

A standardized format for identifying support for newly introduced claims or claim amendments could also ease burden on the examiner. A suitable format would be one that *assists* the examiner without unduly burdening the applicant or being so rigid as to cause concerns about unintended admissions or estoppel.

5. Evaluate the effect of examiner's incentives on prosecution

Under the present "count" and "disposal" system[xxxii], examiners may be penalized for conducting a careful, efficient and effective examination, and are rewarded for practices that extend examination, increase costs, and virtually ensure filing of RCEs and continuation applications. Examiners have disincentives to taking steps that would advance prosecution without the need for continuation application or RCEs. For example, RCEs are often filed solely to "compensate" an examiner for consideration of a response that under a less distorted system would be considered as part of the normal process of advancing prosecution to grant or abandonment. RCEs are also frequently filed to respond to a new ground of rejection or new argument made by the examiner in a final Office Action.[xxxiii] Problems with the system of incentives and time allotment are well known and widely discussed.[xxxiv] The system should be revised to encourage rather than impede prosecution.

It is notable and commendable that the majority of fine Examiners in Group 1600 conduct a conscientious and through examination *in spite* of the disincentives integral to the system.

6. Implement or expand quality control procedures

Poor quality work by either the attorney or the examiner in a case will tend to unnecessarily extend prosecution. The present quality control initiatives by the Office appear to take effect largely after an allowance, to identify any claims improperly allowed by the examiner. However, quality control should be implemented or increased throughout the examination process. As part of the attempt to expedite examination, Office Actions should be more carefully reviewed by a person other than the examiner. A reviewer does not have to master the invention (or even the art) to recognize Office Action comments that are unclear, contain conclusory statements, or are mere non-responsive repetitions of text from prior Office Actions. Such actions, while uncommon, extend prosecution inordinately and out of proportion to their number.

Finally, practitioners do not currently have a good mechanism for calling attention to problem examiners or problem examinations or for praising excellent examiners. Private sector employers rely on customer feedback for valuable information concerning employee work. The Office should consider availing itself of this resource in a way that fully insulates the practitioner and applicants from any backlash.

7. Optional Expedited Examination

Current "Make Special" practice shifts certain burdens from the Office to the Applicant *and* constrains the scope of prosecution. However, it is widely believed that filing a petition to make special may actually extend prosecution because of delays in the petition branch and by the examiner. Thus there is little incentive for applicants to accept the burdens of Make Special practice prosecution. Introduction of a well-designed process for accelerated examination would reduce Office burden and expedite prosecution.

8. Others

There is no shortage of suggestions for improving the prosecution process. Many proposals have been made by the Office itself, and several have been implemented.[xxxv] While suggestions 1-7 above are submitted for consideration, I do not suppose they are new or necessarily superior to other proposals. The more important point is that the solution to the problem of application back-log, or the perceived problem of increasing numbers of RCEs filed, lies in improving the examination system, not on introducing rules that will deny applicants, particularly in the biotechnology arts, legitimate patent protection.

Finally, the desirability of adequate funding for the Office is so uncontroversial and obvious that it hardly need be discussed. Patent attorneys and their clients should actively support funding initiatives.

IV. The Office does not have the authority to implement the proposed rules and, in any event, these changes should not be imposed by Office fiat.

The Office proposal to fundamentally change the patent system with unvetted rules of its own design is unwise and overreaching. The extent of discussion (little), hearings (none), and comments (a single round of submissions) presupposes that a small group of individuals has the wisdom to design a fundamentally changed patent system. Changes of this type and magnitude are more appropriately carried out through a legislative process.

Moreover, the Office assertion that it has the power to impose these rules is doubtful at best:

1. The proposed new rules are impermissibly contrary to 35 USC § 120

The proposed new rules are inconsistent with the codification of continuation practice at 35 USC § 120. 35 USC § 120 provides applicants the right to file continuation applications. The Office argues, correctly but irrelevantly, that "Applicants should understand, however, that there is not an unfettered right to file multiple continuing applications without making a bona fide attempt to claim the applicant's invention" and that the proposed rules merely limit the number of applications that can be filed.[xxxvi] However, under the proposed new rules an applicant who has relied on a single RCE in a parent would be prohibited from filing *any* continuation application under 35 USC § 120, *except* at the discretion of the Director. The Director has no authority to preclude filing of a continuation application under 35 USC § 120 because an Applicant has filed an RCE under an unrelated provision in 35 USC § 132.

