Restriction Practice for

- Genus Claims
- Species Claims
 - Linking Claims and Markush Claims

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Objectives

- Basis for Requiring Restriction
- What is serious burden?
- Genus Claims
- Species Claims
- Linking Claims
- Markush Claims

Basic Restriction Guidelines

- Every restriction requirement has two criteria:
 - The inventions, as claimed, must be independent or distinct and
 - There would be a serious burden on the examiner if restriction were not required.



What is "Serious Burden"?

Basically, the search and examination for one of the claimed inventions is not required for another of the claimed inventions.

MPEP 808.02

Showing Serious Burden

- The examiner must provide reasons why a serious burden would exist in order to support a restriction requirement.
- A serious burden may be prima facie shown if the inventions have <u>separate classification</u> or <u>separate status in the art</u> when the inventions are classifiable together or a <u>different field of</u> <u>search</u> as defined in MPEP 808.02.
- The prima facie showing may be rebutted by the applicant.

Showing Serious Burden (cont.)

- Serious burden may be established based on a different field of search if it is necessary to search for one of the inventions in a manner not likely to result in finding art pertinent to the other invention(s), e.g.,
 - searching different classes/subclasses
 - searching different electronic resources
 - employing different search queries
 - A serious burden may be shown when the inventions are classified together if the examiner can explain how the searches differ.

FP 8.21.03

Obvious variants are not distinct inventions

- Distinctness between related inventions requires that at least one invention would not have been obvious over the other (i.e., that the inventions are not obvious variants).
- If the claims on their face are obvious over each other, restriction is not proper.
- For example of obvious variants, the application claims a method of connecting two parts together.
 - In one embodiment, the method requires a screw.
 - In a second embodiment, the method requires a nail.

The examiner should group together embodiments considered clearly unpatentable over each other; see MPEP 806.04(h).

When is Restriction Not an Option?

- If the search and examination of all the claims in an application can be made <u>without serious burden</u>, the examiner must examine all of the claims on the merits, even if the claims are drawn to independent or distinct inventions.
- If there is an express admission that the claimed inventions are <u>obvious over each other</u> within the meaning of 35 U.S.C. 103, restriction should not be required.

MPEP section 803

When is Restriction Not an Option?

When the inventions are *not distinct as claimed*, restriction is never proper. MPEP 806. For example:

Claim 1. A transgenic animal comprising SEQ ID No 1.
Claim 2. A transgenic rodent comprising SEQ ID No 1.
Claim 3. A transgenic mouse comprising SEQ ID No 1.

Restriction among claims 1, 2 and 3 is not proper because claims 1, 2 and 3 overlap in scope as genus, subgenus and species claim.

When is Restriction Not an Option?

When the claims define the same essential characteristics of a single disclosed embodiment of an invention, restriction is not proper. MPEP 806.03

For example, the specification discloses a compound of formula 1 having an x-ray diffraction pattern depicted in Figure 12.

Claim 1. A compound of formula 1.

Claim 2. A compound having the x-ray diffraction pattern as depicted in Fig 12.

One should not restrict claim 1 from claim 2 as both claims merely define the same essential characteristics of a single disclosed embodiment of an invention.

What are Species?

- Species are always specifically different embodiments of an invention.
- Species typically are disclosed as examples or figures in the specification.
- Species may be independent or related.
- MPEP 806.04(e).

What is a Genus claim?

- A claim that encompasses two or more disclosed embodiments (species) within its scope is considered to be a generic or genus claim.
 - See MPEP 806.04(d) and 806.04(e) for further definition.



Three Ways to Claim a Genus

 As a series of single species claims Claim 1. An orange. Claim 2. A lemon.

- As a Markush claim reading upon plural species Claim 3. A citrus fruit selected from the group consisting of an orange or a lemon.
- Encompassed by a linking claim which reads upon but is not necessarily limited to plural species disclosed in the specification.

Claim 4. A citrus fruit.

Test for Distinctness Between Species

Species are distinct when:

each species, as claimed, requires a mutually exclusive characteristic not required for the other species

<u>AND</u>

the species, as claimed, are not obvious variants of each other

MPEP 806.04(f)

Election of Species

- When an election of species is appropriate, FP 8.01 or 8.02 should be used to communicate the requirement. The examiner explains why the species are independent or distinct in these form paragraphs.
 - Use form paragraph 8.01 when claims limited to species are present
 - Use form paragraph 8.02 when no claims limited to species are present
- A restriction requirement may contain a requirement to elect a single invention and/or a provisional requirement to elect a species for examination purposes.

Linking Claims

- Definition: A linking claim is a claim which, if allowable, would prevent restriction between two or more otherwise properly divisible (restrictable) inventions. MPEP 809 and 809.03.
 - Linking claims and linked inventions are usually either product claims linking properly divisible product inventions, or process claims linking properly divisible process inventions.
 - Most kinds of Linking claims are
 - Genus claims linking species claims
 - Subcombination claims linking plural combinations that require the subcombination.
 - Restriction can be required when there are linking claims and claims to distinct inventions.
 - If a linked invention is elected, the linking claims are examined with the elected invention.

