**From:**
**Sent:** Friday, August 13, 2010 2:23 PM
**To:** Restriction_Comments
**Cc:** Leilani Legaspi; Terry Kramer; Arlir Amado; Leo J. Jennings; Shoshana Marvin
**Subject:** Restriction Comments on behalf of Kramer & Amado, PC - Docket No. PTO-P-2010-0030

Please see attached comments regarding restriction practice pursuant to 75 Fed. Reg. 33,584.

Andreas Baltatzis
Director
KRAMER & AMADO, P.C.
Direct 703.519.9806
Main 703.519.9801
Fax 703.519.9802
E-Mail: abaltatzis@KramerAmado.com
www.KramerAmado.com

KRAMER | AMADO PC
PATENT RESEARCH SERVICES
INTELLECTUAL PROPERTY LAW

1725 DUKE STREET, SUITE 240
ALEXANDRIA, VIRGINIA 22314

TEL 703.519.9801
FAX 703.519.9802

KramerAmado.com

# United States Patent Office Docket No. PTO-P-2010-0030

**To:** Commissioner for Patents

**Attn:** Ms. Linda S. Therkorn
*Office of the Associate Commissioner for Patent Examination Policy*

**From:** Kramer & Amado, PC

**Re:** *Response to Request for Comments on Proposed Changes to Restriction Practice in Patent Applications* 75 Fed. Reg. 33,584 (2010)

**Date:** August 13, 2010

---

Dear Ms. Therkorn:

In reply to the questions presented by the United States Patent Office ("USPTO") in 75 Fed. Reg. 33,584 (June 14, 2010), Kramer & Amado PC submits the following comments.

## WHAT SHOULD BE INCLUDED IN AN OFFICE ACTION THAT SETS FORTH A RESTRICTION REQUIREMENT?

### Office actions must include particular reasons for restriction requirement(s)

Cost Shifting. Unwarranted restriction requirements result in prosecution delays, excessive claim fees and costs, and superfluous filing of multiple divisional patents further increasing backlog. It is manifestly unfair to shift the burden and cost of inadequate explanation of policy or untrained personnel to patent applicants. Because restriction practice has caused much confusion for Examiners with regard to the definition of serious burden and the definition of inventions as independent or distinct, the USPTO should include more specific and detailed language as to when restriction is required, and importantly, when restriction is *not* required, in the Examiner

notes that accompany such form paragraphs. The USPTO should further include language recommending against restriction unless *necessary* in order to decrease backlog.

Distinctness. To minimize applicant confusion, the USPTO should clarify the MPEP to indicate to examiners that a restriction requirement must *always* set forth the reasons why the inventions (or species) are independent or distinct. For example, the revisions to form paragraphs 8.01, 8.02, and 8.21 set forth in the Changes to Restriction Form Paragraphs memorandum of January 21, 2010, requiring examiners to include an explanation as to why the species or grouping(s) are independent of distinct, are a worthwhile attempt to clarify the process for examiners. However, as written, such revisions are inadequate.

Further, to help applicants avoid filing unnecessary divisional applications, the USPTO should revise the MPEP to require examiners to group together inventions or species that are not patentably distinct from each other, and require election of either a single invention or species, or a single grouping of patentably indistinct species. Some examiners needlessly require multiple restrictions (*e.g.*, 5-way, 6-way, 10-way restrictions) within a grouping of patentably indistinct species. The Office should therefore revise the MPEP to indicate that applicants should not be required to elect a specific invention or species within a grouping patentably indistinct species.

The following examples provide situations in which examiners consistently and inappropriately require restriction. Such examples should be included in form paragraph examiner notes as guidelines for Examiners.

**Example 1**: Species which are not patentably distinct from each other

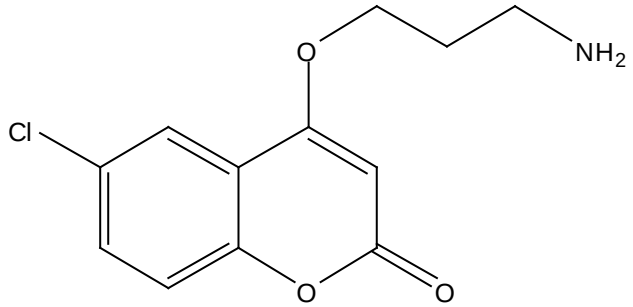
Claim 1. (original) An antibody XYZ comprising a detectable label.
Claim 2. (new) The antibody of claim 1, where the detectable label is rhodamine.
Claim 3. (new) The antibody of claim 1, where the detectable label is fluorescein.
Claim 4. (new) The antibody of claim 1, where the detectable label is acridine orange.
Claim 5. (new) The antibody of claim 1, where the detectable label is ethidium bromide.