If the Office believes it currently has authority to implement the proposed changes to continuation practice, one wonders why legislation has been introduced in Congress to *give* the Director authority to limit the circumstances under which an continuation applications may be filed (e.g., see HR 2795, Sec. 123).

2. The proposed new rules are contrary to the holding in *In re Henriksen* 158 USPQ 224

The Office intends for the proposed new rules to apply to any application pending on the date of implementation. This retroactive application to applications filed and prosecuted under the existing rules would divest an unknown number of Applicants of rights to

which they otherwise would be entitled. However, in *In re Henriksen* 158 USPQ 224 (CCPA 1968) the Court proscribed a retroactive rule change that "may have the effect of divesting applicants of valuable rights to which, but for the change in Patent Office position brought about by the board's decision, they were entitled."[xxxvii]

The Office distinguishes *Henriksen* as being limited to the case in which the applicant had no prior notice and for which the Office had promulgated no rules. Under the regime proposed by the Office, the applicant has notice (*but* is impotent to adjust prosecution of already pending applications in response to the notice) and the changes have support in the rules (*but* not in rules in effect during the filing and prosecution of the earlier-filed application).[xxxviii] The effectively retroactive effect of the proposed rules is contrary to *Henriksen*. Moreover, the holding in *Henriksen* was not limited to the specific, and egregious, facts of that case. Rather, the Court observed that authority for a change in continuation practice lies with Congress *even* in an egregious case:

> " . . . the cure for this deplorable state of affairs rests with Congress, not with us. If a restriction is to be imposed, it must be based upon law, legislatively or judicially expressed. It is our view, as the judiciary, that it is for Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction as sought by the board is to be imposed."[xxxix]

The Office relies on *In re Bogese*[xl] for the proposition the Office may, by rule change, drastically reduce or eliminate access to continuation practice. In *Bogese*, the panel majority observed that *Henriksen* does not "imply that the PTO must allow dilatory tactics in the prosecution of applications or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution." *Bogese* was a case in which an applicant filed *thirteen* pre-GATT continuation applications between 1980 and 1994 without *attempting* to advance prosecution. The *Bogese* court held that the PTO has power to deal with intentional, sustained, unreasonable and egregious delays by an applicant; the court did not imply that the Office has authority to prohibit the filing of continuation applications to manage examination backlog. The Office does not have such authority and may not legitimately implement the proposed rules.

3. It is extraordinary that the Office has rushed ill-considered rules but treads cautiously in implementing the initiatives of the *21st Century Strategic Plan.* It is astounding that the Office intends to implement over-reaching rules with the knowledge that Congress is currently considering legislation that would provide the Office with legitimate authority and guidance to reform continuation practice.

In the *21st Century Strategic Plan* and elsewhere, the Office has proposed an impressive array of practice changes and is in the process of investigating or cautiously

implementing them. It is extraordinary that implementation of practices widely accepted as desirable is proceeding in a measured and deliberate manner, while the sweeping changes of the proposed rules are intended to be imposed rapidly and by PTO fiat.

V. Implementation of the rules in their current form would result in an unprecedented back-log of applications.

The chief purported goal of the new rules is to reduce Office back-log. Notably, none of the materials provided by the Office provide any prediction of the extent of the expected reduction.[xli] I believe that, if the rules are implemented in their current form, prosecution burden in the Office will increase:

- In the vast majority of cases in which the Director asserts an "amendment, argument, or evidence to be pursued in the continuation or RCE could not have been submitted prior to the close of prosecution in the application" the applicant will appeal the finding. This problem will be exacerbated by the vague (and therefore arbitrary) standard for determining whether an amendment "could have" been submitted earlier. Both the decision of the Director and the decision on appeal will require the attention and resources of the Office.

