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From: Kettner, Dave [mailto:dave@warf.org]
Sent: Tuesday, May 02, 2006 4:29 PM
To: AB93Comments; AB94Comments
Cc: Kettner, Dave
Subject: Comments on Proposed Rules - WARF

Dear Mr. Bahr,

Please find attached the Comments of the Wisconsin Alumni Research Foundation on the following Proposed Rules:

Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims
Docket No.: 2005-P-066, 71 Fed. Reg. 48 (January 3, 2006); and

Changes to Practice for the Examination of Claims in Patent Applications
Docket No.: 2005-P-067, 71 Fed. Reg. 61 (January 3, 2006)

If the attached document is unreadable for any reason, please contact me immediately. Thank you.

Regards,

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April 28, 2006

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

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

Comments on Proposed Rules:
"Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims,"
Docket No.: 2005-P-066, 71 Fed. Reg. 48 (January 3, 2006); and
"Changes to Practice for the Examination of Claims in Patent Applications,"
Docket No.: 2005-P-067, 71 Fed. Reg. 61 (January 3, 2006)

Dear Under Secretary Dudas:

The Proposed Rules, both individually and collectively, will (1) significantly impact the ability of academic and nonprofit research institutions, and other applicants, to fully claim their inventions, (2) increase patent prosecution costs, and (3) create uncertainty in the patent prosecution process. In view of these concerns, Wisconsin Alumni Research Foundation ("WARF") respectfully submits the general comments below, as well as specific comments to individual elements of each of the Proposed Rules.

I. University Technology Transfer

WARF was founded in 1925 as one of the first organizations to engage in university technology transfer. It exists to support scientific research at the University of Wisconsin – Madison, and carries out this mission by patenting university technology and licensing it to the private sector for the benefit of the university, the inventors and the public. Year-by-year, the UW-Madison ranks in the top ten universities in terms of patents granted by the United States Patent and Trademark Office ("PTO"). As recognition of its excellence in technology transfer, WARF recently received the National Medal of Technology, an annual award conferred by the

President of the United States that recognizes significant and lasting contributions to the country's economic, environmental and social well-being through the development and commercialization of technology.

To understand WARF's position – and that of many other university technology transfer offices – an understanding of university patent licensing is necessary. In 1980, Congress enacted the Patent and Trademark Law Amendments Act (Public Law No. 96-517, 94 Stat. 3019 (1980)), which is more commonly known as the Bayh-Dole Act.[1] The Bayh-Dole Act firmly established the cardinal principle that *the public benefits from a policy that permits universities and small businesses to elect ownership of and to pursue patent protection for technologies invented with federal funding and, thereby, becoming participants in the commercialization process.* After passage of the Bayh-Dole Act, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions. In 1980, approximately 25 U.S. universities had technology transfer offices. Today, more than 230 U.S. universities have such offices, many of which have patented and licensed groundbreaking technologies that have significantly advanced developments in multiple areas. The list of university inventions is indeed impressive, among others, the following:

- Magnetic resonance imaging (University of Wisconsin – Madison)
- Lithography system for manufacturing nano-devices (University of Texas – Austin)
- Rheumatoid arthritis relief (University of California - San Diego)
- Helping emphysema victims breath again (University of Florida)
- Effective Aneurysm Treatment (UCLA)
- Lice Shampoo (Purdue Research Foundation)
- Google (Stanford University)
- Turf grass (Rutgers University)
- Vitamin D (University of Wisconsin – Madison)

These inventions, and many others, affect Americans in their daily lives, whether as hospital patients, farmers, employees in both large and small businesses, scientists, students and entrepreneurs.

Universities must be able to pursue their mission of creating and disseminating knowledge in an open environment, while concurrently protecting their inventions through strong intellectual property laws. Because of university publication requirements, university technology transfer offices are pressured to file patent applications early and often to protect both the initial discovery concepts and the additional supported practical embodiments. Such an approach is also required in order to meet the statutory goals and obligations of the Bayh-Dole Act, which is to promote commercialization of inventions developed with federal funds for the public benefit by providing technologies attractive for development by small businesses and potential licensees.

[1] The Bayh-Dole Act has since been amended twice, in 1984 and 2000. The first amendment, P.L. 98-620 (November 8, 1984), removed certain restrictions on exclusive licensing and designated the Department of Commerce as the federal agency responsible for overseeing and monitoring compliance. The second amendment, P.L. 106-404 (November 1, 2000) streamlined the process by which federal agencies commercialize inventions made by their employees.

