

EXHIBIT 25



PATENT PUBLIC ADVISORY COMMITTEE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

May 3, 2006

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Attn: Robert W. Bahr
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Re: Comments on Proposed Rules: "Changes to Practice for the Examination of Claims in Patent Applications" 71 Fed. Reg. 61 (Jan. 3, 2006), and "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48 (Jan. 3, 2006)

Dear Under Secretary Dudas:

At the outset we wish to reaffirm that we agree with the Office that improving patent quality is a mutually shared responsibility of both applicants and the Office.¹ In that respect, we do not disagree with the overall objectives of the Proposed Rules, which seek to place greater responsibility on applicants

¹ In the Annual Report sent last November to the President and Congress, we noted that "While PPAC agrees with the objective of a more balanced sharing of the responsibility for improving patent quality as between both applicants and the Office, where the line should be drawn to achieve that balance and whether these proposed rule changes adequately reflect that balance will require continued dialog between PPAC, the Office and the diverse community of users." (Emphasis added).

who present inordinate numbers of claims or claims of such complex breadth and scope that their examination consumes inordinate resources of the Office, or which seek to curb unreasonable practices such as intentionally seeking to maintain long periods of pendency in the hope of eventually surfacing with claims that are broad enough to cover large segments of industries and markets that have developed during the period of pendency.

That said, however, we believe there is a serious question as to whether the scope and sweep of these Proposed Rules is appropriately tailored to address those who are responsible for such practices, thus placing responsibility where it rightfully belongs, as opposed to unnecessarily impacting *all* applicants, most of whom do not engage in such practices.

With that in mind, these comments are offered² in a spirit of what we hope is helpful critique, consistent with our prior dialogue with the Office on these matters and our statutory mandate of advising the PTO concerning the “policies, goals, performance, budget and user fees . . . with respect to patents.” 35 U.S.C. § 5(d).

I. Introduction and Background

The Proposed Rules would change (1) the way in which claims in an application are examined by limiting the number of claims that may be presented for initial examination by the Office, and would (2) limit the circumstances under which an applicant may file continuation applications, requests for continued examination of applications, and, in some cases, continuation-in-part applications (e.g., when containing “patentably indistinct” claims). These proposed changes to the practice, taken both

² These comments are joined by all voting members of PPAC except Mr. Grant and Mr. Kamen. Mr. Grant is “not in agreement with all the positions represented in [these comments] and believe[s] that at least some portion of the PTO’s proposed rules are reasonable alternatives being considered by the Office to respond to the challenges it faces, including the proposed rule concerning continuations and CIPs, for example.” Mr. Kamen’s schedule did not allow sufficient time to fully consider these comments. Mr. Kamen has stated that he understands and, in some instances, agrees with the concerns expressed in these comments, but he also believes “that at least some portion of the PTO’s proposed rules are reasonable alternatives being considered by the Office to respond to the challenges it faces.” Mr. Kamen encourages the Office in its efforts to find creative solutions to further improve the patent system, as well as efforts by the user community to work together to identify optimal solutions that will foster innovation.

individually and together, are troubling in regard to the way they may potentially impact many applicants and their ability to claim an invention in its full scope, as well as the opportunity to fully develop claims of full and proper scope through prosecution with the Office.

In the first instance, the Office proposes to severely limit the number of claims it will accept in an application for initial examination by the Office, which will tend to limit the ability of an applicant to claim an invention in its full scope. In the second instance, the Office proposes severely limiting the opportunity for continued presentation of claims through continuation and continued examination practice, which also works to an applicant's disadvantage, particularly given the limited number of claims the Office will accept for initial examination in the first instance.

Together, as a practical matter, these proposals may well tend to require applicants to (1) reduce the scope of the claims pursued and (2) to accept more narrow claims as a result of the more limited opportunity for continued presentation of claims.³ In light of these concerns we respectfully submit the following comments and recommendations.

II. Comments On Proposed "Changes to Practice for the Examination of Claims in Patent Application" 71 Fed. Reg. 61 (Jan. 3, 2006)

A. Summary of the Proposed Changes for Examination of Claims, and Underlying Objectives of the Office

³ The Office argues that neither proposal is "absolute" in the sense that applicants are not "absolutely" precluded from presenting more than ten claims for examination, nor are they "absolutely" precluded from filing a second continuation application or a second request for continuing examination (RCE). However, in a practical sense we believe these "non-absolute" alternatives will be of little comfort to applicants.

Notwithstanding the significantly higher fees imposed on applicants under the recently enacted Fee Modernization Act, unless an applicant voluntarily limits the claims for initial examination, an applicant will now have to accept the even higher costs of doing the initial search and examination itself. In addition, applicants will also have the attendant risks of adversely affecting claim scope as a result of estoppel by argument, and the attendant risks of inequitable conduct that will surely arise out of having to conduct the search themselves and then prepare the examination support document as proposed.