- Applicants will have every incentive to appeal any final rejection, in part to maintain extended copendency for purposes of prosecution of divisional applications.

- The number of divisional applications filed will rise due to the requirement that all divisional applications be filed during the pendency of the parent, possibly resulting in a net increase in Office burden.

- The number of petitions for review of restriction requirements will rise substantially as the consequences of restriction change.

Although there might or might not be a change in the *number* of so-called "continued examination filings" upon implementation of the rule, it is predictable that the net result of implementation will be to clog the application process, increase the number of applications pending and under appeal, lengthen pendencies, and thereby increase uncertainty by the public as to what claims will ultimately issue.

Moreover, if implemented, the rules will be challenged in the courts. Such a challenge would likely succeed. The process then necessary to restore rights denied to applicants will be nightmarish for both the Office and applicants.

VI. Should the proposed regulations be implemented, at minimum the following changes should be made:

A. The rules should not be retroactive, and should not apply to applications filed prior to implementation of the rules or to progeny of such applications.

B. The rules as they apply to divisional practice[xlii] should be modified to account for the economic impossibility, in many cases, of pursuing numerous divisional applications simultaneously. The application of the rules to divisional applications is particularly problematic because, although the Office's efforts to improve restriction practice have resulted in significant improvements, restriction practice remains unpredictable, highly subjective, and sometimes arbitrary.

C. If the second set of new rules proposed by the Office, directed to examination of *claims*,[xliii] is implemented, the *combined* effect of the claims rules and continuation rules on the ability of applicants' legitimate patent rights must be considered. Adjustments to both rule sets should be made after consultation with applicants. To do otherwise is to assume, I believe incorrectly, the Office acting alone has the wisdom to design and implement two fundamental changes to the patent system, consider and balance the effects of the changes on the rights of applicants' in a variety of industries, and appreciate the effects of the changes not only on the operation of the PTO but also on the U.S. economy.

VII. Should the proposed regulations be implemented, the standard for determining whether or not an amendment, argument, or evidence presented "could not have been previously submitted" should be explained.

Well in advance of implementation of the proposed rules, in current or modified form, the standard for determining whether a second RCE or second continuation is permitted should be clarified and an appeal process put in place. The proposed rules require a showing that an "amendment, argument, or evidence presented could not have been previously submitted." As a matter of basic logic, establishing that an amendment or argument "could not have been" submitted earlier will often be impossible. Presumably, virtually *any* valid amendment could be submitted at any time. If an amendment is made in good faith and is rejected (with or without cause) by the examiner, is a subsequent amendment one that "could not have been made earlier"? If an amendment is rejected under §112, 2nd as lacking antecedent basis, is a corrective amendment one that "could not have been made earlier"? If an examiner is not persuaded by an argument, is a subsequent argument further addressing the examiner's concerns one that "could not have been made earlier"? (It is already easy to anticipate 75 page responses,

as applicants pack in each and every argument that "could be" made to an enablement, written description or art rejection.)

In addition to clarification of the standard, the procedure for determining whether an argument, evidence or amendment "could have been" earlier presented should be published. Will the examiner make the determination? What will the appeal process be? Once the standard, process for determining sufficiency of a showing, and process for appeal are established, the public should be afforded an opportunity to comment prior to implementation. Applicants should have ample assurance and confidence that any pre-appeal decisions under the standard will be predictable rather than capricious.

The proposed new rules for continuation practice are ill-conceived. The fact that problems faced by the Office must be addressed and resolved is not disputed. However, the particular changes proposed by the Office in connection with continuation practice will weaken the patent system and will particularly damage the biotechnology industry. These detrimental effects will be unaccompanied by any commensurate benefit to the Office. The proposed rules should not be implemented. Thank you for your consideration of these comments.

Respectfully Submitted,

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The views expressed here are mine and are not to be attributed to any other person or entity including any other attorney at Townsend and Townsend and Crew LLP or any client of the firm.

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[i] The proposed rules are discussed at 71 Fed. Reg. 48 (January 3, 2006) (hereinafter "Fed. Reg.") and in PowerPoint presentations available at the PTO website (http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html).

