DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

August 4, 2005

The Honorable John Doll
Acting Commissioner for Patents
United States Patent and Trademark Office
Attention: Robert A. Clark
Mail Stop Comments
Patents, Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Via: unity.comments@uspto.gov

Re: Requests for Comments on Green Paper Concerning Restriction Practice

Dear Mr. Doll:

The National Institutes of Health, Office of Technology would like to submit the following comments pursuant to the U.S. Patent and Trademark Office's request for comments (70 FR 32761 (June 6, 2005)). Consideration of these remarks is respectfully requested.

BACKGROUND: The National Institutes of Health (NIH), through its Office of Technology Transfer (OTT), has primary responsibility for the patenting and licensing of inventions arising from research activities of the intramural research programs of the NIH and the Food and Drug Administration (FDA). While OTT files patent applications in many technological disciplines, most inventions are within the chemical, biotechnological, and medical device arts.

PRESENT RESTRICTION PRACTICE: NIH recognizes the personnel intensive nature of the patent examination process and the administrative difficulties currently facing the U.S. Patent and Trademark Office (USPTO). We also understand that the USPTO uses restriction practice as one tool for managing this administrative burden. While it would be most desirable if all aspects of an invention were examined in a single application, it is clear that this is an untenable prospect under the current examination system. NIH also recognizes that examination under the Patent Cooperation Treaty (PCT) represents an added administrative burden because examiners must master PCT Unity of Invention standards in addition to the US restriction practice codified in 35 U.S.C. §121.

Dividing a single patent application into many via the restriction mechanism has a significant impact on the ability of inventors to actualize their inventions and bring new technologies to the public. USPTO statistics, as well as anecdotal reports, support the conclusion that most "inventions" that are "restricted" out of an initial patent application are never filed as divisional applications due to prosecution cost. Consequently, many technologies are left fallow.

NIH recognizes that it is difficult to measure examination quality and that each patent application should be viewed on its own merits. However, restriction practice can substantially affect the economic value of an invention. Business decisions need to be made at the earliest opportunity, making predictability in restriction activities essential. Although reasonable people can differ on how the claims within a particular patent application are restricted, we believe that consistency of restriction practice is most critical to the applicant. If an applicant can, with some reliability, predict what restriction will ensue from submission of a particular set of claims, then business, development, and funding activities will take place in a more informed manner.

SPECIFIC COMMENTS RELATING TO THE USPTO'S GREEN PAPER

1. The proposed inclusion of multiple "inventions" to be examined within a single patent application raises an issue regarding the competency of a single examiner to provide a high quality of examination for all inventions.

2. Disparity in restriction practice among examiners creates an atmosphere of uncertainty. The development of mechanisms for providing the public with consistent and legally supportable restrictions would assist in the management of IP portfolios.

The following comments specifically relate to options 1 and 2 of the green paper:

COMMENTS ON GREEN PAPER OPTION 1

Option 1 - Advantages:

1. The practice is clearly set forth, i.e., the maximum numbers of inventions and species that will be examined are clear and determined by applicant's willingness to pay.

2. The practice would insure uniformity among art units and work groups.

3. Unlike Option 2, the USPTO does not need to examine the applications on the merits (i.e., compliance with 35 U.S.C. § 112, 1st paragraph) prior to sending out a Restriction Requirement.

4. Reimbursement of fees based on successful protests is allowed.

5. Rejoinder of claims based on the *In re Ochiai* ruling is applicable.

Option 1 - Disadvantages:

1. If option 1 is implemented, it is unclear whether payment for examination of additional inventions would be equivalent to an admission by applicant that independent or distinct inventions have been claimed. Such an admission could affect later rejoinder. If this option is implemented, the USPTO should establish clear rules and procedures for avoiding inappropriate admissions and preserve rejoinder options.

2. The consequences of this option on patent validity and enforceability are unclear. If claims to several inventions are issued in a single application, it may create greater vulnerability for the patent holder because all of the inventions will stand or fall with the single patent.

3. Many new applications enter the USPTO via the Patent Cooperation Treaty and are therefore entitled to treatment under unity of invention standards. Maintaining unity of invention standards in concert with US restriction practice promotes complexity in examination.

4. The concept of paying for additional species changes historical Markush practice that required, upon a determination by the examiner that the elected species is patentable, that the search be extended to include a reasonable number of species and potential allowance of a generic claim without payment of additional fees. It is unclear how implementation of this option will affect this historical practice.

COMMENTS ON GREEN PAPER OPTION 2

Option 2 - Advantages:

1. Unity of invention is already familiar to U.S. examiners and is consistent with most foreign practice. Adoption of this option would avoid the confusion inherent in having two different restriction standards.

2. Consistency in application throughout the office would be more readily achieved.

3. Fewer divisional applications would be required.

4. It would maximize the patent term for related inventions.

Option 2 - Disdvantages:

1. It is unclear whether the requirement that additional inventions meet the standards of 35 U.S.C. § 112, 1st paragraph, novelty and unobviousness would constitute an ***examination on the merits.*** To the extent that this requirement would constitute an examination on the merits, it is unclear if the necessity for a restriction would be obviated because all inventions would appear to have already been examined. If this option is implemented, this question would need to be clarified in rules and procedures.

2. Similarly, if establishment of a lack of unity requires a substantive examination on the merits, would an office action that is limited to a presentation of a lack of unity be considered to be a first action on the merits that would allow the next office action to be made final? If this option is implemented, appropriate procedures should be clearly established and vetted.

3. There will need to be sufficient examination on the merits to determine enablement of the special technical feature. Would a determination of lack of enablement at this stage be appealable?

CONCERNS REGARDING BOTH OPTIONS 1 AND 2:

1. If multiple inventions are examined in a single application, a number of questions will need to be addressed, especially if "team examination" is implemented to provide necessary expertise. These questions include:

    - If multiple inventions are examined by different examiners, will there be concurrent or sequential examination?

    - How would one examiner's action impact the other(s)? How will discrepancies between examiners be resolved?

2. Would paying fees to get more inventions examined be construed as an admission that the inventions are patentably distinct?

3. If the Examiner alleges that the special technical feature fails to satisfy 35 U.S.C. §§ 112, 1st paragraph, 101, 102 and 103, will an office action limited to a presentation of a lack of unity also address other issues such as those under 35 USC 112, 2nd and 6th paragraphs?

4. Will applicants have the opportunity to traverse the examiner's finding regarding the special technical feature, and will any traversal be considered? (Note the comments regarding the need for the examiner to find that the original special technical feature complied with 35 U.S.C. §§112, 101, 102 and 103.)

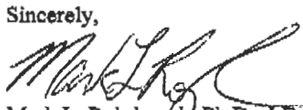
5. If traversal is permitted, will such traversal permit the applicant to identify a different special technical feature?

6. Options 1 and 2 and the front-loaded costs associated therewith, may create inequities between small and large entities because smaller entities may not have the financial resources to use these proposed mechanisms.

Conclusion

NIH applauds the USPTO's efforts to address restriction practice and appreciates the administrative burden currently confronting the USPTO. We encourage the USPTO to continue its efforts in addressing this critical examination area to provide an equitable solution that continues to provide incentives to innovate.

Sincerely,



Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer
National Institutes of Health