Likewise, opportunities for continued examination come at the higher cost of pursuing continued claim presentation opportunities through the more costly and less certain administrative route of petition and appeal. After the first RCE or continuation, subsequent filings are only available by way of a petition showing "good cause," which will shift PTO resources away from the core function of examination to administrative procedures, thus increasing per application costs for both applicants and the Office, especially where appeals result when seeking review of a petition's denial.

The Office proposes to limit the number of claims examined in an application to not more than ten "representative" claims. The Office states that it will provide examination for all independent claims, up to ten total, or all independent claims and designated dependent claims, up to ten claims total. If the representative claims are found to be allowable, remaining dependent claims will be examined for compliance with statutory sections 101 (statutory subject matter) and 112, paragraphs one and two (enablement and indefiniteness).

The objective of the Office with the proposed rule for changing the examination of claims is to "allow the Office to do a better, more thorough and reliable examination since the number of claims receiving initial examination will be at a level which can be more effectively and efficiently evaluated by an examiner." 71 Fed. Reg. 61.

Where an applicant presents a number of claims for examination in excess of ten, the applicant will be required to submit an "examination support document" (ESD) for the claims prior to examination by the Office. The ESD will in effect require an applicant to conduct a search encompassing U.S. patents and patent publications, foreign patent documents, and non-patent literature, and to then provide (1) a detailed explanation of how the search was done (e.g., class and subclasses searched, databases searched and search logic), (2) an explanation of the claim limitations for all claims and why they are patentable over each cited reference, (3) a statement of the utility for each independent claim, and (4) an explanation of where the limitations of each claim are supported in the written specification and drawings, including any applications related by filing date.

Thus, the proposed rule has the further objective that if an applicant declines to designate fewer than ten representative claims for initial examination, that applicant will be required to "share . . . the burden so imposed Specifically, [such] an applicant . . . will be required to assist the Office with this more extensive examination by providing an examination support document covering all of the claims designated for initial examination." 71 Fed. Reg. at 62.

B. Specific Comments On the Proposed Rule and Its Objectives

As noted above, PPAC does not disagree that there are some applications which are so complex and which contain so many claims or claims of such complexity that they

absorb inordinate examining resources. However, that said, it is far from clear why *all* applicants should be limited in the number of claims presented for initial examination as proposed under the current rule. As acknowledged by the Office in the proposed rule, only 1.2% of all non-provisional applications currently include more than ten independent claims. Or, stated in other terms, approximately 90% of all non-provisional applications currently filed contain six or fewer independent claims and forty or fewer total claims. Initial examination of applications with six independent claims or less and not more than forty claims total does not seem to PPAC to impose an undue examination burden.

This is especially true in view of the recently enacted fee bill, which already imposes a surcharge on independent claims in excess of three and total claims in excess of twenty.⁴ These surcharges presumably were to reflect actual increased costs imposed on the Office by the presentation of such additional claims. There is no explanation in the Proposed Rule as to why the surcharges recently enacted are inadequate to provide the Office with the resources needed to handle such cases. In other words, it would seem that the Office is not being unduly burdened and, in fact, is being given the dollars needed through the recent fee increase to provide adequate resources for handling all but the so-called "problem" cases. Thus, PPAC questions whether the Office has presented sufficient justification under these circumstances for imposing such limitations on *all* applicants, as opposed to those few who truly burden the Office in an inordinate way (e.g., those applicants who present dozens or even hundreds of claims, or claims of such breadth that they encompass literally thousands of possible claimed combinations, as in the case of biotech claims with unduly broad Markush groups of gene sequences/proteins, or chemical applications with unduly broad Markush groups of chemicals).

As noted in the Proposed Rule, this is not the first time this proposal has been visited by the Office. It was previously considered and public input was sought

⁴ The surcharge imposed under the fee bill has apparently resulted in a net reduction (from fewer than 6600 in FY 04, or about 2.1%, to about half that number currently, or about 1.2% for FY 06 to date) in the number of cases having more than ten independent claims filed. Thus the surcharge appears to be having a significant impact in and of itself in terms of reducing the number of claims filed for initial examination. We are aware that some applicants, especially large filers, have voluntarily reduced initial claims presented to three independent claims and twenty claims total to avoid the surcharge.

beginning in late 1998,⁵ but was ultimately dropped by the Office.⁶ It was again revisited by the Office during its development of the *21st Century Strategic Plan*.⁷ These proposals were strongly criticized by those working with the Office on the Strategic Plan as unworkable, and ultimately were dropped from the Strategic Plan.⁸

PPAC believes that many PTO stakeholders who supported the fee increase see the Proposed Rule as unfair if for no other reason than what was thought to have been tacit agreement by the Office to withdraw these objectionable elements of the Strategic Plan in return for obtaining broad-based support for the increased fees under the PTO's Fee Modernization Act, is now being repudiated by the Office by effectively resurrecting these previously rejected parts of the Strategic Plan in the form of the currently Proposed Rule.

