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Attn: Robert A. Bahr

Attached please find comments on the proposed rule change from the Intellectual Property Law Section of the North Carolina Bar Association.

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**Comments on Proposed Changes to Practice for Continuing Applications, Requests
for Continued Examination Practice, and Applications Containing Patentably
Indistinct Claims**

Docket No. 2005-P-066
RIN 0651-AB93

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Attn: Robert A. Bahr:

In response to the Proposed Rulemaking published January 3, 2006, at Federal Register, Vol. 71, No. 1, p. 49-61, The Intellectual Property Section of the North Carolina Bar Association ("NCBA/IP") submits the following comments. Separate comments are submitted concurrently herewith directed to the related claim examination proposed rulemaking.

Executive Summary:

The NCBA/IP opposes the proposed rulemaking on a variety of grounds. As an initial matter, the NCBA/IP submits that the United States Patent and Trademark Office ("Patent Office") lacks authority to implement the proposed rulemaking. Even were the Patent Office to have authority, the NCBA/IP submits that the proposed rulemaking will not work to meet the goals of reduced workload for the Patent Office or improved quality of examination. While not meeting the advanced Patent Office goals, the proposed changes will create significant new burdens and costs on applicants. In addition, the proposed rulemaking is contrary to the goal of improved harmonization with intellectual property law in other countries, in particular, with other PCT member countries. Should the Patent Office still desire changes related to continuing applications, the NCBA/IP requests consideration of alternatives, such as those of other Patent Cooperation Treaty ("PCT") member countries as discussed below.

At a minimum, the NCBA/IP submits the proposed rulemaking should be revised to: 1) expand the grounds allowing additional continuations/RCEs, 2) allow divisional applications to be filed claiming priority to the restricted parent through intervening previously filed divisionals, and 3) change restriction practice and increase Examiner training/quality control on restrictions/elections.

The Patent Office Lacks Statutory Authority:

The Patent Office derives its rulemaking authority from 35 U.S.C. § 2, which states, in pertinent part, that "The Office . . . may establish regulations, not inconsistent

with law . . .” (Emphasis added). As described below, it is clear that, under U.S. patent law, there are no statutory limits as to the number of continuing applications that can be filed. Accordingly, the Patent Office does not have the authority to adopt a rule that limits the number of continuing applications that can be filed.

35 U.S.C. §120 states that “[a]n application for patent for an invention. . . *shall* have the same effect, as to such invention, as though filed on the date of the prior application. . . .” Use of the word “shall” means that Congress intended the statute to represent the minimum requirements to obtain the benefit of the filing date of the prior application. An agency, like the Patent Office, may not promulgate a rule or regulation that adds a requirement that does not exist under the statute. 2 Am Jur 2d, §132, page 141. Likewise, a regulation that contravenes a statute is invalid. *See*, R & W Flammann GmbH v. U.S., 339 F.3d 1320 (Fed. Cir. 2003), *citing* United States v. Vogel Fertilizer Co., 455 U.S. 16 (1982). The Federal Circuit further has held that “[e]ven substantive rules cannot be promulgated that are contrary to statute. If the intent of Congress is clear, that is the end of the matter. . . .” *Travelstead v. Derwinski*, 976 F.2d 1244, 1250 (Fed. Cir. 1992), *citing* *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

It is also clear from the judicial interpretation of the statute that there are no statutory limits as to the number of continuing applications that can be filed. The C.C.P.A. has held that there is no statutory basis under 35 U.S.C. § 120 to limit the number of continuation applications allowed an applicant who otherwise complies with the requirements of 35 U.S.C. § 120. *See In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968); *In re Bogese II*, 303 F.3d 1362 (Fed. Cir. 2002) (holding that the PTO’s forfeiture of an applicant’s rights to a patent due to unreasonable delay was not arbitrary does not alter the holding of *Henriksen*).

It is even clear from recent Congressional actions that there are no statutory limits as to the number of continuing applications that can be filed. The Patent Reform Act of 2005, introduced in the House of Representatives last year, included a proposed new section 123 to the patent statute that, if enacted, would have granted the Director a limited authority to adopt regulations that placed limitations on the filing of continuation applications. *See*, The Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 8 (2005). The language of the proposed § 123 is as follows:

Sec. 123. Limitations on continuation applications

The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application. No such regulation may deny applicants an adequate opportunity to obtain claims for any invention disclosed in an application for patent.

The Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 8 (2005). It is clear from this proposed language that Congress appreciates that the Director does not have the statutory authority under the existing patent laws to limit the number of continuing applications that an applicant can file, and that Congress would need to grant the Director this additional authority to enable the Director to promulgate such rules.

The Patent Office appears to acknowledge that it has no authority to place an absolute limit on the number of copending continuing applications originating from an original application, but asserts, “The Office does not attempt that here.” Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 50 (January 3, 2006). While it is true that the Patent Office is not proposing a rule that would set a *per se* absolute limit on the number of continuing applications that could be filed, the proposed rules leave it to the Director’s discretion as to whether a further continuing application can be filed. If the Director exercises his discretion in any way and disallows the filing of a further continuing application, at that point in time the Director will exceed his authority as described above by placing a limit on the number of continuing applications that can be filed. Adopting the proposed rule changes therefore will expose the Patent Office to lawsuits challenging the agency’s authority to implement the rules.

For at least the foregoing reasons, the Patent Office does not have the authority to adopt a rule that limits the number of continuing applications that can be filed.

The proposed limitations to the filing of divisional applications exceed the Patent Office’s rulemaking authority

35 U.S.C. §121 states 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. 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.” As described above, the Patent Office has no authority to limit the number of continuation applications that comply with the statutory requirements of 35 U.S.C. § 120. Accordingly, the Patent Office also does not have the authority to adopt a rule that limits the number of applications to which a divisional application can claim priority.

The proposed limitations to the filing of Requests for Continued Examination exceed the Patent Office’s rulemaking authority

35 U.S.C. § 132 (b) states, “[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.” (Emphasis added). If Congress had intended to grant the Director the authority to use his discretion to limit the number of continued examinations that an applicant could request, Congress would have done so explicitly.

Congress has not done so, and accordingly, the Patent Office does not have the authority to adopt a rule that limits the number of Requests for Continued Examination that an applicant can file.

The proposed rule under which the Patent Office will presume claims to be patentably indistinct on the basis of overlapping subject matter in a concurrently filed application exceed the Patent Office's rulemaking authority

The Patent Office has the statutory burden to prove that a claimed invention is not patentable. 35 U.S.C. §102 states that a *person shall be entitled to a patent unless*. . . “

The Patent Office does not have the authority to shift the burden to applicant to prove the patentability of a claimed invention absent evidence that establishes a *prima facie* case that the claimed invention is not patentable. 35 U.S.C. §103. The mere existence of overlapping subject matter in the disclosure of co-pending applications does not establish a *prima facie* case that the claimed invention is not patentable.

Statutory double patenting can only occur when the subject matter claimed in different applications or in an application and an issued patent is the same. Obviousness-type double patenting requires that the claimed invention be obvious in view of the claims of the co-owned application or patent, not in view of the disclosure of the co-owned application or patent. Thus, mere overlapping subject matter in the disclosure does not establish a *prima facie* case of unpatentability. In fact, any similarity of disclosures, substantial or otherwise, is irrelevant to a determination of statutory or obviousness-type double patenting.

For at least the foregoing reasons, the proposed rule under which the Patent Office will presume claims to be patentably indistinct on the basis of overlapping subject matter in a concurrently filed application exceeds the Patent Office's rulemaking authority.

The Patent Office Goals Will Not be met:

Even were the Patent Office to have authority to limit continuing application practice as proposed, such a change would not address the Patent Office workload or quality of examination goals. As an initial matter, based on data presented by the Patent Office at various town hall meetings, only a limited number of cases would be affected by the proposed rulemaking. While this data may have been presented in anticipation of the outcry of objections from affected parties, it also follows that the potential benefit to the Patent Office is likewise, at best, very limited.

An unintended effect of the proposed rulemaking is that the number of applications filed will likely increase, not decrease, in light of the limitation of claiming back to only a single case. In other words, numerous divisional applications may be filed during pendency of the restricted parent application that might otherwise never have been filed. In some art units, where multi-way restrictions are common under current practice, divisionals may be filed in series, and additional information relevant to the desirability

of filing of further applications may be obtained during pendency of the preceding application. As a result, various cases will no longer be of interest to the applicants in light of information that was not available during pendency of the original restricted application.