Many small businesses begin as spin-offs from initial discoveries made within an academic setting. The early years of new biotechnology companies are unstable and uncertain. Attracting investors to these high-risk ventures is difficult. However, investors are continually drawn to such companies because of the potential for high returns realized upon the discovery, development and successful marketing and/or licensing of an effective treatment or valuable product. This pressure, along with academic publication requirements, drives universities to file patent applications early in the development stage. Consequently, universities file patent applications years before a product or technology is fully developed or commercialized. During this time, they may agree to initially narrow patents and continue to perform "proof of concept" experiments to further support their initial discovery. With the initial patent in hand, patent owners can point to other pending applications (continuations) which are broader and more comprehensive to secure further licensing interest.

As an example, while a researcher may have contemplated and claimed a product for human use (or a method of treatment in humans), the researcher may not have had human clinical data at the time of filing. In general, the university will file patent applications based on promising animal and/or *in vitro* data and then, if necessary and available, submit additional empirical evidence during patent prosecution. Sometimes this evidence can only come in the form of clinical data, which can take years to obtain. The time required to conduct such experiments often requires applicants to file continuation applications. Further, obtaining substantive consideration of such experiments by patent examiners often requires the filing of continuations because of the PTO's restrictive "after final practice".

Faced with increasing patent prosecution costs, and absent the opportunity to file continuation applications, universities may be forced to accept protection on less than they had a right to protect, i.e., their inventions in their entirety. Some resource-limited universities may also be forced to decide not to pursue patent protection at all due to the associated costs and the uncertainty of the prosecution process. Without protection on commercially useful technologies, potential licensees would not invest into the further development of the technologies. Consequently, promising technologies would simply languish on the laboratory shelves and gather dust as had been the case before the enactment of the Bayh-Dole Act.

II. General Comments

The Proposed Rules would (1) change the way in which claims in an application are examined by limiting the number of claims that may be presented for initial examination, and (2) limit the circumstances under which an applicant may file continuations, requests for continued examination and, in some cases, continuation-in-part applications. Individually and collectively, the proposed changes are troubling because they may potentially impact an applicant's ability to claim an invention to its full scope and limit the applicant's opportunity to fully develop claims through the prosecution process. The Proposed Rules are also problematic as they are likely to significantly increase the cost of patent prosecution, while not effectively assisting the PTO in reducing the backlog of cases under examination. Finally, the Proposed Rules raise questions regarding the legality of the changes given the statutory authority provided to the PTO, as well as

A. The Proposed Rules Will Limit the Ability of Applicants to Claim the Full Scope of their Inventions.

The Proposed Rules set forth in "Changes to Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61, will severely limit the number of claims the PTO will accept for initial examination in an application. The Proposed Rules in "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48, will further limit the opportunity of the applicant to continue presenting claims through continuation and continued examination practice. Together, as a practical matter, these proposals may well tend to require applicants to (1) reduce the scope of the claims they pursue, and (2) cause them to accept more narrow claims as a result of the more limited opportunity for continued prosecution.

The PTO 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). 71 Fed. Reg. at 50. However, in a practical sense, these "non-absolute" alternatives will be of little comfort to applicants.

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 by preparing and filing the examination support document (ESD). The filing of the ESD may also present the additional risk of adversely affecting claim scope as a result of estoppel by argument, as well as risks associated with claims of inequitable conduct that will surely arise from conducting the search and preparing and filing the ESD. As a result, the applicant is more likely to limit the initial examination to ten designated claims as opposed to bearing the additional costs of the ESD and the risks associated therewith.

The issue is further enhanced by limiting the opportunity for continued presentation of claims by means of continuation or continued examination practice. Opportunities for continued examination come at the higher cost and uncertainty of pursuing the right to present additional claims through the more costly and less certain administrative route of petition and appeal. After the first RCE or continuation, subsequent filings will only be available by way of a petition showing "good cause." Notwithstanding the ambiguity of the meaning of "good cause," the determination of whether or not an applicant has shown "good cause" will shift PTO resources away from the core function of examination and to administrative determinations of whether an applicant has the right to pursue prosecution of claims covering the full scope of his invention. Ultimately, this process will result in an increase in per application time and costs for both the applicant and the PTO, especially where appeals may result from the denial of a petition. Collectively, in their application, the Proposed Rules are likely to have the effect of limiting the ability of applicants to claim the full scope of their inventions to which they are entitled under the Patent Act.

B. The Proposed Rules Are Not Likely to Reduce the PTO Backlog

One of the reasons offered for the Proposed Rules, is that the PTO desires to reduce the backlog of pending patent applications. 71 Fed. Reg. at 50. The PTO indicates that of the number of continuation and continuation-in-part applications filed in fiscal year 2005, about 11,800 were second or subsequent continuation/CIP applications. Id. Of the requests for continued examination filed in fiscal year 2005, just under 10,000 were second or subsequent requests for continued examination. Id. Collectively, such applications amounted to less than 6% of the reported 369,000 applications filed in fiscal year 2005.