Example of a Linking Claim – Genus claim linking species claims

- Claim 1. A composition for reducing HIV viral load in an HIV infected patient, comprising an agent inhibiting viral replication and a pharmaceutically acceptable carrier. (genus linking claim)
- Claim 2. The composition of claim 1, wherein the agent is a polypeptide having the amino acid sequence of SEQ ID NO:2.
- Claim 3. The composition of claim 1, wherein the agent is a polynucleotide having the sequence of SEQ ID NO:5.
- Claim 4. The composition of claim 1, wherein the agent is 3,3'methoxysilyl-3,3'-organophosphate.

Restriction may be proper between claims 2, 3 and 4, however Claim 1 cannot be restricted from any of claims 2, 3 and 4. Claim 1 links claims 2, 3 and 4 and must be examined with the elected claim 2, 3 or 4.

Subcombination Linking Plural Combinations

- Claim 1. A kit comprising a first primer consisting of SEQ ID No 1 and a second primer consisting of SEQ ID No 2.
- Claim 2. A kit comprising a first primer consisting of SEQ ID No 1 and a second primer consisting of SEQ ID No 3.

Claim 3. A primer consisting of SEQ ID No 1.

The specification discloses that a primer consisting of

- SEQ ID No 1 can be used to detect HIV infection;
- SEQ ID No 2 can be used to detect influenza infection and
- SEQ ID No 3 can be used to detect hepatitis infection

Restriction between combination claims 1 and 2 may be proper. Claim 3 cannot be restricted from claim 1 or claim 2; it is a linking claim that will be examined with the elected combination.

MPEP 806.05(c)(subsection III)

Allowable Linking Claims

- When a linking claim is allowable, a restriction requirement between the inventions it links cannot be maintained.
 - The restriction requirement should be withdrawn, even if claims to non-elected linked inventions have been canceled.
 - Any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be <u>rejoined</u> and fully examined for patentability.
 - The Office must provide Applicant with an opportunity to reinstate canceled claims when a restriction requirement is withdrawn based on the allowability of the linking claim.

MPEP 809.03 and 821.04(a)

Practical Tips on Linking Claims

- When requiring a restriction involving linking claims per MPEP 809.03, the linking claims should not appear in the list of claims for any particular group. The linking claims appear only in FP 8.12.
- When requiring a restriction involving genusspecies linking claims per MPEP 809.02, there are no groupings and the linking claims appear as the generic claims in FP 8.01.

Overview of Markush Claims

- A Markush claim recites a plurality of alternatively usable substances or members.
 - Alternatives may be "selected from the group consisting of A, B and C."
 - The group of alternatives A, B, and C is commonly referred to as a "Markush group"

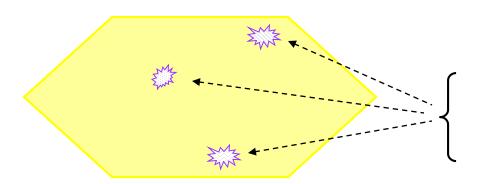
See MPEP 803.02

Example of a Markush Claim

Markush _____ {

Claim 1: A polymer blend comprising a natural rubber and a thermoplastic elastomer wherein said elastomer is <u>selected from the group consisting of</u> <u>polyurethane rubber, poly(styrene-butadiene) rubber</u> <u>and polyolefin rubber</u>.

In <u>**Pictorial**</u> representation, the area within the hexagon represents the polymer blend of a natural rubber and any thermoplastic elastomer.



Distinct species encompassed by claim 1: polyurethane rubber, poly(styrene-butadiene) rubber and polyolefin rubber.

Restriction of Markush Claim

- A Markush claim may include independent and distinct inventions and be subject to restriction. MPEP 803.02
- Restriction is proper where two or more members of the group are so unrelated and diverse that a prior art reference would anticipate the claim with respect to one of the members but would not render the claim obvious with respect to the other members.
- If restriction is proper, then a provisional election of a single species may be required. FP 8.01 or 8.02.

Markush Claim - Practical Tip

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.

MPEP 803.02

Markush Claim - Practical Tip

- Should the elected species be found allowable, the search/examination of the Markush type claim will be extended to determine the patentability of the claim, including the non-elected species.
- Should the elected species be found not allowable, the provisional election will be given effect and examination limited to the elected species.
- If examiner finds art on another species, the examiner does NOT extend search to cover ALL the non-elected species.
 - See MPEP 803.02

Markush Claim - Practical Tip

Should the examiner require election of a species recited in a Markush claim, and the elected species is canceled in response to a prior art rejection, such response is considered proper and the examination of the Markush type claim will be extended to the non-elected species to determine the patentability of the claim. The next Office action could be made final if appropriate (MPEP 706.07(a)).