Furthermore, in the chemical/biotechnology area, the problems created by the proposed rules are further exacerbated by the fact that, at the beginning of prosecution, the applicant may have thousands of target compounds. By the time the application is prosecuted, the applicant may have identified hundreds of patentable compounds that need to be claimed separately. In this scenario, with the early claiming burdens resulting from the proposed rules, the applicant may never have an opportunity to claim these compounds.

In addition to increased filings due to the limitations on divisional practice, applicants may be more likely to traverse restriction requirements. This will significantly add to the Patent Office's workload. Patent applicants may also choose to file PCT applications in order to avoid onerous restriction requirements.

In limiting the ability of applicants to resolve issues with an Examiner in a pending application, additional unintended consequences may burden the Patent Office. For example, the Patent Office notes the success of the Pre-appeal brief panel review procedure under current practice. However, under the proposed rulemaking, the number of petitions for such panel review is likely to increase dramatically. In other words, any savings in Patent Office resources provided by reducing the opportunity for continued prosecution before an Examiner will likely be offset by an increased burden in panel review, involving three examiners in each instance. This increased workload may, in turn, reduce the quality of those panel reviews, resulting in an increased number of appeals that proceed to the Board of Patent Appeals as a result of oversights by the reviewing panels.

The failure of the proposed rules to achieve their intended goals reflects an inadequate fact-finding prior to their proposal. Rules promulgated by the Patent Office are governed by the Administrative Procedure Act (the "APA"). *See, e.g., Dickinson v. Zurko*, 527 U.S. 150, 50 USPQ2d 1930 (1999). The APA creates an "obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based." *In re Sang-Su Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002). The comments accompanying the proposed rules are largely conclusory, omit significant areas of fact-finding, and do not contain a record of primary evidence from which the rule-making can be reviewed. For example, any proposal to limit continuation filings should at the very least examine the number of issued patents that have been found valid, enforceable and infringed, yet would have been constrained by the rules now being proposed if the rules had previously been in effect, and compare that number to the number of patents that have been found unenforceable due to inappropriate delay in the Patent Office. Further fact-finding is clearly required.

For at least the reasons discussed above, the NCBA/IP believes the proposed rulemaking will fail to reduce Patent Office workload or improve the quality of examinations. In addition, alternatives are available, as will be discussed below in the context of patent harmonization.

The Proposal is Contrary to Harmonization Goals:

The Patent Office has, on multiple occasions beginning in June, 1995, proposed significant rule changes. The stated goals for the June, 1995 rule changes related to the harmonization of the U.S. patent law with the rest of the world. Toward that end, the Patent Office has changed the rules to permit the filing of provisional patent applications, to limit patent term, and the like.

The Patent Office has now proposed rule changes regarding several aspects of patent prosecution, including limiting the availability of divisional filings to those filed during the pendency of a single priority application, and limitations on the ability to pursue continuation applications. The articulated goal of these proposed rule changes is to reduce the existing backlog of cases at the Patent Office.

To add to the difficulty in practicing patent law, in addition to these significant rule changes, there has been a flurry of court cases on issues as diverse as utility guidelines, enablement standards, prosecution history estoppel, prosecution laches, determination of claim scope, interpretation of claim terms, and the like. Accordingly, U.S. patent law has been in such a state of flux, it is extremely burdensome for patent applicants and patent practitioners to keep up with all of these changes, and to develop a cohesive patent strategy.

To some extent, rule changes are necessary and appropriate. However, it is our opinion that the Patent Office cannot keep changing their goals in ways that are totally inconsistent with important goals that the Patent Office has formerly identified. That is, the Patent Office should take appropriate steps to ensure that any proposed rule changes for the purported goal of reducing its backlog of cases are consistent with its previously stated goal of patent harmonization. At present, it appears that the Patent Office has proposed several rule changes that are totally inconsistent with the goal of patent harmonization.

It should not be necessary for any commentator to outline each proposed rule change that is inconsistent with the goal of reducing the Patent Office backlog and the goal of global patent harmonization to realize there is a problem. That said, one glaring example is the proposed rule on restriction practice. As proposed, a divisional application may claim the benefit of only a single prior-filed non-provisional application. That is, upon issuance of a parent application, all divisionals must have already been filed or they cannot be pursued. Currently, a divisional application can be filed as long as there is another co-pending related application.

