

#### **Restriction Practice Updates**

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Form Paragraph (FP) Changes published 21 January 2010.

Applies to US applications only

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Election of Species requirements

- FP 8.01 when species claims are present
- FP 8.02 generic claims only

Reconsideration and Finality of a Restriction Requirement

- for both U.S. applications under 35 U.S.C. 111(a) and U.S. national stage entries under 35 U.S.C. 371.



# Restriction Form Paragraph Changes Memo dated 1/21/10

Memorandum Entitled "Changes to Restriction Form Paragraphs" published on 1/21/10.

FPs 8.01, 8.02, 8.21.01-8.21.03 and 8.22 currently in MPEP 800 (8<sup>th</sup> Edition, rev. 7, July 2008),

correspond to changed FPs 8.01, 8.02 and 8.21 in 1/21/10 Memo and Office action Correspondence Subsystem (OACS).

http://www.uspto.gov/patents/law/exam/20100121 rstrctn fp chngs.pdf



#### Do the FPs apply to Instant Application?

#### Yes, if

the application is filed under 35 U.S.C. 111(a), and plural inventions under 35 U.S.C. 121 are claimed.

Note: The claims of the application must be compared to determine if they describe plural independent or distinct inventions. MPEP 806.01

#### No, if

the application is filed in the National stage under 35 U.S.C. 371 and plural inventions are claimed.

PCT unity of invention standards must be used. See MPEP Chapter 1800 for details.



# Confusion over the 4/25/07 Restriction Form Paragraphs

The 1/21/10 memo supersedes the 4/25/07 memo and addresses confusion over

- (1) Whether applicant must always elect a single species?
- (2) Why the species are independent or distinct?
- (3) Why there would be a burden if election of species were not required?



### MPEP 803 Requires the Examiner to Provide Reasons

"Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases."

**MPEP 803** 



### MPEP 808 Requires the Examiner to Provide Reasons

"The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given."

**MPEP 808** 



#### Burden Discussed in 1/21/10 Memo

"As noted in MPEP 803 and 808.02, if the examination and search of all the claims in an application can be made without serious burden, restriction should not be required, even though they are drawn to independent or distinct inventions, including species."

1/21/10 memo



#### **Burden Discussed in MPEP 803**

"If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

**MPEP 803** 



### Prima Facie Showing of Burden Discussed in MPEP 803

"For purposes of the initial requirement, 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 as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant."

**MPEP 803** 



#### **Burden Discussed in MPEP 803.02**

"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.

In such a case, the examiner will not follow the procedure described below and will not require provisional election of a single species. See MPEP § 808.02."

MPEP 803.02



#### Burden Discussed in MPEP 808.02

"Where, however, 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."



#### Examiners are Now Required to Specify a Reason for Burden in FPs 8.01, 8.02 and 8.21

"To help ensure that all restriction requirements, including election of species requirement, set forth the requisite burden, and to give applicants notice of why there is burden, form paragraphs 8.01, 8.02 and 8.21 have been revised to provide for the examiner to specify at least one applicable reason.

Possible applicable reason are listed in the examiner notes to the form paragraphs, and are consistent with MPEP 808.02."

1/21/10 Memo



# Changes to Form Paragraph 8.21: To Establish Burden AND Requirement for Election and Means for Traversal for all Restrictions, other than an Election of Species

The examiner is required to provide reasons for burden.

"Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply: [1]."

Memo 1/21/10



# Three Examples of Reasons to Establish Prima Facie Showing for Burden

"In bracket 1 insert the applicable reason(s) why there is search and/or examination burden:

- --the inventions have acquired a separate status in the art in view of their different classification
- --the inventions have acquired a separate status in the art in view of their recognized divergent subject matter
- --the inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources or employing different search strategies or search queries.)"

MPEP 808.02 and Examiner Note 2 of FP 8.21 dated 1/21/10



### First Example of a Reason to Establish Prima Facie Showing for Burden

(A) Separate classification thereof: This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.



