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From: Marcy_Rossell@hgsi.com [mailto:Marcy_Rossell@hgsi.com]
Sent: Tuesday, May 02, 2006 1:52 PM
To: AB93Comments
Subject: Comments on Proposed Rules

Attn: Robert W. Bahr
Deputy Commissioner for Patent Examination Policy

Dear Mr. Bahr,

Please find attached a PDF file with comments from Human Genome Sciences, Inc. (HGS) regarding the U.S. Patent Office proposal to change practice for continuing applications, requests for continued examination, and applications containing patentably indistinct claims as published at 71 Fed. Reg. 48 (January 3, 2006).

HGS is grateful for the opportunity to submit these comments.

Sincerely,

Kenley K. Hoover
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May 2, 2006

Via email to:
AB93Comments@uspto.gov

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

Attn: Robert W. Bahr
Deputy Commissioner for Patent Examination Policy

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

Dear Under Secretary Dudas:

Human Genome Sciences, Inc. (HGS) is grateful for the opportunity to provide comments on the U.S. Patent Office (USPTO) proposal directed to changes to practice for continuing applications, requests for continued examination, and applications containing patentably indistinct claims published at 71 Fed. Reg. 48 (January 3, 2006).

Please find enclosed herewith HGS' comments, suggestions, and alternative proposals with respect to the proposed rule changes (35 pages). HGS respectfully requests that the USPTO would fully consider the remarks submitted herein.

Sincererly,

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Associate General Counsel
Intellectual Property

Kenley K. Hoover, Ph.D., J.D.
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HGS

Human Genome Sciences, Inc.
May 2, 2006

Comments On Proposed *Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims* as published in Federal Register, Vol. 71, No. 1, pages 48-61, January 3, 2006.

Human Genome Sciences, Inc. (HGS) is grateful for the opportunity to provide comments on the U.S. Patent Office proposal *Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*. 71 Fed. Reg. 48 (January 3, 2006) (to be codified at 37 C.F.R. pt.1). HGS is an emerging biopharmaceutical company seeking to discover, develop, and manufacture protein and antibody drugs to treat significant unmet medical needs (such as systemic lupus erythematosus, hepatitis C infection, and advanced-stage cancers). HGS appreciates and endorses the goals of the U.S. Patent Office in seeking to reduce patent application pendency and to provide expeditious public notice of intellectual property rights. However, HGS strongly believes the present rule change proposal will provide neither of these benefits, but would instead have many adverse consequences for the U.S. Patent Office, for small- and large-entity inventors, and for the biotechnology industry and other sectors of the U.S. economy. Accordingly, HGS respectfully opposes implementation of the proposed rules. Some of the reasons for which HGS is opposed to implementation of the proposed rules to change practices for continuing applications, requests for continued examination, and applications containing patentably indistinct claims are discussed below. Additionally, HGS submits herein some suggested alternatives and other considerations. It is respectfully requested that the Office consider these suggestions and comments as part of its approach to achieving the improvements desired by both the Office and patent applicants.

I. THE PROPOSED RULES LIMITING CONTINUING APPLICATION FILINGS VIOLATE STATUTORY AND FEDERAL COMMON LAW

A) THE PROPOSED RULES LIMITING CONTINUING APPLICATION FILINGS VIOLATE STATUTORY LAW

The United States Patent and Trademark Office (hereinafter "USPTO" or "the Office") should not adopt the proposed rules limiting continuing applications because enacting such rules exceeds the scope of the Office's authority (as conferred by Congress) and the proposed rules are a *prima facie* violation of statutory law. Title 35 U.S.C. § 2(b)(2) grants the USPTO authority to establish regulations "not inconsistent with law".[1] However, the rules proposed in Federal Register, Vol. 71, No. 1, pages 48-61 (January 3, 2006) to limit continuing applications would be inconsistent with the law. Therefore, enacting these rules would be a breach of USPTO authority under 35 U.S.C. § 2(b)(2).

The Office has proposed revising the rules to "require that second or subsequent continued examination filings, whether a continuation application, a continuation-in-part application, or a request for continued examination, be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted." 71 Fed. Reg. at 48. Without such a showing (under the proposed rules), "The Office will refuse to enter, or will delete if present, any specific reference" to such second or subsequent continuing applications. 71 Fed. Reg. at 60 (proposed rule 1.78(d)(3)).

More particularly, proposed rule 1.78(d)(1) would limit continuation, continuation-in-part, and divisional applications to "only a single prior-filed application". 71 Fed. Reg. at 59 (proposed rule 1.78(d)(1)(i)-(ii)). Likewise, proposed rule 1.78(d)(1) would also limit continuations and continuations-in-part of divisional applications to "only a single divisional application" where "no request for continued examination" was previously filed in the parent divisional application. 71 Fed. Reg. at 59 (proposed rule

[1] **35 U.S.C. 2 Powers and duties.**
(b) SPECIFIC POWERS.— The Office— (2) may establish regulations, not inconsistent with law, which— (A) shall govern the conduct of proceedings in the Office; (B) shall be made in accordance with section 553 of title 5; (C) shall facilitate and expedite the processing of patent applications …

1.78(d)(1)(iii)). The only exception to these limitations would be to allow second and subsequent continuing applications "to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior filed application." 71 Fed. Reg. at 59 (proposed rule 1.78(d)(1)(iv)). Furthermore, to be granted the right to pursue a second or subsequent continuing application, applicants will be required to file "a petition accompanied by the fee set forth in § 1.17(f) and a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted during prosecution of the prior-filed application." 71 Fed. Reg. at 59 (proposed rule 1.78(d)(1)(iv)(emphasis added).

The rule changes proposed in § 1.78 to limit continuing applications are inconsistent with the law because Title 35 U.S.C. §§ 120, 121, and 365(c) provide that, so long as other conditions of patent application filing have been met, a patent application "shall have" or "shall be" entitled to benefit of the filing date of previously filed patent applications. For example, 35 U.S.C. § 120 states:

> An application for patent for an invention ...filed by an inventor or inventors named in the previously filed application ***shall have*** the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.[2, 3]

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[2] The full text of Title 35 U.S.C. 120 is as follows: "**35 U.S.C. 120 Benefit of earlier filing date in the United States.** An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section."

[3] For a thorough Federal Circuit analysis of the language and legislative history of 35 U.S.C. §120 *see* In re Henrikson, 399 F.2d 253 (C.C.P.A. 1968) (concluding that 35 U.S.C. §120 places no limitation on the number of copending continuing applications which may be filed).

Similarly, 35 U.S.C. § 121 and 365 (c) utilize "*shall be*" language in guaranteeing an applicants ability to obtain the benefit of earlier filed copending patent applications. [4,5]

The "shall have" and "shall be" language of the patent statutes mandate that granting benefit of the filing date of an earlier filed application is not optional. The statute does not say, "An application for patent for an invention...*may have* the same effect..." at the option or discretion of the U.S. Patent Office. Indeed, in In re Henriksen the U.S. Court of Customs and Patent Appeals (CCPA)[6] looked closely at the language of 35 U.S.C. § 120 and at the intent of Congress, based on the legislative history, in drafting this particular statute to determine the number of copending continuing applications that a patent applicant may file and still retain benefit of earlier filing dates. In re Henrikson, 399 F.2d 253 (C.C.P.A. 1968). In so doing, the Court concluded: "We agree with appellant's analysis to the effect that the statute provides no limit to the number of applications that may be copending." Henriksen at 261. Hence, the proposed rules to limit second and subsequent continuing applications would be a *prima facie* violation of 35 U.S.C. § 120 because under these rules the Office will "refuse to enter, or will delete if present" the benefit of priority claimed to prior applications (proposed rule 1.78 (d)(3)) in all second or subsequent continuing applications, including divisional and continuation-in-part applications (proposed rule 1.78 (d)(1)), *pursuant to the subjective discretion of the Patent Office Director*, even though all of the statutory requirements for filing continuing applications under 35 U.S.C. § 120, 121, or 365(c) have otherwise been met. Therefore, since the proposed rules are inconsistent with 35 U.S.C. § 120, 121, and 365(c), if these rules are enacted, the Office will also be violating 35 U.S.C. §2, limiting Office authority to establishing regulations "not inconsistent with law".