[ii] Attribution of the new rules to the "Office" warrants comment, given the diverse roles of those employed at the PTO. I wish to make clear my respect for the helpful, conscientious, and skilled examiners, administrators and others at the PTO with whom I work daily, and to acknowledge both the difficult circumstances under which the agency operates and the significant initiatives the Office has taken to improve the examination process. This

comment addresses what is in my view an exceptional lapse of judgment by those at the Office promoting the new rules. It is not intended to question their dedication or intentions.

[iii] Fed. Reg. at 48, col.3; 49, col. 1.

[iv] Fed. Reg. at 48-51.

[v] Fed. Reg. at 49, col. 1 and col. 3; at 50, col. 2; and at 51, col. 1.

[vi] Fed. Reg. at 48, col. 1 and col. 3.

[vii] Fed. Reg. at 48, col. 3.

[viii] Slide #2, *Objectives of Proposed Changes* from 25 January 2006 presentation available at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html.

[ix] Slide #8, *Technology Centers Rework Statistics* from the 25 January 2006 presentation (see note viii) suggests that "reworking" refers to actions "that are in a Continuing (CONs and CIPs), RCE, CPA or 129(a) applications.") However, this definition renders the term superfluous as used in the bolded quotation. Elsewhere the Office uses the even less-clear term “recycling” (e.g., Slide #33 *Continuations/Double Patenting Proposed Rulemaking* "Limit the “recycling” of old applications to permit the USPTO to focus examining resources on “new” applications” (available as in note viii, supra).

[x] Slide #8, note ix *supra*. The “rework statistics” include first Office Actions in that are in a continuation and continuation-in-part applications, RCEs, CPAs and rule 129(a) applications. I have assumed that the number of CPA and Rule 129(a) applications prosecuted in FY 2005 is insignificant. Technology center 1600 examines applications in biotechnology and organic chemistry. TC 3600 examines in transportation, electronic commerce, construction, agriculture. The lowest % "rework" is in TC 2800 (semiconductors, electrical and optical systems and components).

[xi] Each of these patents matured from a family with a number of continuation applications. See http://164.195.100.11/netahtml/srchnum.htm.

[xii] The Office statement also asserts the desirability of "focus[ing] the Office's limited examining resources on new applications disclosing "new" inventions." The Office should explain what is meant by ““new” inventions” and why such inventions are more entitled to fair and adequate examination than "old" inventions (i.e., 1-5 years "older"?). If a goal of the patent system is to foster innovation, investment, productivity and economic growth, the value of an invention, at least not in the biotechnology arena, is not defined by whether it is one-, two- or five-years old.

[xiii] Fed. Reg. at 48, col. 3.

[xiv] Fed. Reg. at 49, col. 2. ("the current volume of continued examination filings . . .are having a crippling effect . .").

[xv] Slide #9 *Continuation Filing Rates* from the from 25 January 2006 presentation referenced at note viii.

[xvi] None of the terms "continued examination filings," "continued examination filing," "continued examination applications" or "continued examination application" are found in the patent statutes, patent rules, or M.P.E.P. Continuation applications are discussed at M.P.E.P. § 201.07.

[xvii] Figures for "Continuation Applications Filed," "RCEs/CPAs/R129s Filed" and "Utility Applications Filed" were very kindly provided by Robert A. Clarke, Deputy Director, USPTO Office of Patent Legal Administration. Calculations of % of total are mine. Divisional applications are not included.

FY	Utility Applications Filed	Continuation Applications Filed as % of Total	C-I-P
2001	324,211	6.6%	4.3%
2002	331,580	7.7%	4.4%
2003	331,729	7.9%	4.4%
2004	353,319	7.9%	4.1%
2005	381,797	8.1%	3.9%

[xviii] Under the proposed rules divisional applications could claim priority to only a single prior filed application. This effectively requires that all divisional applications be filed during the pendency of the parent. Fed. Reg. at 53, col. 2-3.