It is unclear to WARF how limiting the examination of these applications will improve the ability of the PTO to address its current backlog of cases, especially in light of the proposed petition process associated with requesting examination on these cases and given that the cases to be eliminated are often the most easily examined. The implementation of the petition process will ultimately require the examiner and/or other PTO officer to review the application, its history and the petition for examination, and then prepare a well-reasoned response as to the denial or grant of the petition. If denied, additional PTO resources may also be called upon to address any appeal of the decision to deny the petition.

When compared to the actual time allocated to the examination of second and subsequently filed continuation/CIP applications and requests for continued examination, the time savings are likely to be negligible or, in a worse case scenario, result in an increase in time allocation and backlog. Examination of second and subsequently filed continuation/CIP applications and requests for continued examination are often conducted by the same examiner as in the original case and often do not require extensive additional prior art searching or examination. In most of these cases, the issues have already been defined and the exchange is directed primarily to discussing claims appropriate to the scope of the invention. As a result, the time and resource allocation to examining these additional applications is typically not consistent to the time and resources associated with examining each newly filed patent application. As a result, eliminating the examination of second and subsequently filed continuation/CIP applications and requests for continued examination is not likely to capture additional time necessary to reduce the PTO backlog.

The rationale offered for limiting the number of claims examined per application 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 evaluated by an examiner." 71 Fed. Reg. at 61. Fewer claims do not necessarily provide for a "better, more thorough and reliable" examination. Such improved examination requires a well-trained, knowledgeable examining corps, the appropriate tools and adequate time in which to examine. Without the examination of a range of claims from broad to narrow, the appropriate amount of time and the appropriate training, it is less likely that examiners will be able to indicate allowable subject matter early in the prosecution. In fact, more claims, encompassing additional specific embodiments help to define the invention, in many cases allowing examiners to better understand the subject matter sought to be protected. In addition, it is equally possible that the imposition of these rule changes may yield more first continuing applications as applicants attempt to present amended claims to find the scope of the claims that the examiner will allow.

WARF continues to support the PTO's *Strategic Plan*, but urges the PTO to **not** adopt rules which ultimately reduce the rights afforded under the Patent Act. The PTO must address the challenges of rising workloads and the shift of applications from traditional arts to more complex technologies, but must do so in a well reasoned manner. The changes provided by the Proposed Rules do not appear to address the backlog issues in a manner that justifies reducing the ability of applicants to pursue the rights afforded to them under the Patent Act.

C. The Proposed Rules Extend Beyond the Statutory Authority of the PTO

WARF recognizes that the Director of the PTO has the authority to establish regulations not inconsistent with law. However, the provisions of 35 U.S.C. §§ 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 the 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. Arguably, this raises the issue of the authority of the Director to establish regulations, such as the Proposed Rules, that are arguably inconsistent with the above statutory provisions.

Several elements of the Proposed Rules raise questions as to whether their application will be contrary to the statutory authority afforded to the PTO. For example, although the PTO indicates that its proposed requirements for filing any second or subsequent continuing application is not intended to limit the number of continuing applications, its manner of implementation may ultimately have that effect and, therefore, conflict with the 35 U.S.C. §§ 131[2] and 132[3] and the holdings of *In re Henriksen,* 399 F.2d 253 (CCPA 1968) and *In re Hogan*, 559 F.2d. 595 (CCPA 1977).[4] Proposed Rule 1.78(d)(iv) requires the applicant to submit with each second or subsequent continuing application a petition showing to the satisfaction of the Director that the amendment, argument, or evidence introduced in the application could not have been submitted during the prosecution of the prior-filed application. Such a rule, however, sets a threshold not allowed under law for obtaining a patent, that is not that the invention is not entitled to a patent, but that the applicant was precluded from earlier arguing on behalf of its patentability. 35 U.S.C. § 131 clearly states that the Director **shall cause an examination to be made** of the application . . . and **if on such examination** it appears that the applicant is entitled to a patent under law, the Director shall issue a patent therefore. The statute does not provide for the Director to cause an examination to be made, but only if the reasons for patentability could not have been submitted in a prior-filed application. 35 U.S.C. § 132(b) also requires the Director to prescribe regulations **to provide for the continued examination for applications for patent at the request of the applicant**, not that the Director can limit the ability of the applicant to obtain examination of continuing applications.

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[2] "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 law, the Director shall issue a patent therefore." 35 U.S.C. § 131.

[3] "The Director shall prescribe regulations to provide for the continued examination for applications for patent at the request of the applicant." 35 U.S.C. § 132(b).

[4] 71 Fed.Reg. at 50 (January 3, 2006), citing *In re Hogan* and *In re Henriksen* and stating that 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."