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[4] 35 U.S.C. 121 Divisional applications. If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it *shall be* entitled to the benefit of the filing date of the original application...

[5] 35 U.S.C. 365 (c) Right of priority; benefit of the filing date of a prior application. In accordance with the conditions and requirements of section 120 of this title, an international application designating the United States *shall be* entitled to the benefit of the filing date of a prior national application or a prior international application designating the United States, and a national application *shall be* entitled to the benefit of the filing date of a prior international application designating the United States...

[6] The United States Court of Customs and Patent Appeals (hereinafter the "CCPA") is the predecessor to the United States Court of Appeals for the Federal Circuit (hereinafter the "Federal Circuit").

B) THE PROPOSED RULES LIMITING CONTINUING APPLICATION FILINGS VIOLATE FEDERAL COMMON LAW

HGS respectfully submits that the proposed rules to limit continuing applications violate longstanding and well-established federal common law. In this respect, the Office has noted that it "is aware of case law which *suggests* that the Office has no authority to place an absolute limit on the number of copending continuing applications..." 71 Fed. Reg. at 50 (emphasis added). HGS respectfully disagrees with the above characterization, and submits that federal case law has done more than simply *suggest* lack of such authority. The CCPA has unmistakably articulated that it is the province of Congress to decide the appropriateness of limiting continuing patent applications. Consider the ruling of the CCPA in In re Henriksen:

> The sole issue presented by this appeal is the interpretation of 35 USC 120. Simply stated, the question is whether the language of section 120 limits an applicant to the benefit of the filing date of the second preceding application in a chain of copending applications. We reverse the decision of the Patent Office Board of Appeals, 154 USPQ 53 (Pat. Off. Bd. App. 1966). We hold here that under that section of the statute, in view of its long-standing interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the statute.

In re Henriksen, 399 F.2d 253, 253-254 (C.C.P.A. 1968). Continuing, the Court in In re Henriksen concluded:

> The action of the board is akin to a retroactive rule change which 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. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanctions such a result... 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 the 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.

Henriksen at 261-262. Likewise, the court in In re Hogan further affirmed "The 24 years [of continuing application] pendency herein may be decried, but a limit upon continuing applications is a matter of policy for the Congress, not for us. *See In re* Henriksen, 55 CCPA 1384, 1395, 399 F.2d 253, 262, 158 USPQ 224, 231 (1968)." In re Hogan, 559 F.2d 595, 604 (n13), 595-611 (CCPA, July 28, 1977).

Accordingly, the PTO's proposed rule changes to allow multiple continuing applications only at the discretion of the Office, appears to be an attempt by the Office to circumvent established federal common law. In this respect, the Office has noted that although it is aware of case law which "suggests" the Office:

> has no authority to place an *absolute* limit on the number of copending continuing applications... The Office does not attempt that here. No limit is placed on the number of continuing applications. Rather applicants are required to show that later filed applications in a multiple-continuing chain are necessary to claim the invention and do not contain unnecessarily delayed evidence, arguments, or amendments that could have been presented earlier.

71 Fed. Reg. at 50.

Despite the offer of such assurances, it cannot be overlooked that the proposed rule changes seek to circumvent federal common law by allowing second and subsequent continuing applications only at the *subjective* discretion of the Office because the rules as proposed, and the Office commentary presented therewith, provide no indication, clarification, or examples of the standard required to make a sufficient showing to obtain a granted petition for second and subsequent continuing applications. As such, the proposed rules will allow additional continuation applications only if applicants provide some unknown, subjectively satisfactory showing that the application is "necessary to claim the invention" and does not contain "unnecessarily delayed evidence, arguments, or amendments that could have been presented earlier". 71 Fed. Reg. at 50. Consequently,

the proposed rules would create arbitrary and inconsistent boundaries on continuing application filings.

The Office has also indicated that the proposed rules are not an attempt to prevent situations of prosecution laches (where an applicant extends application pendency by filing multiple continuing applications without making substantive attempts to advance prosecution). In this regard, the Office noted:

> The proposed rules are not an attempt to codify Bogese II or to simply combat such extreme cases of prosecution laches. Nor do these rules set a *per se* limit on the number of continuing applications... Rather, they require that applicants who file multiple continuing applications for the same initial application show that the third and following applications in the chain are necessary to advance prosecution. In particular, the proposed rules require that any second or subsequent continuing application show to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted during the prosecution of the initial application or the first continuing application.

71 Fed. Reg. at 50 (emphasis added). HGS respectfully submits that if the proposed rules are not an attempt to codify Bogese, and are not an attempt to combat prosecution laches, the only significant effect of the new rules will be to penalize good-faith patent applicants. Hence, the dissenting opinion of Circuit Judge Newman in Bogese applies equally well to the Office's currently proposed rules:

> Such persistent, expensive, and burdensome refilings as indulged in by Bogese are surely rare, and will be more so now that patent life runs from the first filing date, no matter how many times the case is refiled. The solution to such a rare situation is not to add a new ground of examiner discretion, fraught with uncertainty and potential abuse. This new power will simply increase the burden on all applicants, in order to punish a rare transgressor.

In Re Bogese, 303 F.3d 1362, 1372 (Fed. Cir. 2002). Therefore, unless the standard required for showing that subsequent continuation applications are "necessary to advance prosecution" has a rather low threshold, the proposed rules will produce a *de facto* codification of Bogese. Additionally, the fact that the Patent Office has not proposed placing an "absolute" bar limiting continuing applications, does not negate the fact that

the proposed rules would inevitably impose subjective, arbitrary, and inconsistent limits on the number of continuing applications allowed.

In view of the above, HGS respectfully submits that the rules proposed to limit continuing applications by denying priority to previously filed applications contravene well-established precedent in federal common law and the legislative intent of federal statutory law. HGS urges the USPTO not to implement these proposed rules.

II. THE PROPOSED RULES TO LIMIT CONTINUING APPLICATIONS WILL NOT ACHIEVE THE DESIRED OBJECTIVES

A. THE PROPOSED RULES TO LIMIT CONTINUING APPLICATIONS WILL NOT ACHIEVE THE OBJECTIVE OF REDUCING PATENT PENDENCY

The Office has alleged that limiting continuing applications will significantly reduce the backlog of pending patent applications. For example, the Office has stated:

> The changes proposed in this notice will also allow the Office to focus its patent examining resources on new applications instead of multiple continued examination filings that contain amendments or evidence that could have been submitted earlier, and thus allow the Office to reduce the backlog of unexamined applications. This will mean faster and more effective examination for the vast majority of applicants without any additional work on the applicant's part.

71 Fed. Reg. at 49 (emphasis added).

> The current volume of continued examination filings-including both continuing applications and requests for continued examination-and duplicative applications that contain "conflicting" or patentably indistinct claims, are having a crippling effect on the Office's ability to examine "new" (*i.e.*, non-continuing) applications... Unrestricted continued examination filings and multiple applications containing patentably indistinct claims, however, are now having such an impact on the Office's ability to examine new applications that it is now appropriate for the Office

> to clarify the applicants duty to advance the application to final action by placing some restrictions on the filing of multiple continuing applications, requests for continued examination [RCE's] and other multiple applications to the same invention.