# Second Example of a Reason to Establish Prima Facie Showing for Burden

(B) A separate status in the art when they are classifiable together: Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.



### Third Example of a Reason to Establish Prima Facie Showing for Burden

of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes /subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.



# Two Form Paragraphs to Require an Election of Species in US Applications

"An examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim

- using form paragraph 8.01 when claims limited to species are present or
- using form paragraph 8.02 when no species claims are present.

See MPEP § 808.01(a) and § 809.02(a)."

MPEP 803.02



#### **Example of Single Species Claims; FP 8.01**

Claim 1. A composition comprising Compound X.

Claim 2. A composition comprising Compound Y.

Claim 3. A composition comprising Compound Z.

Claims 1, 2 and 3 are each limited to single species of compound X, Y or Z. The specification teaches that compounds X, Y and Z are all pain relievers.

Because single species claims are present in this claim set, if an election of species requirement is warranted, the examiner should use FP 8.01.



#### Example of a claim set which contains only generic claims; species are disclosed; FP 8.02

(Generic) Claim 1. A composition comprising a pain reliever.

(Markush) Claim 2. A composition comprising a pain reliever selected from the group consisting Compound X, Compound Y or Compound Z.

Claims 1 and 2 are both generic to more than one species of citrus fruit. When either claims 1 or 2 are present in a claim set that lacks any single species claims, if an election of species requirement is warranted, the examiner should use FP 8.02.



# Example of a claim set which includes both species and generic claims; FP 8.01

(Generic) Claim 1. A composition comprising a pain reliever.

(Markush) Claim 2. A composition comprising a pain reliever selected from the group consisting Compound X, Compound Y or Compound Z.

Claim 3. A composition comprising Compound X.

Claim 4. A composition comprising Compound Y.

Claim 5. A composition comprising Compound Z.

When both generic and species claims are present, if an election of species requirement is warranted, the examiner should use FP 8.01.

This holds true regardless of the presence of generic claim 1 or Markush claim 2.

This also applies regardless of the independent or dependent format of the species claims.



### Changes to Form Paragraph 8.01: Requiring an Election of Species; Species Claim(s) Present

The examiner is required to provide reasons for independence, distinction and burden.

"The species are independent or distinct because [2]."

"There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: [4]."

Applicant is required to elect "a species or a group of patentably indistinct species."

Memo 1/21/10



### Changes to Form Paragraph 8.02: Requiring an Election of Species; No Species Claim Present

The examiner is required to provide reasons for independence, distinction and burden.

"The species are independent or distinct because [3]."

"There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: [4]."

Applicant is required to elect "a species or a group of patentably indistinct species."

Memo 1/21/10



#### 37 CFR 1.146: Election of Species

"In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.

However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application."

37 CFR 1.146.



## Restriction Between Mutually Exclusive Species

"Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive.

Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first.

This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope."

806.04(f)



#### What does "Mutually Exclusive" Mean?

Claims to different species are <u>mutually exclusive</u> if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. MPEP 806.04(f)

This may also be expressed by saying that to require restriction between claims limited to species, the claims <u>must</u> not overlap in scope. MPEP 806.04(f)



# Three Types of "Species" which are Not Considered Patentably Distinct

Where the "species" are identical.

- the scope of the first and second "species" is identical.

Where the "species" overlap in scope.

 an embodiment within one "species" anticipates an embodiment in a second "species"

Where the species are distinct, (neither anticipates the other) but would be obvious over each other in view of 35 USC 103.



# Example: "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.

Practice Tip: If an examiner requires an election between the "Species" of Claims 1, 2 and 3, Applicant may wish to elect the "group of species of claims 1, 2 and 3" and traverse such a requirement using MPEP 806.03, 806.04(f) and 806.04(h).



#### Example: "Species" are not patentably distinct because the claims describe a single disclosed embodiment

Claim 1. A compound of formula 1.