In those cases where the claims for initial examination are limited to ten claims, those remaining dependent claims in excess of ten will only be examined if the independent claims from which they depend are determined to be patentable, and then only as to sections 101 and 112, as noted. There will be no separate search of the prior

⁵ See Changes to Implement the Patent Business Goals, 63 FR 53497, 53506-08 (Oct. 5, 1998), 1215 Off. Gaz. Pat. Office 87, 95-97 (Oct. 27, 1998).

⁶ See Changes to Implement the Patent Business Goals, 64 FR 53771, 53774-75 (Oct. 4, 1999), 1228 Off. Gaz. Pat. Office 15, 17-18 (Nov. 2, 1999).

⁷ Among the concept papers distributed by the PTO for review and comment during its strategic planning process were papers entitled "Limitation on Number of Claims," and "Four Tracks Patent Examination Process." These included proposals for limiting claims examined in some of the tracks, and for requiring claim-by-claim analysis of prior art searched by the applicant under some tracks.

⁸ In Oct. 2002 AIPLA, IPO, INTA and BIO joined in a letter sent to the Director of OMB detailing the circumstances under which they could be expected to support the PTO's increased fees as proposed under the then contemplated Fee Modernization Act. That letter noted parts of the plan that would defeat the sought-for support, stating that "Among the proposals . . . with which we disagree are the following:

[The requirement] for patent applications already filed, of a search by applicants (or an applicant-sponsored search by a Certified Search Contractor) together with a "claim-by-claim" analysis of the information contained in such a search (referred to as a "mandatory Information Disclosure Statement").

ABA IPL Section joined in a separate letter to the same effect. Those parts of the Strategic Plan opposed by AIPLA, IPO, INTA and ABA IPL Section were later dropped, which then resulted in a further joint letter dated Nov. 22, 2002 to the Director of OMB, in which AIPLA, IPO and INTA stated: "We are pleased that we can now report, in light of proposed refinements to the Plan recently shared with us by Under Secretary Rogan, that we whole-heartedly endorse the Plan." ABA IPL Section submitted a separate letter to the same effect.

art for such non-designated dependent claims in order to examine them as to novelty and non-obviousness under sections 102 and 103 in the event the independent claims are rejected on art.

In an era when patent quality and pendency have become such major concerns, PPAC believes this is an unwise course. PPAC believes that not performing a search of the prior art and examining dependent claims which are not designated as representative' as to their novelty and non-obviousness will be detrimental to all parties, even the Examiner's efficiency. After a first Office Action, an applicant may decide to incorporate a limitation from a dependent claim into the rejected independent claim. Unless that dependent claim was designated as a representative claim, it will not have been searched as to the prior art as part of the initial Office Action. Thus, the examiner will then have to repeat his or her search. Given the current practice of making the second Office Action final, this coupled with the proposed limitations on continued examination practice, discussed further below, will delay and thus exacerbate the efficiency with which the ultimate issues as to patentability in an application are reached, and will curtail and possibly prevent an applicant's ability to even reach some such issues.

We believe it would be more efficient for the examiner to do a thorough search of the art and initially test all claims within reason (and certainly in cases not containing more than six independent claims and forty claims total) as to their novelty and non-obviousness over the art, rather than doing piecemeal searching.

There is also some question as to whether the statute permits the PTO to forego searching the prior art for claims for which search and examination fees have been paid. And in any event, at least for the vast majority of cases which do not fall within the so-called "problem" category, it seems fundamentally unfair to charge applicants the higher claim fees recently enacted, and then not search and *fully* examine (including as to patentability over the prior art) all claims for which those fees have been paid.

The Notice equates the proposed limitation to ten independent claims for initial examination with the practice before the Board during appeals. However, there are important differences in the Board's procedure that should be understood. During the appeal, there is no limitation on the number of representative claims. More importantly, at the point of the appeal, an applicant has a fully developed record based on a prior art

search and examination of all claims, with which to then make an informed decision regarding what claims are separately patentable from each other. At that point, *after* all of the claims have been searched and examined as to the prior art, an applicant knows what additional features may render a claim separately patentable over the prior art. Thus, an applicant clearly knows at that stage which claims truly matter in terms of novelty or non-obviousness over the art, for purposes of the issues on appeal, and which do not. This is very different from being forced to make a decision *before* examination is even begun.

Also, where there are applications that are commonly owned (or subject to an obligation to assign them to the same person or entity) all the claims in *all* such applications will be embraced by a single limit of ten claims unless it can be shown that the claims in the other applications are separate and distinct from one another (proposed 1.75(b)(4)).