71 Fed. Reg. at 49 (emphasis added). In reality, however, for the reasons provided below, the burden on the Office will not be reduced (and may in fact be increased) by the proposed rules to limit continuation application filings.

1) DATA PRESENTED BY THE U.S.P.T.O. SHOW THAT THE PROPOSED RULES WILL NOT SIGNIFICANTLY REDUCE THE PATENT APPLICATION BACKLOG.

In contrast to the assertions made by the Office, *supra*, the Office's own data and comments show that the proposed rules limiting continuing applications cannot produce a significant reduction in the patent application backlog. For example, the Office has noted:

> Of the roughly 63,000 continuing applications filed in fiscal year 2005, about 44,500 were designated as continuation/continuation-in-part (CIP) applications, and about 18,500 were designated as divisional applications. About 11,800 of the continuation/CIP applications were second or subsequent continuation/CIP applications. Of the over 52,000 requests for continued examination [RCE] filed in fiscal year 2005, just under 10,000 were second or subsequent requests for continued examination. Thus, the Office's proposed requirements for seeking second and subsequent continuations <u>will not have an effect on the vast majority of patent applications</u>.

71 Fed. Reg. at 50 (emphasis added).

Hence, in fiscal year 2005, less than 20% of <u>*all*</u> *continuation applications* filed were second, third, or higher order continuations ((11,800/63,000)x100 = 18.7%). Therefore, under the proposed rules over 80% of all continuation applications filed in 2005 would still be allowed as a matter of right (*i.e.*, without petition). 71 Fed. Reg. at 48. Furthermore, in fiscal year 2005, the number of second or subsequent continuation/CIP

application filings represented **only 3.7%** of all new application filings ((11,800 second or subsequent continuation applications/317,000[7] non-provisional applications)x100 = 3.7%). Accordingly, if no second or subsequent continuing applications were allowed in 2005, this would have reduced the new application filing backlog by only 3.7%! Moreover, under the proposed rules, once petitions to file second or subsequent continuation applications were considered and granted, the sought after reduction in patent application backlog would have been even less than 3.7%.

Similarly, in fiscal year 2005 less than 20% of *all requests for continued examination* (RCE) were second or subsequent RCE's ((10,000/52,000)x100 = 19.2%). Thus, under the proposed rules over 80% of all RCE's filed in 2005 would still be allowed as a matter of right (*i.e.*, without petition). 71 Fed. Reg. at 48. Likewise, it is noteworthy that second or subsequent RCE filings in fiscal year 2005 represented **only 3.2%** of all new application filings ((10,000 second or subsequent RCE/317,000 non-provisional applications)x100 = 3.2%)! Accordingly, if no second or subsequent RCE's were allowed in 2005, this would have reduced the new application filing backlog by only 3.2%. However, once petitions for subsequent RCE's were considered and granted, the reduction in RCE filings would have been even less. Finally, even if the Office allowed no second or subsequent continuations or RCE's in 2005, the new application filing rate would have been reduced by only 6.9% (3.7% continuations + 3.2% RCE's = 6.9%). Therefore, these figures clearly show that the Office's application examination backlog is not due to the number or rate of second or subsequent continuing or RCE patent application filings. Instead, in fiscal year 2005, new applications (minus second or subsequent continuations and RCE's) represented approximately 93% of new filings with the Office. Furthermore, the Office has also acknowledged in meetings with interested parties that limiting continuing application filings will have little impact on the patent application backlog. For example, at the March 7, 2006 Biotechnology/Chemical/Pharmaceutical Customer Partnership Meeting the Commissioner for Patents (John Doll) agreed in response to questioning that limiting

[7] "The Office's Patent Application Locating and Monitoring (PALM) records show that, in fiscal year 2005, the Office received approximately 317,000 non-provisional applications..." 71 Fed. Reg. 48, 50 (Jan. 3, 2006).

second and subsequent continuing applications would not have a significant effect in reducing the patent application backlog. Therefore, the proposed rules to limit continuing application filings will provide little, if any, benefit to the Office or public, while creating significant actual and potential economic injury to patent applicants (discussed further below).

2) CONTINUATION APPLICATIONS IMPOSE A SUBSTANTIALLY REDUCED EXAMINATION BURDEN COMPARED TO NEW APPLICATIONS.

The proposed rules limiting continuation applications will not significantly reduce the examination backlog because continuation applications are much less time consuming for examiners to review than are new applications.[8] Consider that when the same examiner reviews a continuation application, he or she has previously reviewed the same specification, considered the merits of the application, and written an office action in consideration of the application and corresponding prior art. Furthermore, claims in a continuing application are usually related (even though patentably distinct) or involve overlapping (or the same) prior art issues compared to the parent application. This is especially true in biotechnology patent applications where the claims in the initial and subsequently filed continuing applications are often drawn, in sequence, to a particular gene, the protein encoded by the gene, antibodies that bind the protein, and methods of using the gene, protein, and antibodies. Hence, an examiner is far better situated to more quickly and efficiently prepare a first office action in a continuing application than in an entirely new application. Accordingly, removing continuing applications from examiner dockets will actually cause average per application examination time to *increase* instead of decrease because more applications on the examiner's docket will require *de novo* examination.

[8] *See e.g.*, Comments submitted by Bob Vanderhyde, page 2, penultimate paragraph (Mar. 8, 2006); http://www.uspto.gov/web/offices/pac/dapp/opla/comments/FPP_continuation/vanderhye.pdf. HGS also notes that the Office has not shown data to the contrary (*e.g.*, via survey of patent examiners).

3) LIMITING CONTINUATION APPLICATIONS WILL NOT SIGNIFICANTLY REDUCE THE PATENT APPLICATION BACKLOG BECAUSE ART UNITS WITH HIGHEST INVENTORY AND LONGEST FIRST ACTION PENDENCY DO NOT COINCIDE WITH ART UNITS HAVING THE HIGHEST NUMBER OF CONTINUING APPLICATIONS.

The Office has released data showing that compared to other art units, Art Unit 1600 (Biotechnology and Organic Chemistry) has one of the highest continuing application filing rates. For example, in fiscal year 2005, 42.4% of the new applications filed in 1600 were continuing applications (excluding divisionals).[9] By the Office comparison, however, only 24.1-28.5% of new applications filed in Art Units 1700, 2100, 2600, 2800, 3600, and 3700 were continuations (excluding divisionals).[10] In spite of this higher continuation application filing rate, however, Art Unit 1600 has shorter application pendency time than art units with substantially lower continuing application filing rates! For example, Art Unit 1640 has an average first action pendency time of 27.7 months, compared to Art Units 1743, 3731, 2123, 2617, and 3628 with average first action pendency times of 30.8, 30.9, 39.7, 50.4, and 52.1 months.[11] Similarly, as of September 30, 2005, Art Unit 1600 had one of the lowest pending application inventories, compared to other art units with substantially lower continuing application filing rates. For example, as September 30, 2005, Art Unit 1600 had 62,644 new applications pending while all other art units indicated (*i.e.*, Art Units 1700, 2100, 2600, 2800, 3600, and 3700) had between 70,354 and 115,585 new applications pending.[12] Likewise, on this same date, Art Unit 1600 had 107,647 *total* applications pending, whereas all other art units indicated (*i.e.*, Art Units 1700, 2100, 2600, 2800, 3600, and 3700) had between 117,045 and 167,721 *total* applications pending.[13] Accordingly, the Office's own data shows that there is actually an inverse correlation between continuing application filing rates and the patent examination backlog among art units. As such, the data actually

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[9] *See e.g.*, U.S.P.T.O. slide presentation at Chicago Town Hall Meeting on Proposed Rule Changes to Improve Patent Examination (Feb. 1, 2006); slide available on the U.S.P.T.O. internet website *at*: http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides.ppt#18

[10] *Id.*

[11] *Id. at*: http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides.ppt#12

[12] *Id. at*: http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides.ppt#14

[13] *Id.*

indicate that limiting continuing applications is more likely to increase the patent examination backlog, instead of reducing it.