For this example, it is being assumed that the labels are all known in the prior art and obvious over each other. If it would have been obvious to add any of the various fluorescent dyes to the antibody XYZ, then the examiner should not require an election of species or restriction amongst the dyes recited in claims 2-5, per MPEP 806.04(b) and 808.01.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict? at 16, (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

**Example 2**: Species are not patentably distinct because their scope is identical

Claim 1. A compound of formula I given by




Claim 2. The compound 6-chloro-4-(3-aminopropoxy)-1-benzopyran-2-one.
Claim 3. The chromane compound of formula I.

Claims 1, 2 and 3 are not distinct from each other as the claims merely define the same essential characteristics of a single disclosed embodiments of an invention.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: Restriction Practice Updates, at 29 (June 2010). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

**Example 3**: "Species" not distinct as claimed when the claims vary in breath or scope of definition.

Claim 1. An isolated nucleic acid molecule having SEQ ID No 1.
Claim 2. A vector comprising the nucleic acid molecule of claim 1.
Claim 3. A host cell comprising the vector of claim 2.

Claims 1, 2 and 3 are not distinct because claims 1, 2 and 3 vary in breadth or scope of definition.
claim 1 encompass (overlaps in scope with) claim 2.
claim 2 encompass (overlaps in scope with) claim 3.
claim 3 is encompassed by both claims 1 and 2.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: Restriction Form Paragraphs, at 31 (June 2010). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

## Serious Burden In the Absence of a Restriction

Clarifying the burden standard. The burden standard is poorly defined and is a significant cause for concern. Thus, it is vitally important that the USPTO require examiners to clarify why there would be a serious burden in the absence of a restriction requirement. A prevalent industry concern shared by both practitioners and applicants is that restriction is often required even where there would not be a serious burden on the examiner. Thus, the USPTO should clarify the burden requirement for examiners, and emphasize that the burden is properly rebutted when applicants provide appropriate showings and/or evidence. Although the revisions to form paragraphs 8.01, 8.02, and 8.21 set forth in the Changes to Restriction Form Paragraphs

memorandum of January 21, 2010, instruct the examiner to specify at least one reason the examination and search cannot be made without serious burden, the revisions are inadequate as written.

Burden is a rebuttable presumption. The MPEP provides that "[A] serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search …. [t]hat prima facie showing may be rebutted by appropriate showings or evidence by the applicant." *See* MPEP 803. However, appropriate showings or evidence by the applicant are often disregarded. Moreover, the MPEP does not provide guidance to the Examiners for determining what showings or evidence are appropriate.

Suggested search is an appropriate showing. For these reasons, the USPTO should require withdrawal of restriction requirement(s) when an applicant provides a suggested search scope that includes a reasonable amount of art dependent on the technology at issue. Further, the USPTO should also include guidelines in the examiner notes that clarify when serious burden is not present. The following MPEP provisions should be emphasized in Examiner training and practice:

*"Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper." MPEP 806*

*"Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction there between should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition." MPEP 806.03*

*"Where … the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions." MPEP 808.02*

*"If the subject matter was already examined together on the merits, it would not be a burden on the examiner to continue to examine the subject matter, even if it is directed to independent and distinct inventions."*

There is no "additional burden" for application examination. The USPTO should not revise the MPEP to include an explanation that "a serious burden on the examiner" would encompass a search burden as well as an examination burden. Determination of allowable inventions necessitates examination of the application as well as a search of the prior art. Patent Examiners have traditionally performed both functions. No new "additional burden" is present because the Examiner's role in determining allowable claims necessarily and obviously includes an examination of the application as well as the prior art.