This will of itself significantly increase the burden imposed by the ten claim limit, and will impose this limit on a much wider circle than just a single application, thereby further constricting the number of claims that will be initially examined even under the that limit.

PPAC is also deeply concerned with the Proposed Rule in terms of the examination support document (ESD) procedure as set forth. As noted above, for applicants who do not limit initial examination to ten representative claims, the required examination support document (ESD) procedure will in effect require an applicant to conduct a search that in some ways even exceeds that done by the examiner, requiring an applicant to search U.S. patents and patent publications, foreign patent documents, and non-patent literature, and to then provide (1) a detailed explanation of how the search was done (e.g., class and subclasses searched, databases searched and search logic), (2) an explanation of the claim limitations for all independent and designated dependent claims that are found in each cited reference, (3) a concise statement of the utility for each independent claim, and (4) an explanation of where the limitations of each claim are supported in the written specification and drawings, including any applications related by filing date.

This further requirement is said by the Office to have the objective that if an applicant declines to designate fewer than ten representative claims for initial examination, that applicant will be required to “share . . . the burden so imposed Specifically, [such] an applicant . . . will be required to assist the Office with this more extensive examination by providing an examination support document covering all of the claims designated for initial examination.” 71 Fed. Reg. at 62.

However, there is a subtle but significant point to note which makes the proposed ESD procedure far different from simply “sharing the burden” for examination of such claims. Specifically, this procedure is in effect a shift in the burden of proof which otherwise exists during examination. It is settled law that an Examiner has the burden in the first instance of making a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445-46 (Fed. Cir. 1992) (“the examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” (Emphasis added)). However, the ESD procedure requires an applicant in the first instance to prove *patentability*. Thus, contrary to established precedent, the practical effect is that the Office would be *presuming* unpatentability by requiring the applicant to make the case *for* patentability in its ESD. We believe this contravenes clear Federal Circuit precedent and goes beyond the rule making authority of the Office.

Under the proposed pre-examination search procedure which must be performed when submitting an ESD, an applicant must certify that U.S. patents and publications have been searched, that foreign patent documents have been searched, and that non-patent literature has been searched. None of these categories may be omitted from the pre-examination search unless “the applicant can justify with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source.” Proposed Rule 1.261(b). In other words, the applicant would be required to somehow prove the “non-existence” of more pertinent art, clearly an impossible burden. This goes well beyond even what most examiners do in our view. Currently, as PPAC understands the examination process, examiners do not continue looking for art once they find prior art that is sufficient to sustain a *prima facie* case of unpatentability.

The Proposed Rule goes beyond the search requirements for patent examiners in other ways. There is no rule of reason applied to foreign patent searching and non-patent literature searching. How many foreign countries' patents must be searched? What is the outer boundary for a non-patent literature search? Must the world's non-patent literature in every language be searched?

The Office notice notes that not even foreign search reports from other patent offices, such as the European Patent Office, long recognized by many applicants as being highly qualified and respected in the quality of its prior art searching, will suffice for the pre-examination search or ESD. This seems to PPAC to be strangely at odds with the objective of promoting greater reliance and use of work done by other competent patent offices, and avoiding duplicative effort.

The Office notice states that the ESD required under the Proposed Rule is similar in its requirements to the current requirements for cases under petition to make special. See Manual of Patent Examining Procedure (MPEP) § 708.02. We believe the ESD requirements go well beyond those for making an application special. There is no requirement when making an application special for an applicant to give a detailed explanation of the utility of each independent claim, nor where each limitation of each claim finds support in the written description of the application, including applications related by filing date. Nor is there any requirement as to providing a detailed certification of having searched U.S. and foreign patent documents and non-patent literature, including a detailed explanation of search protocol used.

Even assuming an applicant provides an acceptable ESD, the Proposed Rule gives no indication of how the ESD will be used by the Office. Will an Examiner simply adopt the results of the pre-examination search and the conclusions of patentability? If so, the implications are troubling. Examiners are trained over a period of years as to how to search claims, and must pass certain competency exams to attain primary examiner status. There would almost certainly be a wide variation in the quality and thoroughness of the searching performed by applicants, and in the quality of the analysis of those search results as set forth the ESD. This would further detract from the confidence of the public in the quality of granted patents. If an Examiner is not to simply accept the results

of the pre-examination search and the conclusions drawn in the ESD, will further searching be performed and if so, will that be required among U.S. and foreign patent documents and non-patent literature with a scope commensurate to that required under the rule for applicants? If so, it is difficult for PPAC to understand how the stated objective of the Office in "sharing the burden" is accomplished, since this would not seem to yield any real savings in time or cost for the Office.