4) LIMITING CONTINUATION APPLICATIONS IS MORE LIKELY TO INCREASE, RATHER THAN DECREASE, THE PTO BURDEN.

Under the proposed rules, to have second or subsequent continuing applications examined, applicants will be required to submit a petition explaining why an amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application. 71 Fed. Reg. at 48 (proposed rule 1.78(d)(1)(iv). These petitions in and of themselves will create an extra burden for the Office because such petitions will need to be reviewed, considered, and answered. Additionally, if the proposed rules are implemented the Office should expect increased demand from applicants for higher and more thorough levels of office action review at every step in prosecution. Patent applicants will insist upon more thorough application review, consideration of arguments and explanations of rejections and objections at each of stage of examination. The Office should also expect Applicants to call with increasing frequency for higher levels of review (*e.g.*, by supervisory examiners) in response to adverse office actions at each stage of examination. This will include increased requests for interviews with the examiners and their supervisors. Moreover, by limiting applicants ability to file continuing applications, applicants will have no alternative except to appeal rejected patent applications with increasing frequency. In sum, the overall effect of the proposed rules is more likely to increase, rather than decrease, the burden on the Office by substituting a patent applicants right to second and subsequent continuations with increased numbers of petitions, demands for higher level review, and appeals.

5) THE PROPOSED RULE CHANGES WILL HAVE AN ADVERSE IMPACT ON THE U.S. PATENT SYSTEM AND WILL CREATE MORE PROBLEMS THAN ARE SOLVED

The proposed rule changes limiting continuing applications will create more problems than they solve. As discussed above, the rules proposed for limiting continuation applications will have a negligible, if not an overtly adverse, effect on

reducing the backlog of pending applications. Additionally, the ripple effect of the proposed rule changes will create many additional problems which will need to be addressed, managed, and accommodated.

For example, the proposed rules do not adequately suggest or define the standard which will be applied in determining whether or not to grant a petition to file a second or subsequent continuation application. The standard offered in the proposed new rules, namely "a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application", appears vague, subjective, and arbitrary. As such, this standard may create a *de facto*, arbitrary limit of one continuation application for each new application filed, despite the Office's recognition that such action has been prohibited by federal court. *See,* In re Hogan, 559 F.2d 595, 603 (C.C.P.A. 1977) *and* In re Henrikson, 399 F.2d 253, 262 (C.C.P.A. 1968); *see also,* 71 Fed. Reg. at 50.

Considering the language of the proposed rules more closely, it is noted that the Office has not provided any guidance or examples indicating the boundaries of "could not have been previously submitted." 71 Fed. Reg. at 48. As a practical example, consider that it is not uncommon for Examiners to make a final rejection citing new grounds of rejection, but alleging justification for the new grounds by asserting "new grounds of rejection were necessitated by applicant's amendment." In such a situation, will applicants be given an opportunity to provide justification for the amendment in view of the new grounds of rejection? Will new, late-stage rejections provide an acceptable basis for Applicants to petition that the new "amendment, argument, or evidence presented could not have been previously submitted"? Alternatively, consider situations where the Examiner makes a final rejection over a reference previously cited, but now bases the rejection on a different rationale. Will this change in the Examiner's position provide an acceptable basis for Applicants to be granted a petition on grounds that the new "amendment, argument, or evidence presented could not have been previously submitted"?

Another adverse impact of the proposed rule is the likelihood of creating a decrease in public disclosure of new inventions because companies will be more

motivated to keep new technology as trade secrets (which would defeat both the public notice motivation of the Office and the advancement of technology through public disclosure). An increase in trade secret technology could result from the proposed rule changes because some technologies change or develop so rapidly and incessantly that the only means of obtaining meaningful patent protection is via the benefit conferred through continuing applications, where earlier filed applications do not become prior art against later filed improvements of the invention (*i.e.*, continuation-in-part applications). Without the ability to obtain adequate patent protection in such technologies, the motivation to maintain trade secrets will be heightened.

Yet another example of an adverse impact of the proposed rules is that limiting continuing applications unfairly penalizes applicants who must copy claims to protect their invention through declaration of an interference. As such, to obtain an interference under 35 U.S.C. § 135, an applicant must file an application which claims the same, or substantially the same, subject matter of an issued patent or published patent application. Hence, for an applicant (who was actually the first to invent) to be certain of obtaining a declared interference against an applicant or patentee (who was later to invent) the first applicant must file a new continuing application with claims copied directly from the later patent or published application. Hence, in conjunction with the proposed rules, this implicit requirement of 35 U.S.C. §135 would require the *bona fide* first inventor to use their only matter of right continuation application to copy claims of a third party, *or perhaps* even be barred from obtaining an interference if they can no longer file a continuing application. In contrast, and unless otherwise addressed, the proposed rules limiting continuing applications could also be used as a defense mechanism by third parties to force another party to file their only available (if that) continuation application by means of the third party filing an application with substantially similar, or identical, claims. Perhaps the Office intends to address issues such as these, for example, by establishing a policy that obtaining a declaration of an interference will be considered *prima facie* a sufficient showing for granting a petition to file a continuation, but the rules as proposed provide no indication of such intent.

Finally, the Office should also consider the innumerable problems and rift in the U.S. Patent system that will occur should the new rules be implemented and later overturned, in whole or in-part, by a federal court or congressional legislation. Should this happen, the Office will either have to re-implement the "old rules" or re-develop new, acceptable rules. This will create substantial uncertainty and confusion both in the Patent Office and with the public at large. Furthermore, the depth and degree to which patent rights are irretrievably lost during the interim of the proposed rules implementation and overturn of the rules will be immeasurable and economically catastrophic for some inventors.

B) THE PROPOSED RULES TO LIMIT CONTINUING APPLICATION FILINGS WILL NOT ACHIEVE THE OBJECTIVE OF EXPEDITING PUBLIC NOTICE OF ISSUED CLAIMS

The Office has indicated another rationale for limiting 2nd and subsequent continuing application filings is to provide expeditious public notice regarding the grant (or not) of intellectual property rights. For example, the Office stated, "...the possible issuance of multiple patents arising from such a process tends to defeat the public notice function of claims in the initial application." 71 Fed. Reg. at 48. Similarly, the Office asserted, "...when the continued examination process fails to reach a final resolution, and when multiple applications containing claims to patentably indistinct inventions are filed, the public is left uncertain as to what the set of patents resulting from the initial application will cover." 71 Fed. Reg. at 49. Although providing expedited public notice of patent rights is a laudable goal, the proposed rules will not promote more efficient public notice of intellectual property rights than the current rules. Moreover, the Office's interest in expediting public notice of patent rights should not be realized by denying applicants the opportunity to fully prosecute the intellectual property rights to which they are statutorily entitled.