It is also unclear what an applicant will need to provide in order to establish to the satisfaction of the Director that the amendment, argument, or evidence introduced in the continuing application could not have been submitted during the prosecution of the prior-filed application. Given the effects caused by the changes set forth in Proposed Rule 1.75 limiting prosecution to a designated ten claims or requiring the filing of an EDS, it is highly likely that applicants will desire to employ a strategy involving the pursuit of a smaller number of narrow claims to achieve issuance of their prior-filed applications, followed by the prosecution of more broader claims more appropriate to the full scope of their invention. However, given that they could have made such claims in the earlier-filed application, it is unclear whether they would have such right, which may be in conflict with the holdings of *In re Hogan*, *supra*, and *In re Henriksen*, *supra*. Ultimately, the combination of Proposed Rule 1.78 and 1.75 may create an absolute bar precluding the filing of continuing applications claiming an invention to which a statutory right exists.

In addition, the PTO may lack authority to refuse to examine claims because there are too many, in its view, or contain too many alternatives.[5] Proposed Rule 1.78(f)(1) requires that if a nonprovisional application is filed on the same date as other nonprovisional applications or patents, and contains "substantial overlapping disclosure" with those other applications or patents, a rebuttable presumption is created that the nonprovisional application contains at least one claim that is not patentably distinct from the other applications or patents. The applicant must then either rebut the presumption to the satisfaction of the Director or file a terminal disclaimer. 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 PTO.

Again, this contravenes clear precedent and the duty the PTO has, in the first instance, to make a *prima facie* case of unpatentability before the burden shifts to the applicant to rebut that *prima facie* case. *See In re Oetiker,* 977 F.2d 1443 (Fed. Cir. 1992). The PTO also does "NOT ... have authority to issue substantive rules" that result in non-examination of claims, and does not have the authority to overrule the Federal Circuit's instructions on its burden to demonstrate unpatentability. 35 U.S.C. § 2(b)(2)(A); *see also Merck & Co. v. Kessler,* 80 F.3d 1543,1550 (Fed. Cir. 1996) (emphasis in original).

D. The Retroactivity of the Proposed Rules Penalizes Earlier-Filed Applications

The Federal Register Notices for both Proposed Rules indicate that the rules shall apply retroactively to any application filed on or after the effective date of the final rule with respect to both Proposed Rules and, with respect to changes related to Proposed Rule 1.75, any application in which a first Office Action on the merits was not mailed before the effective date of that final rule. Such retroactivity appears to deny applicants' due process under both the Administrative Procedures Act and the Fifth Amendment, and is likely to cause significant hardship to most, if not all, applicants. Moreover, such retroactivity may amount to an *ex post facto* regulation and suffer from unconstitutional infirmity.

[5] *In re Harnisch*, 631 F.2d 216 (CCPA 1980).

The changes to Proposed Rule 1.78 would retroactively apply to many pending applications, particularly to those that are presently continuing applications. If a continuing application is already pending before the PTO, a second continuing application would therefore be prohibited without the granting of a petition. Such an effect may cause undue hardship for those applicants under their existing patent strategy such that they may be foreclosed from seeking patent protection for those inventions properly patentable. For example, any applicant presently working on a continuing application to which a restriction requirement has been applied will need to file a divisional application on any non-elected invention or risk the possibility that the PTO will deny their petition on the grounds that the application could have been earlier presented. If adopted, WARF recommends that the changes to Proposed Rule 1.78 apply only to those applications claiming the benefit of applications filed on or after the effective date of the new rules.

If the changes to Proposed Rule 1.75 are applied retroactively, the proposed limits on claim examination would apply to any unexamined application pending at the PTO at the time the Proposed Rules are made effective. In other words, each such applicant would be required to either designate ten claims or file an EDS. In some instances, such a choice would not be feasible given the patent strategy already being implemented by the applicant. In other instances, given the proposed changes to continuation practice, such a choice may significantly impact their ability to even pursue full patent protection for their inventions without incurring significant and unanticipated costs. Ultimately, the cost of retroactively applying the changes to the Proposed Rules would be enormous to both the PTO and the applicants as they would both have to review each pending application for compliance. For the applicant, it may also involve determining not to pursue certain aspects of their invention due to the limitations on continuations and the costs associated with changing their patent strategy. If adopted, WARF recommends that the changes to Proposed Rule 1.75 should apply only to those applications filed after the effective date of the new rules.

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

WARF opposes limiting continuation practice and believes such a change in the rules would negatively impact universities and other entities that engage in basic research. Universities rely on filing robust initial applications that can be made more specific through additional claim language as the usefulness of a given discovery manifests itself. In addition to the general comments above, the following comments are offered on the specific provisions of the proposed rules.