MPEP 803.02 and 821.03

Examination Practice for Markush Claim versus Linking Claim

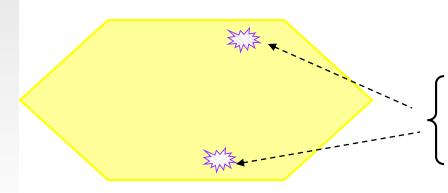
Markush Claim MPEP 803.02

Claim 1. A citrus fruit treated with fungicide XYZ, wherein the citrus fruit is an orange or a lime.Claim 2. The orange of claim 1.Claim 3. The lime of claim 1.

Linking Claim MPEP 809

Claim 1. A citrus fruit treated with fungicide XYZ.
Claim 2. The citrus fruit of claim 1, which is an orange.
Claim 3. The citrus fruit of claim 1, which is a lime.

In <u>**Pictorial</u>** representation, the area within the hexagon represents the scope of Linking Claim 1, any citrus fruit treated with fungicide XYZ.</u>



Distinct species encompassed by Markush claim 1: Orange treated with fungicide XYZ

Lime treated with fungicide XYZ

Markush Claim MPEP 803.02

Claim 1. A citrus fruit treated with fungicide XYZ, wherein the citrus fruit is an orange or a lime.Claim 2. The orange of claim 1.Claim 3. The lime of claim 1.

Linking Claim MPEP 809

Claim 1. A citrus fruit treated with fungicide XYZ.Claim 2. The citrus fruit of claim 1, which is an orange.Claim 3. The citrus fruit of claim 1, which is a lime.

For Markush Claims and Linking Claims:

(1) If the species of claim 2 is elected,

claim 3 would be withdrawn from consideration.

(2) If prior art is found against claim 2,

both claims 1 and 2 would be rejected.

Markush Claim MPEP 803.02

Claim 1. A citrus fruit treated with fungicide XYZ, wherein the citrus fruit is an orange or a lime.Claim 2. The orange of claim 1.

Claim 3. The lime of claim 1.

For Markush Claim Set:

(3A) If claim 2 is allowable, allow claim 2 and extend the search and examination for the species of claim 3.

(3B) Search and examination is limited to species of the Markush group of claim 1.

Markush Claim MPEP 803.02

Claim 1. A citrus fruit treated with fungicide XYZ, wherein the citrus fruit is an orange or a lime.Claim 2. The orange of claim 1.

Claim 3. The lime of claim 1.

For Markush Claim Set:

(4) If prior art is found against claim 3, bring claim 3 back into consideration and reject both claims 1 and 3 against the prior art.



Linking Claim MPEP 809

Claim 1. A citrus fruit treated with fungicide XYZ.
Claim 2. The citrus fruit of claim 1, which is an orange.
Claim 3. The citrus fruit of claim 1, which is a lime.

For Linking Claim Set:

(3) If claim 2 is allowable, then allow claim 2. The examiner may now extend the search and examination for <u>any species</u> of citrus fruit encompassed by claim 1.

Lemon treated with fungicide XYZ

Linking Claim MPEP 809

Claim 1. A citrus fruit treated with fungicide XYZ.Claim 2. The citrus fruit of claim 1, which is an orange.Claim 3. The citrus fruit of claim 1, which is a lime.

For Linking Claim Set:

(4A) If prior art is found, no matter that it is a species *other* than orange or lime, reject claim 1. Examiner is not required to extend the search and examination to claim 3.

Lemon treated with fungicide XYZ		
	BCP Slides for 3/6/07	32

Linking Claim MPEP 809

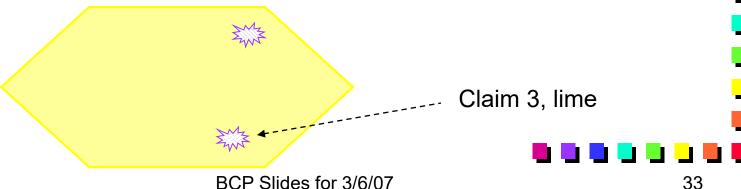
Claim 1. A citrus fruit treated with fungicide XYZ.Claim 2. The citrus fruit of claim 1, which is an orange.Claim 3. The citrus fruit of claim 1, which is a lime.

For Linking Claim Set:

(4B) If the prior art found is the species lime,

bring claim 3 back into consideration and

reject both claims 1 and 3 against the prior art.



Markush Claim MPEP 803.02

Claim 1. A citrus fruit treated with fungicide XYZ, wherein the citrus fruit is an orange or a lime.Claim 2. The orange of claim 1.Claim 3. The lime of claim 1.

Linking Claim MPEP 809

Claim 1. A citrus fruit treated with fungicide XYZ.Claim 2. The citrus fruit of claim 1, which is an orange.Claim 3. The citrus fruit of claim 1, which is a lime.

For both Markush Claim Set and Linking Claim Set:

(5) If claim 1 is allowable, then allow claims 1, 2 and 3.

Restriction Practice for

- Genus Claims
- Species Claims
 - Linking Claims and Markush Claims

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