As an initial matter, it is respectfully submitted that the public notice function is currently adequately fulfilled by the Office. Since the advent of the 18-month publication requirements the public is notified of all applications filed in the U.S. and abroad after 18 months from the earliest claimed filing date. It is also noted that Congressional

Representatives Mr. Howard Berman and Mr. Rick Boucher recently introduced a bill in the House of Representatives to change the current statute so that ***all*** U.S. patent applications (with some limited exceptions) are published within 18 months of the earliest claimed filing date. Hence, this legislation will further expedite public notice by disclosing applications which would have previously gone unpublished when filed in the United States (only) with a non-publication request. H.R. 5096 (April 2006) (*titled* "Patents Depend on Quality Act of 2006" or "PDQ Act"). Furthermore, the Office is also fulfilling the public notice function by providing the public with the ability to check the current status of all published pending or issued patent applications, including "child" applications filed thereon, via the Office's public internet PAIR system.[14]

Furthermore, limiting continuing applications will not expedite public notice of issued claims because this limitation will inevitably lead to increased numbers of appeals filed and waiting upon review. Under the current system when an applicant receives an allowance of some (but not all) claims, the applicant can accept the allowance and file a continuation application in attempt to convince the examiner regarding his/her entitlement to the remaining claims. Under the proposed rules, however, an applicant who has not received an allowance of all claims to which he/she is entitled will have fewer alternatives except to appeal the Examiner's rejection. Thus, the delay imposed by the appeals procedure will nullify the desired effect that the proposed rules would expedite public notice. As such, the proposed rules to limit continuation applications will not provide improved or expedited public notice over the current system where interested third parties can publicly, and conveniently, monitor the current status of all published pending and issued applications throughout their potential, statutorily limited 20 year term.

[14] *See*, http://portal.uspto.gov/external/portal/pair

III. LIMITING CONTINUING APPLICATIONS PLACES AN UNDUE BURDEN ON APPLICANTS

The Office has proposed an important rationale for implementing the new rules is to induce patent applicants to expedite patent prosecution. This rationale, however, places an undue burden on patent applicants, without placing any corresponding accountability on the Office to properly advance patent examination. For example, consider that the Office has asserted:

> Unrestricted continued examination filings and multiple applications containing patentably indistinct claims, however, are now having such an impact on the Office's ability to examine new applications that it is now appropriate for the Office to clarify the *applicants duty to advance the application* to final action by placing some restrictions on the filing of multiple continuing applications, requests for continued examination [RCE's] and other multiple applications to the same invention."

71 Fed. Reg. at 49 (emphasis added). This emphasis, however, discounts the reality that it is often necessary to file continuing applications because of inadequate or incomplete first and second round examination. As such, the proposed rules place all of the onus on applicants to "advance the application" without acknowledgment of the need, or provision for, improved examination quality in the Patent Office. Therefore, the proposed rule changes will burden patent applicants with fewer, more precious opportunities to convince patent examiners of the merits of an invention, without placing any additional onus on the examiners or the Office to insure high quality initial examination and consideration of applicant's arguments. In order to properly advance prosecution, with fewer continuing applications, will also require proper and adequate initial rounds of examination in the Patent Office. Improvements in this area could be obtained via increased supervisory review, improved examiner training, by increasing the time allocated for examiners to perform application review, and by improving the credit system under which examiners perform their duties. Additionally, it is also important to improve after-final examination procedures particularly by providing after-final action disposal credits so that examiners are motivated to consider the merits of an applicant's after-final arguments and amendments. Without changes such as these, if the new rules

are implemented, the inevitable result of adverse office actions will be to force applicants, and the Office, into the lengthy, expensive, and burdensome appeals route.

IV. CONTINUING APPLICATION FILINGS ARE ALREADY LIMITED.

The Office has stated, "...current practice allows an applicant to generate an unlimited string of continued examination filings from an initial application." 71 Fed. Reg. at 48 (emphasis added). This assertion is incorrect. Applicants cannot file an unlimited string of continuing applications because under 36 U.S.C. § 154(a)(2) utility patents are limited to a term "beginning on the date on which the patent issues and ending 20 years [or sooner][15] from the date on which the application for the patent was filed in the United States...". Hence, U.S.C. § 154 already places a statutory time limit on an applicants ability to file continuing applications. Additionally, filing fees, examination fees, and other prosecution costs also place significant financial constraints on applicant's ability to file continuing applications. Furthermore, the courts have also recognized that there is an equitable limit on the ability of applicants to file continuing applications without endeavoring to substantively advance prosecution. *See,* In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002). Accordingly, HGS respectfully submits that the Patent Office should not endeavor to limit continuing applications any further than the term to which they are already limited by Congressionally approved statute.

V. CONTINUING APPLICATIONS ARE OFTEN A PRACTICAL BUSINESS SOLUTION TO THE PATENT EXAMINATION PROCESS

Continuing applications are often a practical business solution to expediting patent allowances while maintaining appropriate entitlement to intellectual property protection. Patent applicants often desire to have a patent issue on their invention as soon as possible to provide at least some modicum of initial protection for an invention, to notify the public of rights in an invention, and to provide a basis for third party venture

[15] "...if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed."

capital investment. To obtain this result it is often necessary to compromise with the examiner on an initial set of claims so as to expedite patent allowance, then to file a continuing application or applications to obtain additional time with which to convince the examiner of the applications merit in the allowance of broader claims.

Additionally, in the biotechnology industry, continuing applications have been the only means of maintaining intellectual property rights while the Patent Office develops policies that equitably address the issues and merits of patent applications in this rapidly changing technology sector. Consider that over the past ten years or so the Office has had to study, develop, and revise policies with respect to utility, enablement, and written description requirements in allowing DNA, protein, and antibody claims in patent applications. For example, in 1999 to 2000 the Office worked to develop "Utility Examination Guidelines" with respect to gene related inventions so that the Office could establish consistent examination policies for examiners to apply in allowing (or not) claims in biotechnology applications. In developing these guidelines, the Office sought, and obtained, public comments. Thereafter, the Office ultimately issued a revised, final set of utility examination guidelines for gene related inventions. *See,* 66 Fed. Reg. 1092 (Jan. 5, 2001) *and history cited therein.* Hence, without the benefit of continuing applications to maintain pendency while the Patent Office developed policy, the entire biotechnology industry would have suffered incalculable losses of intellectual property rights. The loss of such rights would have had a devastating effect on the industry's ability to attract venture capital, which in turn, provides the only means by which the industry can fund research and development of therapeutics to treat diseases and improve human health.

VI. NUMEROUS DIVISIONAL APPLICATIONS ARE OFTEN NECESSARY BECAUSE OF THE OFFICE CURRENT RESTRICTION REQUIREMENT PRACTICES, PARTICULARLY IN THE REALM OF BIOTECHNOLOGY

The Office has, by its own restriction requirement practices, created the need to file increasing numbers of divisional applications, particularly in the biotechnology industry. Biotechnology patent applicants are often faced with restriction requirements

wherein the claims are grouped into 10, 20, 30 and even hundreds of different groups. In view of such restrictions applicants have no choice except to file multiple divisional applications; each of which represents a new application which the Office must consider and act upon. Accordingly, if the Office truly wishes to reduce the number of first action "rework" applications, it needs to completely reform the current restriction requirement policies and practices. Moreover, an essential part of such reform must include creating a fair and equitable system for awarding examiner disposal credits in order to reduce the number of claim groups created by an examiner in each restriction requirement.[16] The Office should genuinely consider adopting a unity of invention standard of restriction practice as is currently practiced internationally such as in Canada, Europe, and Japan.

VII. CONTINUING APPLICATIONS ARE OFTEN NECESSARY FOR OBTAINING ADEQUATE INITIAL AND FINAL PROTECTION OF INVENTIONS, PARTICULARLY IN THE BIOTECHNOLOGY INDUSTRY

As mentioned above, applicants often seek expeditious allowance of an initial set of claims in a patent to establish a basis for third party venture capital investment. The proposed rules, however, are likely to have a significantly adverse impact on biotechnology inventor's ability to obtain necessary venture capital with which to pursue development and production of their invention. Under the proposed rules, an applicant could no longer accept an initial set of claims that encompass less than the full measure of an invention's embodiments, and be free to pursue continuing applications (or voluntary divisional applications) for additional embodiments. Instead, applicants will be forced to appeal for all claims which he/she believes himself/herself to be entitled to, potentially without any patent issuing, while the application is delayed by the appeals process. Hence, during such periods, applicants would be unlikely to attract initial venture capital investment which may be necessary for the invention to move forward towards public availability.