A. Conditions for Claiming Benefit: Continuations or CIPs – 1.78(d)(1)(i)

The proposed changes to Rule 1.78(d)(1)(i) provide that a nonprovisional application that is a continuation application or a CIP may only claim the benefit of a single prior-filed application if: (1) the benefit of such prior-filed application is not claimed in any other nonprovisional application other than a divisional application; and (2) no request for continued examination (RCE) under § 1.114 has been filed in the prior-filed application. The proposed condition would not only limit the number of parent applications to one, but would also limit the

number of continuations or CIPs that could be based on a single parent application to one. In addition, the proposed condition would eliminate the ability to file any continuation or CIP from any application containing an RCE

WARF opposes the proposed rule in that (1) it eliminates access to any of the benefits of §§ 120 and 365(c) as a result of the filing of an RCE, or (2) the PTO has not established that the benefits associated with limiting continuation practice to a single continuation or CIP will outweigh the costs and limitations placed on the applicant to pursue the full scope of patent protection for their inventions. The proposed rule also does not allow for the filing of more than one continuation or CIP based on a single application, or the consolidation of two applications into a single CIP.

As stated above, university technology transfer offices are often pressured to file patent applications early and often to protect both the initial discovery and any additional supported practical embodiments. Consequently, universities file patent applications years before a product or technology is fully developed or commercialized. During this time, they may agree initially to narrow patents and continue to perform "proof of concept" experiments to further support their initial discovery. Such an approach is necessary to meet the statutory goals and obligations of the Bayh-Dole Act, which is to promote commercialization of inventions developed with federal funds for the public benefit by providing technologies attractive for development by small businesses and potential licensees. See 35 U.S.C. § 200 *et seq.* The proposed rule changes would impede the ability of universities to achieve this goal.

B. Conditions for Claiming Benefit: Divisionals – 1.78(d)(1)(ii)

The proposed changes to Rule 1.78(d)(1)(ii) provide that a nonprovisional application that is a divisional application may claim the benefit of only a single prior-filed application. WARF opposes the proposed change as it will have a negative impact on both the applicant and the PTO. It limits the number of parent applications to only a single prior-filed application so that all divisional applications would be required to be filed in parallel or at least before the patenting or abandonment of the application in which the restriction requirement was made.

The requirement to file all possible divisional patent applications in parallel will impose a significant burden on the PTO. PTO statistics over the last several years have shown that there are many more inventions today being identified in applications subject to a restriction requirement. The proposed changes to divisional practice would therefore encourage applicants to file more divisional applications today merely to preserve the opportunity to protect the restricted invention, instead of delaying such prosecution until a time when the value and likelihood of obtaining patent protection is more fully developed. Such an approach will be contrary to the goals of the PTO to reduce its prosecution burden.

In addition, due to the cost of simultaneously filing multiple applications, universities may forego protection of some inventions to which they may be entitled to patent protection. It is common practice for university applicants to submit patent applications encompassing anywhere from a dozen to several hundred nucleic acid sequences. Although biotechnology examiners are required to search up to 10 different nucleic acid sequences in any single patent application, often examiners will restrict each and every individual sequence into separate

inventions. Thus, to obtain the best protection of intellectual property, universities are often forced to file multiple, divisional applications. However, today they can file these divisional applications serially and avoid a heavy financial burden—one many universities cannot bear. The proposed changes would require them to be filed together. A more fair system would permit universities to keep the various aspects of their inventions together and would lighten PTO's burden due to multiple applications.

C. Conditions for Claiming Benefit: Continuation or CIP of a Divisional – 1.78(d)(1)(iii)

The proposed changes to Rule 1.78(d)(1)(iii) provides that a nonprovisional application that is either a continuation or a CIP application may claim the benefit of only a single divisional application in which no request for continued examination (RCE) under § 1.114 has been filed in such prior-filed divisional application. WARF makes the same observations and comments as set forth above with respect to Proposed Rule 1.78(d)(1)(i), *supra*.

D. Petition to File Continuation Applications – 1.78(d)(1)(iv)

The proposed changes to Rule 1.78(d)(1)(iii) have the effect of requiring any second or subsequent filed continuing application of any type to be accompanied by a petition indicating why an amendment, argument, or evidence presented in that application could not have been submitted during the prosecution of the prior-filed application. The petition must be filed within four months of the filing date of the continuing application or within four months of a date on which the national stage commenced in the U.S. if the continuing application is a PCT application. The petition must establish to the satisfaction of the PTO that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application.

WARF opposes the proposed standard as it believes that the standard will be difficult to meet, especially in light of the proposed limitations on claim prosecution. The examples provided by the PTO do not provide clear direction as to what would be a showing of "good cause" for granting the petition. In addition, there exists a substantial danger that a different standard will be applied by the different technology centers and amongst the over 4000 patent examiners. The risks associated with the denial of such a petition will be substantial due to the potential loss of patent rights, and may result in vigorous challenges before the PTO and in the courts. Ultimately, the petition process is likely to cause an increase in the administrative operations of the PTO in conflict with its interest to reduce its backlog.

If the proposed petition requirement is adopted, WARF suggests that a separate and adequately staffed office will need to be created in order to address these issues.