Many of the provisions in the requirements for the ESD seem so onerous as to border on punitive. For example, the Proposed Rule indicates that an ESD must be submitted if the number of representative claims is greater than ten *as initially submitted* in an application. In view of the inability to file "voluntary" divisional applications,⁹ an applicant will want to submit all claims in a single application to determine whether the claims will be restricted. In arts such as the biotech and pharmaceutical arts, restrictions are often made that greatly reduce the number of claims in an application. Thus, rather than have the ESD filed upon initial filing, it should not be required until *after* the time for issuing a restriction requirement has passed. In PPAC's view it is unfair to require an applicant to prepare and file the ESD when the claims may be restricted by the Office such that fewer than ten representative claims are pending for examination. Instead, there should be a time period by which the Examiner must issue a restriction requirement or indicate that there will be none. The time period for submission of an ESD should then be set after that.

A non-extendible one-month time period also seems unnecessarily short for responding when an applicant is notified by the Office that an ESD has been omitted, especially in view of the required scope of the pre-examination search and the complexity of the analysis required as to the claims in the ESD. We see no reason why the time period should be not be set for at least two months, and extendible upon payment of extension fees as in the case currently provided for applicants when responding to an office action.

In short, the ESD is in essence a technique of having the applicant examine his or her own application, and will never happen in most cases since the complexity, cost and

⁹ Eliminating this right may itself violate the Paris Convention, *see, e.g.*, Article 4(G)(2).

attendant risks to the applicant in preparing an ESD will simply be prohibitive. The validity of patents that result from applications where Examination Support Documents are filed would be easily challenged in court on the basis of inequitable conduct.

This excessive burden should not be placed on applicants, and will ultimately be detrimental to patent quality, efficiency of examination, and will undermine public confidence in the patent system both here and abroad.

C. Alternative Approaches That Should Be Considered

Given that by far the majority of applications (i.e. on the order of 90%) contain less than forty claims total and less than six independent claims, PPAC believes the Office should consider strategies under present Rule 1.105 to address the so-called problem cases on a case by case basis instead of adopting the Proposed Rule, or perhaps scale the Proposed Rule back by requiring only those applicants who present more than six independent claims or more than forty claims total to either designate six independent claims and forty claims total, or else provide a pre-examination search of a nature and type commensurate with that prepared in PCT applications. This would seem to us to represent a much more balanced and reasonable approach, while still addressing those cases which are truly problematic.

Another alternative to consider would be to invite applicants to consider grouping claims in return for avoiding fees otherwise charged upon filing and examination, or in the case of pending applications, in return for a refund of any filing and examination fees paid for such grouped claims. In other words, an applicant could elect to group claims together for examination, where it is recognized by an applicant that limitations in dependent claims are not likely to render a claim separately patentable. Grouping these claims together prior to examination would save the examiner from having to take the time to search those features and make a separate case for unpatentability, yet an applicant would not be forced to arbitrarily limit the number of claims presented for initial examination, having instead the right to voluntarily do so in return for reduced filing and examination fees.

As another alternative, if the international unity of invention standard were applied, this could be used to search for the special technical feature determined under

that standard. An applicant would then be able to have all claims covered by that technical feature examined. Adoption and use of the international unity of invention standard would also tend to enhance harmonization efforts.

At the very least, given the dramatic nature of the proposed changes to practice for the examination of claims under the Proposed Rule and the highly controversial nature of those changes, PPAC believes that the Proposed Rule should be carefully tested by an appropriately designed pilot program, the results of which are reported to PPAC and the public prior to any wholesale adoption.

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

A. Summary of the Proposed Changes to Continuation and Request for Continued Examination Practice, and Comments On the Underlying Objectives of the Office

Concurrent with the limitations imposed on initial claims examined by the Office, the Office also proposes to revise the rules of practice by limiting applicants to a single opportunity to file, as a matter of right, a continuation application, a request for continued examination, or in some cases a continuation-in-part application, in the absence of a showing by the applicant as to why the claims presented, amendment, argument or other evidence presented could not have been previously submitted.

One objective underlying the Proposed Rule is a concern that multiple patents issuing from a series of continuation application filings "tends to defeat the public notice function of patent claims." 71 Fed. Reg. at 48.

We agree with the Office that continuation and continued examination practice is abused by some applicants who intentionally seek to maintain long periods of pendency in the hope of eventually surfacing with claims that are broad enough to cover large segments of industries and markets that have developed during the period of pendency. Seeking to curb such abusive practice is a laudable goal. However, on the other hand, there are also valid reasons why applicants resort to continuation and request for continued examination (RCE) practice. Often, it is difficult to fully develop the scope of

an invention in the limited time allotted to examiners for review of a single application, especially given the current practice of making the second office action final.