**WHAT PRACTICE CHANGES WOULD RESULT IN MORE EFFECTIVE WAYS TO SEEK A HIGHER-LEVEL REVIEW OF RESTRICTION REQUIREMENTS?**

Pre-appeal brief conference as a model. The USPTO should consider using the Pre-Appeal Brief Conference practice as a model for higher-level review of restriction requirements. This successful program offers applicants an avenue to request a panel of examiners to formally review the legal and factual basis of the rejections in their application prior to the filing of an appeal brief. The Pre-Appeal Conference program spares applicants the added time and expense of preparing an appeal brief if a panel review determines an application is not in condition for appeal. In the context of restriction practice, a review panel would spare applicants excessive and unnecessary claim fees and divisional filings from unwarranted applications to avoid dedication of unclaimed material to the public if such a panel determines that restriction is unnecessary. Applicants currently must file a petition to obtain review of a simple Examiner's restriction, causing the file to leave the jurisdiction of the examining group. A Pre-Petition Restriction Conference would allow a panel in the group to review and overturn unnecessary restriction.

Petition. Although USPTO average restriction petition turn-around time about 100 days (*See* Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: FY09 Restriction Petition Update: Comparison of U.S. and National Stage Restriction Practice (December 2009)), very often, turn-around time is much longer. Practitioners and applicants are hesitant to file petitions, even where they can provide evidence that there is no serious burden or that the inventions are not separate and distinct, because of unpredictable lag time. Thus, the MPEP should be revised to include a time limit on the Office's decision on restriction-related petitions. For example, decisions on restriction petitions should be limited to three months or less.

**HOW COULD THE OFFICE CLARIFY REQUIREMENTS FOR RESTRICTION BETWEEN RELATED PRODUCT INVENTIONS OR RELATED PROCESS INVENTIONS WHERE THE RELATIONSHIP IS NOT SPECIFICALLY PROVIDED FOR IN MPEP CH. 800?**

Because Examiners frequently require unwarranted restrictions, the USPTO must provide guidelines in addition to what is presently available to examiners where the relationship is not specifically provided for in the MPEP. The USPTO should provide *examples* of commonly misapplied restriction requirements as guides for Examiners. Such illustrations should be included in a revised MPEP and/or form paragraph materials. Examples are provided below:

**Example 4**: Product/Process distinction

Claim 1. A process to reduce swelling by administering Compound X.

Claim 2. Compound X.

Using FP 8.20, the examiner reasoned that the product and process were distinct because the process can be accomplished by another materially different product, for example, applying ice.

This is incorrect. The process, as claimed, does not encompass application of ice. The process requires administration of Compound X. To establish distinction between Claim 1 and 2, the examiner must show that the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict? at 13 (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

**Example 5**: Election by original presentation practice does not apply to dependent claims

In response to a non-final art rejection on Claim 1, applicants filed the following amendment to add dependent claim 2.

Claim 1. A composition comprising Protein X.

Claim 2. A composition comprising Protein X and a detectable label.

Because claims 1 and 2 would not have been restrictable from each other had they been presented earlier, new claim 2 should be entered and examined along with Claim 1, per MPEP 821.03.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict, at 27 (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

An additional MPEP section is warranted. The USPTO should adopt the proposed MPEP section that would address restriction between related product/process inventions. It would behoove both examiners and applicants if support for a restriction requirement between two or more related process inventions could only be sustained if at least a two-way distinctness *and* a serious burden on the examiner would be present if restriction were not required. The proposed explanations set forth in 75 Fed. Reg. 33586 (June 14, 2010), that define when inventions can properly be considered distinct should be adopted as written.

## HOW COULD THE OFFICE IMPROVE REJOINDER PRACTICE?

The USPTO should adopt the proposed changes to rejoinder practice set forth in 75 Fed. Reg. 33586 (June 14, 2010). Furthermore, in the interests of decreasing the backlog at the USPTO by decreasing the number of pending applications, the USPTO should seek to promote rejoinder of as many claims as possible. Since a better understanding of the invention is often reached after substantive prosecution, the USPTO should require that the Examiner revisit their original restriction requirement in view of the art cited and analysis applied during the prosecution of the allowed claims. The USPTO should further require that the Examiner expressly state why the restriction continues to be appropriate, and where applicable, which claims are eligible for rejoinder or would be eligible for rejoinder after amendment.