E. Continuation-In-Part Applications – 1.78(d)(3)

The proposed changes to Rule 1.78(d)(3) would introduce a new requirement that the applicant must identify which claim or claims in the CIP application are disclosed in the manner provided by the first paragraph of § 112 in the prior filed application.

WARF supports requiring the applicant to identify the new matter included in the CIP application, but opposes requiring the applicant to identify which claim or claims are disclosed in the manner provided by § 112, first paragraph. The responsibility for determining whether a claim is supported in compliance with § 112 is ultimately a legal determination that should remain with the examiner as opposed to the applicant. To require an applicant to offer a legal conclusion regarding compliance with § 112 will simply further increase the applicant's risk of subsequent allegations of inequitable conduct or estoppel by argument.

F. Applications Having at Least One Common Inventor – 1.78(f)(1)

The proposed changes to Rule 1.78(f)(1) would require that an applicant identify separate applications that have the same filing date or filing dates within two months, that name at least one common inventor, and that are owned by the same person.

The proposed requirement is both unnecessary and misguided. To the extent that another application contains relevant disclosure or is a possible basis for double patenting rejection, applicants are already under a duty to disclose this information to the PTO. *See Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003). It is not clear why the PTO needs or desires this information if there is no relevant disclosure and the application is not a possible candidate for a double-patenting rejection.

In any event, it appears as if the failure to disclose would result in a penalty to the applicant, even if the disclosure is not relevant and the application is not a possible candidate for a double-patenting rejection. In today's research environment, it is not uncommon for certain researchers to collaborate with other institutions or industry, or to conduct research and provide disclosures in wholly unrelated areas. As a result, the proposed rule would require any patent applications resulting from such disclosures to be identified to the PTO as part of the prosecution process if filed within the proscribed time frame. Such a disclosure, however, may be contrary to obligations of confidentiality owed to the industrial or institutional partner and provide no benefit to the PTO, especially if the disclosure is not relevant and the application is not a possible candidate for a double-patenting rejection.

The failure to make such a disclosure to the PTO, albeit inadvertent, could potentially arise at the university level, particularly if the inventions are not relevant and not a possible candidate for a double-patenting, and especially if the inventions are in unrelated technology areas. In such a case, it is not uncommon for the prosecution of such applications to be managed by separate individuals at the university and by separate patent counsel. To penalize the applicant that does not provide such a disclosure could be unnecessarily unfair, especially when the inventions are not relevant and the application is not a possible candidate for a double-patenting rejection. The proposed provision should be removed.

G. Double Patent Presumption: Patentably Indistinct Claims – 1.78(f)(2)

The proposed changes to Rule 1.78(f)(2) create a rebuttable presumption of patentably distinct claims in two or more applications that: (1) have the same filing date, (2) name at least

one common inventor, (3) are owned by the same person, and (4) contain a "substantial overlapping disclosure." The applicant must then either rebut the presumption to the satisfaction of the Director or file a terminal disclaimer. 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 one is even asserted.

Again, this contravenes clear precedent. The PTO has the duty to make a *prima facie* case of unpatentability before the burden shifts to the applicant to rebut that *prima facie* case. *See In re Oetiker, supra.* Additionally, the PTO does "NOT ... have authority to issue substantive rules" that result in non-examination of claims, and no authority to overrule the Federal Circuit's instructions on its burden to demonstrate unpatentability. See 35 U.S.C. § 2(b)(2)(A), and *Merck v. Kessler, supra* (emphasis in the original). As stated above, WARF believes it is improper for the PTO to substitute a "presumption" for its duty to examine a claim before it can reject it.

H. Request for Continued Examination (RCE) – 1.114

The proposed changes to Rule 1.114 would provide that an applicant may not file more than a single RCE in any application, and may not file any RCE in any continuing application other than a divisional application unless an acceptable petition is filed in accordance with Proposed Rule 1.78(d)(1)(iv). Because this proposed section essentially adopts the proposed requirements of Proposed Rule 1.78(d)(1), WARF restates its comments above.

IV. Comments on Proposed Rule: "Changes to Practice for the Examination of Claims in Patent Applications," *71 Fed. Reg. 61 (January 3, 2006)*

WARF opposes the proposed rule changes to the extent they limit the number of designated claims to ten, and also opposes the examination supporting document requirement to the extent it is overly burdensome and places the obligation of examining the application on the applicant. In addition to the general comments above, the following comments are offered on the specific provisions of the proposed rules.

A. Designation of Claims for Initial Examination – 1.75(b) (introductory text)

The proposed changes set forth in the introductory text of Rule 1.75(b) defer the examination of non-designated claims until the application is otherwise in condition for allowance. The proposed changes also provide that the mere presentation of a dependent claim in an application is not a designation of the dependent claim for initial examination. In other words, the proposed rule would require applicants to expressly designate all claims in an application as claims designated for initial examination when the number of total claims in the application is ten or less. The failure to so designate all claims will cause the non-designated claims to be held in abeyance until the independent claims are in condition for allowance.