[xix] The numbers of Rule 1.53(b) divisional applications filed 2000-2004 are shown below. The figures were very kindly provided by Robert A. Clarke, Deputy Director, USPTO Office of Patent Legal Administration.

FY	Rule 1.53(b) Divisionals filed
2000	15,755
2001	17,978
2002	18,182
2003	19,678
2004	19,360

[xx] Fed. Reg. at 49, col. 3.

[xxi] Fed. Reg. at 48, col. 3.

[xxii] Fed. Reg. at 49, col. 3.

[xxiii] Fed. Reg. at 48, col. 1.

[xxiv] Fed. Reg. at 48, col. 3.

[xxv] Fed. Reg. at 57, col. 1 (underline added).

[xxvi] There is no indication the Office has accurately assessed what the impact on applicants would be if the rules are implemented, even as to the numbers of applications encompassed by the rules. For example, the Office states the "showing requirement would impact relatively few applicants." See Fed. Reg. at 57, col. 1-col. 2. The Office presents a calculation that in FY 2005 only about 3.7 percent (11,790) of applications filed were a second or subsequent continuation or continuation-in-part applications and that of RCEs filed, only 3.1 percent (9,925) were a second or subsequent request. However, the Office omits from its calculation any continuation applications in which an RCE was filed in the parent; or any RCE filed in any continuation application, both of which would be

restricted under the proposed rules. Moreover, the Office figures do not account for the fact that it is often the most valuable and important inventions that are prosecuted using continuations and RCEs. In addition, complex patent families appear to be more common in the biotechnology arts, a fact, if true, not investigated or considered by the Office.

[xxvii] Fed. Reg. at 48, col. 3.

[xxviii] See §V below.

[xxix] Improvements to examination may not directly prevent an Applicant intent on abusing the patent system. However, problems of misfeasance or abuse should be addressed as described elsewhere in this comment or in other ways more narrowly tailored and proportionate to the problem than the proposed continuation rules.

[xxx] See *Interim Adjustments to the 21st Century Strategic Plan (22 Feb 2006)* available at http://www.uspto.gov/web/offices/com/strat21/index.htm.

[xxxi] Fed. Reg. at 49, col. 3.

[xxxii] See, e.g., M.P.E.P. §1705.

[xxxiii] It is common Office practice to make an Office Action final even when new bases or formulations of a rejection are presented, whether or not *necessitated* by a new amendment.

[xxxiv] For a restrained discussion of some of these issues, see Final Inspection Report IPE-15722, U.S. Department of Commerce "*USPTO Should Reassess How Examiner Goals, Performance Appraisal Plans, and the Award System Stimulate and Reward Examiner Production*" 2004.

[xxxv] See note xxix, supra.

[xxxvi] Fed. Reg. at 50, col. 3.

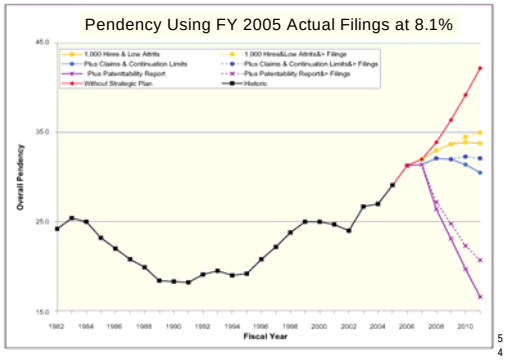
[xxxvii] *Henriksen* at 231.

[xxxviii] Fed. Reg. at 50, col. 3.

[xxxix] *Henriksen* at 231.

[xl] *In re Bogese* 64 USPQ2d 1448 (Fed. Cir. 2002). .

[xli] Notably, the projections provided by the Office consider pendency under seven different scenarios (below). None of the scenarios considered the effect of adopting the proposed new rules for claims without concurrent adoption of rules for continuation. Thus it is not clear what effect on pendency expected by the Office if the examination rules, but not the continuation rules are adopted.



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Slide #15 *Pendency Reduction Action Plan* available as indicated in note viii, supra.

[xlii] See note xviii, supra.

[xliii] See 71 Fed. Reg. 61 (January 3, 2006).