[16] For example, by providing examiners with credits based on the number of claims examined, not based on the number of applications examined.

Continuing applications are also necessary because the final commercial embodiment of an invention may not be decided upon until many years after the initial application is filed; even though the initial application otherwise meets all patentability requirements for the subsequently claimed embodiment. In fact, it may be impossible or, at least, highly impractical for an applicant to immediately identify the final commercial embodiment of an invention. This is especially true in technology sectors such as biotechnology, where it often requires many years to select the final desired commercial embodiment as a result of research and development in manufacturing and clinical testing.

The biotechnology sector relies on the ability to file continuing applications because of the inherent and unique characteristics of the subject matter in this field. Biotechnology inventions often require many years from initial application filing before it is possible to select the final, commercially relevant embodiment of the invention. For example, consider the following: When a new protein is discovered and determined to activate immune cells, a patent application may be filed wherein the protein is described and disclosed in a wide variety of embodiments. For example, the protein may exist in its full-length form or in a variety of truncated or secreted forms. Similarly, the protein may be known to exist in glycosylated form, or may be modified by various other post-translational events. Moreover, the protein could be manufactured by a variety of different host cells such as human cells, non-human animal cells, prokaryotic cells, insect cells, or fungal cells. However, although the patent application fully describes and enables each of these embodiments, it may not be possible to select and particularly claim the final commercially valuable embodiment until years after the initial application filing. As such, if it is not possible to maintain pendency to the earliest initial filing date via continuing applications, then an applicant's earliest disclosure will become prior art against the applicant's own invention.

Of course, the Office might respond that an applicant should claim all embodiments of an invention in the first filed patent application. However, as discussed *supra*, under the Office's current restriction practices, an applicant would be required to file numerous, if not innumerable, divisional applications in order to claim all foreseeable embodiments of the invention. Moreover, should the currently proposed rules be

implemented with the current restriction practices, an applicant would be required to file these numerous, or innumerable, divisional applications in response to the first restriction requirement during pendency of the initial parent application (which would be inordinately cost prohibitive for most patent applicants). At such point then, the Office would be subject to examining an enormous number of applications simultaneously, instead of divisional applications filed and examined in a continuous sequence. Accordingly, the proposed rules to limit continuing applications will have a devastating impact on technology areas such as biotechnology because of the hardship they would impose on an applicant's ability to correctly and definitively claim the commercially important embodiment of the invention. Under such circumstances, the biotechnology industry will experience an enormous loss of capital, intellectual property rights, or both; each of which are critical for the industry to succeed in improving human health.

VIII. THE PROPOSED RULES CREATING A *PRIMA FACIE* PRESUMPTION OF DOUBLE-PATENTING VIOLATE STATUTORY LAW

Proposed rule 1.78(f) would violate statutory law by creating a presumption of double-patenting in the absence of examination of patent application claims. In particular, proposed rule 1.78(f)(2) reads, in part:

> If a nonprovisional application has the same filing date as the filing date of one or more other pending or patented nonprovisional applications, taking into account any filing date for which a benefit is sought under title 35, United States Code, names at least one inventor in common with the one or more other pending or patented nonprovisional applications, is owned by the same person, or subject to an obligation of assignment to the same person, and contains substantial overlapping disclosure as the one or more other pending or patented nonprovisional applications, a rebuttable presumption shall exist that the nonprovisional application contains at least one claim that is not patentably distinct from at least one of the claims in the one or more other pending or patented nonprovisional applications. In this situation, the applicant in the nonprovisional application must either:
>
> (i) Rebut this presumption by explaining to the satisfaction of the Director how the application contains only claims that are patentably distinct from the claims in each of such other pending applications or patents; or

> (ii) Submit a terminal disclaimer in accordance with § 1.321(c). In addition...the applicant must explain to the satisfaction of the Director why there are two or more pending nonprovisional applications naming at least one inventor in common...which contain patentably indistinct claims.

71 Fed. Reg. at 58 (proposed rule 1.78(f)(2))(emphasis added). HGS respectfully submits that proposed rule 1.78(f)(2), creating a rebuttable presumption of double-patenting without prior examination of the claims, is in direct violation of 35 U.S.C. §§ 131 & 132. Consider that 35 U.S.C. § 131 (emphasis added) mandates:

> **35 U.S.C. 131 Examination of application.**
> The Director *shall cause an examination to be made of the application and the alleged new invention*; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

Likewise, 35 U.S.C. § 132 (emphasis added) mandates:

> **35 U.S.C. 132 Notice of rejection; reexamination.**
> (a) Whenever, *on examination, any claim* for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined...

Accordingly, 35 U.S.C. §§ 131 & 132 plainly indicate that the U.S.P.T.O. *must first examine* the application and claims to the invention. Only after examination may the Office notify the applicant of the rejection or objection, including notice of the reasons for the rejection or objection. Therefore, a rule such as 1.78(f)(2), establishing a *prima facie* presumption of double-patenting, without examination of the claimed subject matter, would constitute a *prima facie* breach of the Office' duties under 35 U.S.C. §§ 131 & 132. Therefore, the Office should not implement proposed rule 1.78(f)(2).

IX. PROPOSED ALTERNATIVE SOLUTIONS:

A. Continue to hire and retain more examiners and to improve examiner training; allow sufficient time for recently implemented improvements to effect change.

The most obvious and desirable option for reducing the Office examination backlog is to hire and retain more examiners. In this regard, HGS applauds the PTO for recently implementing programs to retain examiners and improve examiner training. HGS respectfully submits that the Office should continue in these endeavors and allow sufficient time for recently implemented improvements to produce the desired changes. In particular, the Office's implementation of a "Hoteling Program" wherein examiners can "telework" from home should provide a significant incentive for drawing new and retaining experienced patent examiners; just as this program has already done for trademark attorneys.[17] Further, the Office's recent efforts to hire and fully train significant numbers of new examiners is also laudable. The Office's hiring of 978 new examiners in fiscal year 2005 and goal of hiring 1,000 new examiners in fiscal year 2006 can be expected, in due time, to make substantial improvements in reducing patent pendency. Furthermore, institution of the patent examiner training academy should also produce significant improvements in the quality of patent examination by inexperienced examiners. Moreover, this program may also help in retention of new examiners creating and fostering a sense of "community" from the time spent with new colleagues in the training program. HGS respectfully submits that these efforts by the Office are the types of changes which will ultimately be the most effective and satisfactory means of reducing the patent examination backlog. The Office should allow sufficient time to see the results

[17] *See, U.S.P.T.O. Performance and Accountability Report for Fiscal Year 2005*, pages 5-6, available on the internet at: http://www.uspto.gov/web/offices/com/annual/index.html.

of these newly implemented programs before implementing the dramatic changes suggested in the currently proposed rules.

Additionally, the Office should continue to seek additional means and approaches for providing improved incentives (through salary, benefits, and performance expectations) for examiners to join and remain with the Office. HGS believes the Office is in dire need of a critical change in performance expectations with regard to awarding examiner disposal credits. In particular, the disposal credit system must be revised to accurately reflect time allocation requirements and to motivate examiners. For example, examiners should be awarded credits according to the number of claims to be examined in an application, not according to the number of applications. Furthermore, examiners should also be given appropriate credit for reviewing lengthy patent applications. Patent applicants currently pay an additional fee of $250 for each 50 pages (or fraction thereof) for applications exceeding 100 pages. *See*, 35 U.S.C. 41(a)(1)(G) and 37 C.F.R. 1.16(s). Therefore, if the Office has recognized the additional burden of lengthy applications as sufficient justification for increased fee collection, the Office should also recognize the additional burden on examiners by giving them appropriate credit for the additional pages examined and fees collected in remuneration. Additionally, examiners should also be awarded credit for reviewing and responding to after-final office actions in order that applicants receive appropriate consideration of substantive attempts to advance prosecution.