The proposed rule does not make administrative sense, and the PTO should be required to examine all claims in an application if the total of number of claims is ten or less. To require the

applicant to indicate otherwise does not provide any benefit to the PTO, but does have a negative effect on the applicant if the applicant inadvertently fails to designate all of the claims in the application. In addition, limiting examination to only the independent claims is not likely to achieve the PTO's objective of efficiently examining applications as the examination of the entire set of claims is likely to result in a more thorough and reliable examination of the full scope of the invention. For example, if the applicant fails to designate all of the claims for initial examination, the examiner will be limited to examining only the independent claims. If the independent claims are deemed not patentable, the examiner will not examine the dependent claims, which may otherwise be patentable and would have been examined but for the failure of the applicant to properly designate them for initial examination. However, if designated later, the examiner will again have to revisit the newly designated claims in the context of the earlier examination to determine their patentability, thereby duplicating his/her efforts.

In addition, treating an undesignated claim differently than a designated claim during examination violates the fundamental principle that each claim is a separate definition of the invention. At the very least, this kind of different treatment will likely create additional uncertainty and risks for patent holders, thereby undermining patent quality, not improving it. For instance, the failure to examine the undesignated claims will likely create serious questions as to the presumption of validity given to such claims. As noted, those cases where the claims for initial examination are limited to ten claims, the 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 §§ 101 and 112. There will be no separate search of the prior art for such non-designated dependent claims in order to examine them as to novelty and non-obviousness under §§ 102 and 103. If a representative independent claim is subsequently invalidated on art during litigation, does that mean that the non-designated dependent claims that were allowed without any independent search of the art are also invalid?

Finally, it is questionable 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. Regardless, 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.

B. Requirement to File and Examination Support Document – 1.75(b)(1)

The proposed changes to Rule 1.75(b)(1) would require an applicant to submit an "examination support document" (ESD) if (1) the application contains, or is amended to contain, more than ten independent claims, or (2) the number of representative claims designated is greater than ten. The ESD will in effect require an applicant to conduct a search like that done by the examiner, searching U.S. patents and patent publications, foreign patent documents, and non-patent literature.

WARF 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, 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 PTO in the proposed rule, only 1.2% of all nonprovisional applications currently include more than ten independent claims. 71 Fed. Reg. at 61. It is WARF's understanding that approximately 90% of all nonprovisional applications currently filed contain six or fewer independent claims and forty or fewer total claims. It seems a far better approach would be to require 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 6 independent claims and 40 claims total) as to their novelty and non-obviousness over the art, rather than doing piecemeal searching.

This is especially true in view of the examination fees paid to the PTO, which include surcharges on independent claims in excess of three and total claims in excess of twenty. There is no explanation in the Proposed Rule as to why the surcharges are inadequate to provide the PTO with the resources needed to handle such cases. It was the understanding of WARF that the dollars provided through the recent fee increases would provide adequate resources (e.g., full funding) for handling all but the so-called "problem" cases. Thus, WARF questions whether the PTO has presented sufficient justification under these circumstances for imposing such limitations on **all** applicants.

C. Examination Support Document – 1.261

Proposed Rule 1.261 provides that the ESD must include (1) a detailed explanation of how the search was done (e.g., class and subclasses searched, databases searched and search logic), (2) an information disclosure statement, (3) for each reference cited, an explanation of the claim limitations for all claims and why they are patentable over each cited reference, (4) a statement of the utility for each independent claim, and (5) an explanation of where the limitations of each claim are supported in the written specification and drawings, including any applications related by filing date.

The objective of the ESD requirement is to require the applicant to "share the burden" resulting from the initial examination of more than ten representative claims. In particular, "an applicant . . . will be required to assist the PTO 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.

The proposed ESD procedure, however, is significantly more than simply "sharing the burden" for examination of such claims. Specifically, the 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). Under the proposed rules, however, the PTO would now establish a presumption of unpatentability by requiring the applicant to make the case for patentability of the invention in its ESD.

The proposed ESD itself goes beyond that which is expected of current patent examiners and includes significant ambiguities which bring into question the extent of the search and review required. Under the proposed search procedure, an applicant must certify that a thorough search has been conducted of U.S. patents and publications, foreign patent documents, and non-

patent literature. 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." In other words, the applicant would be required to somehow prove the "non-existence" of more pertinent art, clearly an impossible burden. There is no rule of reason applied to foreign patent searching and non-patent literature searching. Serious questions arise: 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 Federal Register 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. 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.

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, 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. It is unfair to require an applicant to prepare and file the ESD when the claims may be restricted by the PTO 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 thereafter.