PPAC believes that while there is some abusive practice that occurs, that practice is limited to a very small number of cases, and most applicants file continuations for legitimate reasons, i.e., they are not seeking to intentionally delay prosecution in the hope of surfacing with a so-called "submarine patent" years later, but rather are seeking to make sure an invention is given its broadest reasonable scope.¹⁰

Further, recent changes to the patent statute enacted in the American Inventors Protection Act of 1999 (hereinafter the AIPA) have significantly helped, in PPAC's view, to curb the ability of those applicants seeking such submarine patents to do so. Specifically, with eighteen month publication and twenty year term limits from date of filing, the patent system is much less susceptible to the kind of incentives to seek submarine patents than it once was. Thus, as the Office seems to acknowledge, abusive continuation practice occurs today in only a relatively small number of cases overall. This of course suggests that the Proposed Rule should be more carefully tailored to address the relatively small number of cases where such abuses are actually present rather than adopting a rule that seems to penalize all applicants across the board.

Yet another objective of the Office in advancing the proposed rule changes to practice for continuing applications and requests for continued examination is to "assure that multiple continued examination filings from a single application do not absorb agency resources unless necessary for effective examination." 71 Fed. Reg. at 50. PPAC of course supports the goal of the Office to reduce pendency. We are aware that continuation applications and requests for continued examination currently account for

¹⁰ For example, in a communications system, it can be crucial to have separate claims directed to the sender, the receiver, and the switch that routes messages between them. Other instances of examples where continuation applications legitimately seek to obtain the full scope of an invention include cases where claims are drafted to deal with exhaustion, repair, replaceable or consumable parts, cases where claims are drafted to literally cover foreseeable equivalents, thereby simplifying complex "doctrine of equivalents" cases so that clear literal infringement claims can be asserted, or cases where claims are drafted to deal with claim construction rules for means-plus-function, product-by-process, functional apparatus, structural apparatus, method-of-making, and method-of-using claims. These are all instances where, by obtaining such claims through the mechanism of continuation practice, such claims actually enhance the public notice function and sharply reduce the costs of patent litigation by turning unclear cases into clear ones.

about 25% of the new applications filed each year. There is little question that this has some impact on the ability of the Office to take up other applications for examination. However, the overall impact on pendency of the Proposed Rules appears to be modest at best.¹¹

PPAC thus questions whether, even with a significant reduction in the number of continuing applications filed, this would have the hoped for impact in reduction of pendency. For example, as far as we are aware there has been no consideration as to any offsetting impact on these gains that would result from the likely diversion of core examiner time away from examination to administrative handling of what could very well be a large influx of petitions attempting to show "good cause" under the Proposed Rule.

PPAC believes that ultimately the goal of reducing pendency will be better achieved by a more thoughtful tailoring of the Proposed Rule to limit its impact to those cases where continuation and request for continued examination practice truly represent an unwarranted effort to prolong and delay issuance of claims, coupled with pursuing a policy of long-term, sustained effort to continue to build the core competency and retention of the examination corps through pursuit of improved hiring policies, improved training, and reduction of attrition for both new hires and long term employees by improving compensation, working conditions and morale. Over time we believe this will result in the required human resources to effectively work through the backlog and to keep pace with the new applications filed each year.

Thus, notwithstanding the laudable objects of the Proposed Rule, PPAC has serious concerns and reservations concerning whether the Proposed Rule is well designed to achieve those objects in the most effective, balanced and fair way. PPAC therefore recommends a more studied and cautious approach¹² before adoption of this kind of sweeping change.

¹¹ As we reported in last year's Annual Report, the PTO estimates a 2.5% gain in the efficiency of the examining corps as a result of this Proposed Rule, and a 5% gain as a result of *both* the rule changes proposed by the Office.

¹² Indeed, this is what is envisioned in H.R. 2795 (the Patent Reform Act of 2005) that is currently under consideration before the House Subcommittee on Courts, the Internet and Intellectual Property. While the Director is given a clear mandate in the bill to curb abusive practice (Sec. 123 provides that "The Director,

B. Specific Comments on the Proposed Rule

There are several aspects of the Proposed Rule which we see as troubling: (1) there is a serious question whether the PTO has exceeded its statutory and regulatory authority in some aspects of the Proposed Rule; (2) the Proposed Rule changes are very complex, will create much difficulty and misunderstanding in their implementation, and very possibly result in a loss of rights to inventors and increased exposure to claims of malpractice for practitioners; (3) the opportunity to obtain continued prosecution beyond the first continuing application would be left to the discretion of a PTO official who would determine whether "the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application," which would in PPAC's view not only be an unfair standard in many cases, but would also open the door to disparate treatment among PTO officials; (4) all divisional applications filed as a result of a restriction requirement would have to be filed before the patenting or abandonment of the original application since a divisional application could rely on only a single parent application; (5) the proposal shifts the burden to applicants to resolve double patenting situations because "the applicant (or the owner of the application) is in a far better position than the Office to determine whether there are one or more other applications or patents containing patentably indistinct claims," thus requiring an applicant to in effect undertake examination of certain patentability requirements of one's own application; and (6) the proposed implementation of these new rules would require any continuing application filed after the effective date of the new rules to comply with the new requirements - i.e., an applicant is basically able to file one continuing application in any series of pending applications and not "one more" continuing application after the effective date of the final rules, in the absence of "good cause."