B. Establish a task force to find better options.

Rather than rush to implement the currently proposed rules, with all of the potential pitfalls noted herein, a better approach would be to establish a task force to determine and recommend implementation of changes that would actually function to reduce the examination backlog. In other words, it would be better to take longer to pursue the correct course of action, than to rush into the wrong course of action.

C. Revise current claim restriction practices and policies.

The restriction requirement practices of the Patent Office have directly contributed to patent applicant's need to file multiple divisional applications. The Office's current restriction requirement practices partition single inventions or discoveries into numerous application filings (*i.e.*, divisional applications). This practice appears to result from an overly-exacting application of restriction practice standards.[18] As such, examiners typically justify office actions with multiple restriction groups by stating that searching all of the groups would constitute an undue burden. However, when a reasonable number of inventive embodiments are closely related, a search broad enough to cover all of them should ordinarily not be considered an undue burden.

Therefore, the trend toward increasingly narrow restriction requirements has, unfortunately, created the need for applicants to file, and the Office to examine, numerous divisional patent applications. It has also made it difficult for inventors to obtain full intellectual property protection for their inventions. Zealous application of restriction practice is particularly noticeable in the biotechnology industry where applicant's claims are commonly restricted into 10, 20, 30 and even hundreds of different groups.[19] As such, under current restriction practice, if an applicant seeks patent coverage for related embodiments of a *single discovery*, the applicant must file *multiple divisional applications* just to have the examiner to consider the merits of each related embodiment. For example, in the case of a therapeutic gene product (*i.e.*, a biotechnology invention), applicants are required to file separate applications for nucleic acids encoding the gene product, anti-sense molecules to inhibit the gene product, methods of detecting

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[18] "United States restriction practice is based on 35 U.S.C. 121, which provides that: '[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.' This allows examiners to limit applicants to one set of patentably indistinct inventions per application. The USPTO may 'restrict' the application to one set of patentably indistinct inventions: (1) If the application includes multiple independent and patentably distinct sets of inventions, and (2) if there is an undue burden to examine more than one invention in the same application. Restriction practice was designed to balance the interest of granting an applicant reasonable breadth of protection in a single patent against the burden on the USPTO of examining multiple inventions in a single application." Official Gazette Notice, No. 24 (June 17, 2003).

[19] HGS will gladly supply the Office with numerous examples of such situations upon request.

the gene product, therapeutic use of the gene product (or anti-sense molecules thereto), antibodies against the gene product, diagnostic and therapeutic uses of said antibodies, and so forth.

If the Office genuinely desires to reduce patent application pendency and backlog by reducing the number of "re-work" applications, it should seriously investigate, and ultimately adopt, examination practices that permit applicants to claim related embodiments of an invention in a single application or, *at least*, fewer applications such as is currently accomplished in other international patent offices (*e.g.*, Canada, Europe, and Japan). Adopting such practices would not only expedite pendency but would also better serve public notice by creating fewer issued patents which the public must discover and assess to avoid involvement in infringing activities. Accordingly, the Office should strongly consider adopting a unity of invention standard of claims examination practice.[20] As part of such consideration, the Office should investigate the examination and art searching techniques already practiced and achieved (apparently without any "undue burden") by foreign patent offices operating under a unity of invention standard (*e.g.*, Canada, Japan, and Europe). Consequently, another component of revising restriction practice should include allowing multiple dependent claims *and* multiple-multiple dependent claims (without charging exorbitant fees[21]) as is currently practiced in other

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[20] For example, under a "[u]nity of Invention standard, restriction would, as a general rule, no longer be permitted between certain related inventions that currently may be restricted under United States restriction practice. Some examples of related inventions that are often filed together and typically can be restricted under current United States practice before a prior art search is conducted, but do not lack unity under the Unity of Invention standard, include: (1) A process, and the apparatus for carrying out the process; (2) a process for making a product, and the product made; (3) an apparatus, and the product made by the apparatus; (4) a product, and the process of using the product. A lack of Unity of Invention is different from restriction practice in some major aspects. Unity of Invention is practiced, with slight variations, in PCT applications and in applications examined by the European Patent Office (EPO) and the Japan Patent Office (JPO). The primary consideration for establishing Unity of Invention is that the claims are entitled to be examined in a single application if the claims are so linked together as to form a single general inventive concept, premised on the concept of a common feature (referred to as a 'special technical feature' in the context of PCT Rule 13) that can be present in multiple inventions within a single application. As long as the same or corresponding common feature is found in each claim and that common feature makes a contribution over the prior art, the claims comply with the requirement for Unity of Invention." Official Gazette Notice, No. 24 (June 17, 2003).

[21] The standard (large entity) fee for a multiple dependent claim is currently $360 plus an additional claim fee for each claim upon which the claim depends. 37 C.F.R. §§ 1.16(j) and 1.175(c). High fees should not be necessary for multiple dependent claims, however, because a claim fee (search fee) was paid for each preceding claim upon which a given multiple dependent claim relies. Hence, for multiple dependent claims,

international patent offices (again, without any apparent "undue burden"). It is important to note that the Office does not have to create, *de novo*, the means and methods for examining claims to related, though perhaps patentably distinct, inventions in a single application. Foreign patent offices are currently practicing just such broad scope claims examination. Therefore, the USPTO should be able to investigate, tailor, and adopt those practices from foreign patent office that best allow the U.S. Office to achieve examination of broad scope claim embodiments in a single patent application. Hence, adoption of an international unity of invention standard will not only produce fewer divisional application filings, but will also accomplish an additional step toward the international harmonization of patent law.

Finally, the Office must create a fair and equitable system for awarding examiner disposal credits in order to reduce the number of claim groups created by an examiner in each restriction requirement. For example, the Office should provide examiners with disposal credits based on the *number of claims* examined, not based on the number of applications examined.

D. Create provision for allowing delayed examination requests.

The Office should create a provision for allowing delayed examination requests. Some countries already provide options for delayed examination. For example, in Canada examination commences only after a request for examination is filed, and it is possible to maintain an application pending for up to five years from the filing date. Similarly, Japan also allows for delayed examination requests. Moreover, in Japan an interested third party can pay a statutory fee and request examination of another party's deferred application. Therefore, under this system, deferred examination does not adversely effect third parties because such parties can request examination and obtain a decision on the merits of applications in which they have a vested interest. The U.S.

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it is only necessary to perform a search and examination of the claim with respect to the additional limitation found in the given multiple dependent claim.

Patent Office should consider implementing a means for requesting delayed examination as an alternative approach to reducing the patent application backlog.[22]

E. Out-source prior art searches.

The Office should consider further expanding the outsourcing of prior art searches to private agencies, additional foreign patent offices, or create its own prior art search office. This would free Examiner time for functions that make better use of their expertise (*i.e.*, reviewing and considering patent applications on their merits instead of attempting to find relevant prior art).

F. De-centralize the PTO.

The Office should consider creating regional patent examination facilities to attract talent from different parts of the United States. Such regional offices would function to attract and retain persons who are otherwise highly qualified, but who do not wish to live in the Washington, D.C. metropolitan area. Regional offices could be established, for example, in a metropolitan center in each U.S. time zone (such as, Chicago, IL; Denver, CO; and, Sacramento, CA). Additionally, regional offices would improve communication between applicants and examiners by making personal interviews more accessible to applicants in other parts of the nation.