In terms of patent harmonization, it is useful to consider the rules other nations/regions follow with respect to the filing of divisional applications. We commonly look to the law of other countries to see how our rules relate to those in the rest of the world. A brief review of Australian and Canadian patent law shows that multiple divisional applications may be filed in these jurisdictions, at any time during the pendency of a patent application claiming priority to a parent application. Thus, the previously stated goal of patent harmonization is thwarted by the proposed rule change.

Current Patent Office restriction practice is problematic itself. Apparently meaningless restrictions are already all too common, resulting in needless divisional patent filings. One potential cause of this problem is the current system at the Patent Office for determining the efficiency of patent examiners. This system awards “counts” for each application that is either issued or which is finally rejected, and, thus, rewards patent examiners for making onerous restrictions, forcing Patent Applicants to file multiple divisional applications. Thus, the Patent Office may have contributed to its own current problems.

U.S. Patent Examiners routinely make restrictions that would never be made under the “unity of invention standard” as applied in PCT patent applications. The Patent Office could consider permitting patent applicants to choose between the current restriction practice or a unity of invention standard in non-PCT national stage applications. This may reduce the number of divisional applications filed. If the Patent Office still saw the need to award counts, it could determine how many restrictions there would have been under the old practice, and subtract that from the number made under the unity of invention standard, and give the Examiner the benefit of the difference between these two numbers.

If the Patent Office is interested in capturing the fees it would otherwise obtain through the filing of multiple divisional applications, the PCT already provides a way to accomplish this goal without requiring the filing of multiple applications. That is, the PCT permits one to pay an additional search fee to search inventions that are restricted out under the unity of invention standard. Under this approach, the Patent Office would get additional fees, and the applicants could get all of the claims searched in a single application.

An alternative approach would be to adopt a “utility model” as used in Australia. In this type of application, a patent is issued without a search being performed, and the search is only conducted in the event that the patent is to be enforced. As relatively few patents are ever enforced, this approach has the potential to significantly reduce the Patent Office’s workload as it provides an alternative that applicants may pursue instead of a regular application. For example, in China, many more utility applications are filed than regular applications.

If one or more of these proposed approaches are not adopted, but rather, the proposed rule is adopted, there are several possible outcomes, as discussed above, that will result in the goals of the Patent Office not being met. None of these outcomes is

favorable to inventors or to the Patent Office. Because of this, we suggest the Patent Office drop the current proposed rulemaking and consider alternatives more suited to the previously stated goal of patent harmonization.

Proposed Amendments to the Proposed Rulemaking:

In light of the comments above, the NCBA/IP believes any detailed proposed revisions are not required. However, the NCBA/IP provides the following comments for consideration by the Patent Office in light of its current concerns.

1) Consider changes to restriction practice as discussed above, such as an applicant option to elect the unity of invention standard. Also, improved Examiner training and a reduction in the number of questionable restriction and election requirements could reduce the number of applications. The focus of restriction practice should be on the burden to the Patent Office of maintaining the claims in a single case, not on how many application disposition counts and fees can be extracted from a single application.

2) Allow divisional applications to claim priority back to an original restricted parent application through intervening applications, as with current practice. Otherwise, a significant number of applications may result that would not otherwise have been filed. This will clearly not help the Patent Office but will greatly burden applicants.

3) Expand the number of reasons allowed for filing more than a single continuation or RCE. For example, patent term extension reasons should be a basis for filing of additional continuations. In addition, filing of an Information Disclosure Statement (IDS) should be considered an allowed reason for filing an additional RCE where the applicant cannot make the certification required for submission of such art at the time of filing of the IDS. In light of current Rule 1.56 practice and inequitable conduct law, applicants are compelled to submit art to avoid being second-guessed as to the materiality of such art, regardless of when the art comes to the applicants' attention or, more accurately, whenever it comes to the attention of their patent prosecutor. In the context of corporate clients where a large number of individuals could fall within the scope of Section 1.56(c), it is a practical impossibility to reliably certify under Section 1.97(e) that none of these individuals ever had knowledge of the art being submitted.

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