in order to prevent abusive practices by patent applicants, shall by regulation limit the circumstances under which an application for patent, other than a divisional application . . . , may be entitled to the benefit under section 120 of the filing date of a prior-filed application."), the bill also clearly contemplates that a proper balance will be struck that does not deny applicants a legitimate right to fully claim an invention ("No such regulation may deny applicants an adequate opportunity to obtain claims for any invention disclosed in an application for patent." Sec. 123.). This of necessity suggests the need for developing a careful record and opportunity for stakeholders to work with the Office in seeking a consensus to achieve this balance, something that will admittedly be will take some time and added work to achieve.

As to exceeding its statutory and regulatory authority, unlike 35 U.S.C. § 132, which specifically delegates to the Director the authority to prescribe regulations to provide for continued examination of applications, and which thus arguably inherently includes the authority to limit the opportunity to make such requests, the provisions of §§ 120, 121, and 365(c) which govern the right to claim priority in continuation applications not only do *not* delegate such authority to the Director, but indicate that if the conditions of these statutory provisions are satisfied, the continuing application “*shall* have the same effect” or “*shall* be entitled” to the filing date of the prior or original application. This at least raises the issue of the authority of the Director to establish regulations that are arguably inconsistent with these statutory provisions.¹³ We believe it is not in the best interest of the public or the patent community for the PTO to adopt a questionable proposal that will most certainly create additional uncertainty and confusion for years to come.

The Proposed Rule (1.78(f)(1)) also requires that if a non-provisional application is filed on the same date as other non-provisional applications or patents, and contains “substantial overlapping disclosure” with those other applications or patents, a rebuttable presumption is created that the non-provisional application contains at least one claim that is not patentably distinct from the other applications or patents. Applicant must then either rebut the presumption to the satisfaction of the director or file a terminal disclaimer. And if a terminal disclaimer is filed, the applicant then must explain why it is necessary to have two applications with patentably indistinct claims. Thus, the rule requires an applicant to anticipate and resolve a possible double patenting rejection before such is even asserted by the Office.

Again, this contravenes clear precedent and the duty the Office has in the first instance to make a *prima facie* case of unpatentability, *In re Oetiker, supra*, before the burden shifts to applicant to rebut that *prima facie* case. Additionally, the PTO does “NOT ... have authority to issue substantive rules,” 35 U.S.C. § 2(b)(2)(A); *Merck &*

¹³ The PTO’s notice acknowledges that *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968) and *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977) at the very least suggest that the PTO has no authority to place an absolute limit on a number of co-pending continuing applications originating from an original application. 71 Fed. Reg. 50. Moreover, there is no requirement in the law that one must file a petition to gain the benefit of an earlier filing date under 35 U.S.C. §§ 120 or 365.

Co. v. Kessler, 80 F.3d 1543,1550 (Fed. Cir. 1996) (emphasis in the original) that result in non-examination of claims, and no authority to overrule the Federal Circuit's instructions on its burden to demonstrate unpatentability. We believe it is improper for the PTO to substitute a "presumption" for its duty to examine a claim before it can reject it.

Moreover, the Proposed Rule is fraught with ambiguity that will increase the difficulty of compliance for applicants, and possibly result in loss of rights. There is no guidance as to what may constitute "substantial overlapping disclosure." The Office also introduces new definitions of terms that have been used in patent practice for over fifty years. Under the PTO's new proposed definition scheme, it would appear that an application that disclosed and claimed only an invention or inventions that were disclosed and claimed in the prior-filed application would meet the definitions of both a continuation and a divisional application. Compare proposed § 1.78(a)(2) and proposed § 1.78(a)(3). Not only is this confusing, but it is arguably inconsistent with § 121 that indicates that the subject of a divisional application must be directed to the invention not prosecuted in the original application. It is not clear why these confusing changes are being proposed or how they fit into the fabric of the PTO proposal.

The Proposed Rule also carries with it the potential for widely disparate and unfair treatment in administration of the rule. To avoid the appearance of setting an absolute limit on the number of continuing applications, and on the opportunity for continued prosecution, the Proposed Rule introduces the possibility that further continued prosecution can be obtained upon petition containing a showing to the satisfaction of the Director that the amendment, argument, or evidence filed in the latest attempt at continued prosecution "could not have been submitted during the prosecution of a prior-filed application."