[22] Currently, there is an MPEP provision permitting requests for delayed examination, however, the standard for obtaining this benefit is too narrow and the length of delay allowed is too short to be meaningful. For example, the MPEP provision allows for not more than a 6 month suspension "upon a showing of good and sufficient cause", or no more than 3 years "from the earliest filing date for which a benefit is claimed". *See*, MPEP 709 & 37 CFR 1.103

G. Allow continuing applications as a matter of right during the statutory term of patent pendency, but create a tiered system of increasing fees.

To deter the potential for frivolous filing of continuing applications, the Office could implement a tiered system of increasing fees, where each new continuing application would be subject to increased filing fees. Note, however, such an increasing fee system should not apply to divisional applications filed in response to USPTO mandated restriction requirements.

H. Do not apply the proposed rules retroactively.

If the proposed rules are implemented, they should not apply *retroactively* to applications which claim benefit of priority to applications that were filed and pending prior to the effective date of the new rules. The Office has stated that the proposed rules limiting continuing application filings would be applied to all applications filed on or after the effective date of the final rule. However, the Office also clarified its intent that application of the rule would bar any new continuation application (filed on or after the effective date) from claiming benefit of a previous continuation application (filed before the effective date), unless applicants were able to make a sufficient showing of "necessity" as required by proposed rule 1.78(d)(1)(iv). In particular, the Office asserted:

> The proposed changes to § 1.78 (if adopted) would be applicable to any application filed on or after the effective date of the final rule. Thus, any application filed on or after the effective date of the final rule seeking to claim the benefit of more than a single prior-filed nonprovisional application or international application under 35 U.SC. 120, 121, 365(c) and § 1.78 would need to either meet the requirements specified in proposed § 1.78(d)(1)(iii) or include a petition under proposed § 1.78(d)(1)(iv). That is, an applicant may only file one continuation or continuation-in-part application (and not "one more" continuation or continuation-in-part application) after the effective date of the final rule without meeting the requirements specified in proposed 1.78(d)(1)(iii) or including a petition under § 1.78(d)(1)(iv).

71 Fed. Reg. at 56. HGS respectfully submits that if the proposed rules are implemented, it would be inequitable and unreasonable to apply these rules *retroactively* to continuing applications which claim the benefit of applications filed *before* the effective date of the proposed rules. Applications filed before the announcement of the proposed rules, if not before the effective date of the proposed rule, were filed in reliance that they would be entitled to the existing framework of the patent rules. Making the rule retroactive violates the statutory benefit relied upon and conferred by 35 U.S.C. §§ 120, 121 and 365(c) for applications filed prior to the effective date of the newly proposed rules. Hence, the opinion of Circuit Judge Newman in Bogese is quite apt with regard to the Office's currently proposed rules.

> If a change in the statutory rules of prosecution is deemed appropriate, it should be processed legislatively. An administrative ruling, applied retrospectively against those who complied with the law is not appropriate...The already burdensome and expensive path to a patent does not benefit from the added encumbrance of an unguided bar that can be imposed as a matter of administrative discretion.

In Re Bogese, 303 F.3d 1362, 1372 (Fed. Cir. 2002).

The U.S. Supreme Court has also disapproved of administrative agencies promulgating retroactive rules. For example, Justice Kennedy, delivering the opinion in Bowen v. Georgetown, stated:

> Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result...By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. See *Brimstone R. Co. v. United States, 276 U.S. 104, 122 (1928)* ("The power to require readjustments for the past is drastic. It . . . ought not to be extended so as to permit unreasonably harsh action without very plain words"). Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.

Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988). Moreover, in his concurring opinion Justice Scalia further articulated:

> The first part of the APA's definition of "rule" states that a rule
>
> > "means the whole or a part of an agency statement of general or particular applicability *and future effect* designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . . ." 5 U. S. C. § 551 (4) (emphasis added).
>
> The only plausible reading of the italicized phrase is that rules have legal consequences only for the future. It could not possibly mean that merely some of their legal consequences must be for the future, though they may also have legal consequences for the past, since that description would not enable rules to be distinguished from "orders," see 5 U. S. C. § 551(6), and would thus destroy the entire dichotomy upon which the most significant portions of the APA are based. (Adjudication -- the process for formulating orders, see § 551(7) -- has future as well as past legal consequences, since the principles announced in an adjudication cannot be departed from in future adjudications without reason.

Bowen at 216. Similarly, Justice Scalia further opined:

> A rule that has unreasonable secondary retroactivity -- for example, altering future regulation in a manner that makes worthless substantial past investment incurred in reliance upon the prior rule -- may for that reason be "arbitrary" or "capricious," see 5 U. S. C. § 706, and thus invalid. In reference to such situations, there are to be found in many cases statements to the effect that "[w]here a rule has retroactive effects, it may nonetheless be sustained in spite of such retroactivity if it is reason-able." General Telephone Co. of Southwest v. United States, 449 F. 2d 846, 863 (CA5 1971). See also National Assn. of Independent Television Producers and Distributors v. FCC, 502 F. 2d 249, 255 (CA2 1974)... It is erroneous, however, to extend this "reasonableness" inquiry to purported rules that not merely affect past transactions but change what was the law in the past. Quite simply, a rule is an agency statement "of future effect," not "of future effect and/or reasonable past effect."

Bowen at 220.

In the present situation, if the Office adopts the proposed rules and applies these new rules to applications which claim the benefit of applications filed prior to the effective date of the new rules, then the Office will be promulgating rules with legal consequences not only of *future effect*, but also legal consequences for the past (despite a lack of express authorization from Congress to pass rules of retroactive effect). The rules as proposed would have legal consequences for the past because under the present rules applicants were free to liberally disclose as much information as possible about an invention, including tangentially related information which might also be separately patentable. Applicants were (and are) free to be so liberal with their disclosure to the public under the rules precisely because the rules allow an applicant to file as many voluntary divisional applications and continuation applications as necessary, when necessary, to claim various embodiments of their invention. However, if the proposed rules are enacted as effective against applications filed before the effective date, then applicants may lose substantial past investments in the inventions which they have researched, developed, and liberally disclosed, because under the new rule limitations they will be barred from claiming embodiments of their invention through continuations and voluntary divisionals. Hence, if the proposed rules are enacted with effect against applications filed prior to the new rules effective date, then the new rules will be altering future regulation in a manner that makes many substantial past investment worthless. As such, the new rules would be changing the law as it was in the past. Accordingly, HGS respectfully submits that if the Office proceeds in implementing the proposed rules, despite the opposition arguments presented here and by others, the rules should not be applied retroactively because to do so would be unreasonable, inequitable, and contrary to previously held federal common law decisions.

I. Advance notice of the effective date of proposed rule changes.

If the Office proceeds in implementing the proposed rules, despite the opposition arguments presented here and by others, the Office is respectfully reminded that the Administrative Procedures Act requires publication of a substantive rule at least 30 days prior to the effective date of the new rule. In particular, 5 U.S.C. § 553(d)(1)-(3) mandates:

> (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except--
> (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
> (2) interpretative rules and statements of policy; or
> (3) as otherwise provided by the agency for good cause found and published with the rule.

Accordingly, should the proposed rules be implemented it is expected that the Office will provide, *at least*, thirty days notice prior to making the rules effective.

XI. CONCLUSION

In view of the explanations, comments, and arguments provided herein, and otherwise, HGS respectfully requests the Patent Office not to implement the proposed rule changes to practices for continuing applications, requests for continued examination, and applications containing patentably indistinct claims.