D. Notice to File ESD or Cancel Independent or Designated Claims – 1.75(b)(3)

The proposed changes to Rule 1.75(b)(3) provide that the applicant will be notified if an application contains or is amended to contain more than ten independent claims, or the number of independent claims and designated dependent claims is greater than ten. The proposed rule change also provides that if prosecution of the application is not closed and it appears that omission is inadvertent, the applicant will have one month to either (1) file an ESD, (2) cancel the requisite number of independent claims and rescind the designation of the requisite number of dependent claims that necessitate the filing of an ESD, or (3) submit a suggested requirement for restriction with an election without traverse of an invention to which there are drawn fewer than ten independent claims and designated dependent claims.

The non-extendible one-month period to file an ESD is significantly too short given the required search and review necessary to file a proper ESD. Considering the demands typically

placed on search firms and prosecuting patent attorneys, and the docket they manage, a one-month time period seems unreasonable. There is no reason why the response period cannot be consistent with present office action practice where an applicant is provided a three-month response period and the option for three one-month extensions by payment of extension fees.

E. Patentably Indistinct Claims in Co-Pending Applications – 1.75(b)(4)

The proposed changes to Rule 1.75(b)(3) provide that if a nonprovisional application (1) contains at least one claim that is patentably indistinct from at least one claim in one or more other nonprovisional applications or patents, and (2) the one or more nonprovisional applications or patents either name at least one inventor in common or are owned by the same person as the nonprovisional application, or are subject to an obligation of assignment to the same person, and (3) the at least one patentably indistinct claim has support under 35 U.S.C. § 112, first paragraph, the PTO may require elimination of the patentably indistinct claims from all but one of the nonprovisional applications. If the patentably indistinct claims are not eliminated, the PTO will treat the independent claims and the dependent designated claims in the first nonprovisional application and in each of such other nonprovisional applications or patents as present in each of the nonprovisional applications for purposes of determining whether or not an ESD needs to be filed.

The proposed rule change raises again the question as to whether the PTO has the authority to ignore claims for which search and examination fees have been paid. The proposed rule would allow the PTO to limit the examination of the claims in separate applications for which fees have been paid if the applications include a patentably indistinct claim. Such a rule applies not only to those claims which are patentably indistinct, but also the other claims in the applications which are patentably distinct. To avoid such a limitation, the applicant would be forced to either cancel the patentably indistinct claims or file an ESD for each application.

To cancel the patentably indistinct claims in favor of pursuing such claims in a single application may give rise to other inventorship and ownership issues. It is well established that inventorship is determined on a claim-by-claim basis, but that ownership of a patent extends to all claims included therein. In certain circumstances, such as when improvements to an underlying invention have been developed through collaborative research, it may be of interest to the parties to pursue patent protection for the underlying invention and the improvements in different applications. In such a case, the inventor of the underlying invention would own outright the patent to the underlying invention, while the inventor and his collaborator would own jointly the patent to the improvement. If the PTO requires the patentably indistinct claims in these applications to be cancelled in favor of the claims in a single application, the PTO will thwart the interests of the parties by providing an ownership interest in a patent to a party not entitled to a right in that patent. Alternatively, if the PTO requires the claims in both applications to be counted towards those claims designated for initial examination, it will cause an unreasonable burden to be placed on the applicants to file an ESD or, as described above, otherwise ignore those claims for which search and examination fees have been paid.

F. Comment on Markush Groups – 1.75(b)(1)

The PTO has requested additional comments on how Markush-style claims should be counted for purposes of determining if an ESD should be filed. If the PTO adopts the proposed rules limiting the examination of claims to a designated set, the PTO should not also further limit the designated claims to count the various alternatives listed in Markush-style claims, whether individually or by commonality. To require each alternative to be counted as a single claim is quite unreasonable as the applicant will quickly exceed ten designated claims, thereby requiring the applicant to either file an ESD, reduce the scope of the patent application, or limit the examination of such claims to only that afforded to non-designated claims after allowance, all of which presents issues as described above. To require the applicant to establish commonality amongst the various alternatives would only further increase the burden placed on both the applicant and the PTO to determine whether or not alternatives are properly organized into a group having a common property, activity or core structure. The PTO should simply count Markush-style claims as a single claim if a limitation on claim examination is adopted.

V. Conclusion

The Patent Act, so instrumental in the successful transfer of university technology to the private sector, is predicated on the conviction that universities must be able to pursue their mission of creating and disseminating knowledge in an open environment, while concurrently protecting their inventions through strong intellectual property laws. As patent owners, universities depend on a high-quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer benefits and, as a result, so does the public. If the system is weakened, the benefits are reduced. With all due respect, it is WARF's position that the proposed rules represent a step backward for university patenting and commercialization efforts and their adoption would thwart the tremendous success universities have experienced in innovation.

WARF appreciates the opportunity to provide comments on the proposed rules and is available to assist the PTO in further developing patent practice and procedures.

Respectfully Submitted,

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