Although continued prosecution beyond one opportunity may be possible in the proposed rules, the standard (i.e., "could not have been submitted") appears to be exceptionally high, and uncertain at least because multiple PTO officials (e.g., some 4,000 patent examiners, 280 supervisory patent examiners, and/or 25 directors) will be called upon to make a decision on these petitions. In addition, applicants would likely not be advised as to whether continued prosecution would be available via an additional

continuing application or request for continued prosecution until prosecution had been completed in the parent application, or the parent application was either patented or abandoned. This will subject applicants to an unreasonable risk of loss of right in our view, simply as a consequence of the administrative process, which in turn will likely result in increased litigation and exposure to malpractice claims.

Further, the PTO proposes to implement its proposed rules in a way that would not give applicants an opportunity to adjust to the new practice in applications *already* filed. At the very least, the PTO should not adopt these proposed new rules except as they might relate to any new, first, and original non-provisional application filed on or after the effective date of the proposed rules. It would be manifestly unfair to applicants who have drafted their applications in reliance on present practice only to have the practice changed, to their detriment.

It is important to note that where an applicant has gone beyond the prescribed limits for continued prosecution and does not meet the high standard of "could not have been submitted" for any new amendment, argument, or evidence, the PTO will refuse to enter or will delete any specific reference to a prior-filed application. Proposed § 1.78(d)(3). Further in this proposed section, the entry or failure to delete a specific reference to a prior-filed application that is not permitted by paragraph (b)(1) of proposed § 1.78 does not constitute a waiver of the provisions of this paragraph. This apparently means that a failure to meet these standards could be used as a basis for attack on the patent when the PTO failed to take action available to it. This seems unnecessary and unwarranted. It penalizes a patentee for a procedural omission by the PTO.

C. Alternative Approaches That Should Be Considered

In light of the concerns expressed above, we believe the Office should consider more careful tailoring of the Proposed Rule to address the relatively small number of cases which are truly at the heart of the problems noted. For example, as to curbing abuses stemming from delayed and prolonged prosecution, we believe the principle of prosecution laches or estoppel could be judiciously employed in that small number of

cases to address that kind of problem.¹⁴ In the alternative, the Proposed Rule could be made to apply to applications which have a pendency, based on their earliest effective filing date, that exceeds a given number of years, for example eight. This would mean that even in critically backlogged art units where examination is not taken up until four to five years, applicants would be given no more than an additional three or four years in which to conclude prosecution or to present any additional claims to related inventions, which does not seem inordinate to us.

As for whether the Proposed Rule is truly a significant way of reducing the PTO's workload and thus reducing pendency, we believe it is worth repeating the observations made by us in last year's Annual Report to the President and Congress:

"With these rule changes, the USPTO anticipates an average efficiency gain from the examining corps of 5%.

...
In addressing the now-protracted problem of reducing pendency, we believe several things should be borne in mind.

First, the causes for the current backlog and increasing patent pendency are varied and complex The USPTO must address the challenges of rising workloads, the shift of applications from traditional arts to more complex technologies, changes in the timing of some of the milestones of the *Strategic Plan* which will delay the efficiency gains outlined in the *Plan*, and last but not least, finding ways to educate applicants and insure greater shared responsibility by them in helping the Office avoid undue expenditure of examining resources.

Second, it must be remembered that the current challenges presented in terms of growing backlog and pendency were not created overnight. They are in large part a result of over a decade's worth of unpredictable and often inadequate resources. Nor will they be solved overnight. It will take sustained, dedicated effort on the part of the Office and applicants, working together. Thus, most important of all is the critical need for continued Administrative and Congressional support for long-term funding stability. Only with stable, long-term funding will the USPTO be able to create a predictable environment for planning purposes. Congress must keep the current fee increases in place beyond 2006, and must insure that the USPTO's appropriation continues to comport with the policy set by the Administration of fully funding the USPTO with all user fees expected to be paid to it during each budget year. Adequate funding will be

¹⁴ See, e.g., *Symbol Tech. Inc. v. Lemelson Med., Ed. & Res. Found.*, 277 F.3d 1361 (Fed. Cir. 2002) (holding that there is a defense of prosecution laches), and *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002) (in which a divided panel (J. Newman, dissenting) applied *Symbol Tech.* in affirming a PTO rejection of an application on grounds of prosecution laches).

essential in the coming years in helping the USPTO accomplish its mission and the related strategic goals of quality, pendency and e-government.”

In conclusion, we urge the Office not implement the Proposed Rules in the absence of further study in the form of well-planned pilots, as well as additional assessment as to the underlying reasons for implementation and whether impacting all applicants is truly warranted in light of those reasons.

Respectfully,

A handwritten signature in dark ink, appearing to read "Rick D. Nydegger", is written over a rectangular area of the document that has been heavily textured with a stippled or grainy effect, possibly for redaction or security purposes.

Rick D. Nydegger
Chair

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Subject: RE: PPAC Comment on Notices of Proposed Rules

5/4/06

A01308