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

The specification discloses a compound of formula 1 having an x-ray diffraction pattern depicted in Figure 12.

Claim 1 is not distinct from claim 2 as both claims merely define the same essential characteristics of a single disclosed embodiment of an invention.

Do not confuse claim limitations with required characteristics.

Claims are read in light of specification, but do not read limitations from specification into claims.

Practice Tip: If an examiner requires an election between the "Species" of Claims 1 and 2, Applicant may wish to elect the group of "species" of claims 1 and 2 and traverse the requirement to elect a single species using MPEP 806.03, 806.04(f) and 806.04(h).



#### Example: "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.

Practice Tip: If an examiner requires an election between the "Species" of Claims 1 and 2, Applicant may wish to elect the group of "species" of Claims 1, 2 and 3 and traverse the requirement to elect a single species using MPEP 806.03, 806.04(f) and 806.04(h).



#### Example: "Species" not distinct as claimed because the claims vary in breath or scope of definition.

Claim 1. A composition comprising an active agent selected from the group consisting of a protein, a cytokine, an interleukin, a leukocytotrophic hormone, IL-2, or a protein consisting of SEQ ID No 1.

The specification discloses that the amino acid sequence of IL-2 is SEQ ID No 1. IL-2 is an interleukin protein, which is a specific type of cytokine and functions as a leukocytotrophic hormone.

For this reason, the "Species" recited in Claim 1 are not distinct because they vary in breadth or scope of definition.

Practice Tip: If an examiner requires an election between the "Species" recited in the alternative of Claim 1, upon election, Applicant may wish to traverse using MPEP 806.03, 806.04(f) and 806.04(h).



### Example: Treatment of "Species" which are Obvious over Each Other

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).



# The examiner should group together species considered unpatentable over each other.

"Election of species should not be required between claimed species that are considered clearly unpatentable (obvious) over each other. In making a requirement for restriction in an application claiming plural species, the examiner should group together species considered clearly unpatentable over each other."

MPEP 808.01(a) Emphasis in original.



### Traversal on the Grounds that the Species are Obvious Variants over Each Other.

"Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case.

In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species."

1/21/10 Memo



#### An Expressed Admission of Obviousness

"If there is an express admission that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required. In re Lee, 199 USPQ 108 (Comm'r Pat. 1978).

**MPEP 803** 



### Implications of an Expressed Admission of Obviousness

Claim 1. A method of attaching Part A to Part B using a nail.

Claim 2. A method of attaching Part A to Part B using a screw.

Claim 1 and Claim 2 are distinct because the method of using a nail does not anticipate using a method of using a screw and vice versa.

However, if applicants make the admission that claims 1 and 2 would be obvious over each other in view of 35 USC 103, and if the examiner found prior art (Church) teaching a method of fixing part A to Part B using a nail, the examiner may set forth an obviousness rejection of claim 2 under 35 USC 103 over the Church reference in view of applicants admission.



# Traversal and Reconsideration in view of the Claims as Currently Amended.

37 CFR 1.143 Reconsideration of requirement.

If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor. (See § 1.111).

37 CFR 1.111(c)

In amending in reply to a rejection of claims in an application or patent under reexamination, the applicant or patent owner must clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. The applicant or patent owner must also show how the amendments avoid such references or objections.



# Traversal and Reconsideration of a Restriction Requirement

#### Combination/Subcombination

"If the combination claims are amended after a restriction requirement such that each combination, as claimed, requires all the limitations of the subcombination as claimed, i.e., if the evidence claim ABbr is deleted or amended to require Bsp, the restriction requirement between the combination and subcombination should not be maintained. MPEP 806.05(c)."

#### Subcombinations Useable Together:

"If applicant proves or provides an argument, supported by facts, that the other use, suggested by the examiner, cannot be accomplished or is not reasonable, the burden is on the examiner to document a viable alternative use or withdraw the requirement." MPEP 806.05(d).



# Traversal and Reconsideration of a Restriction Requirement

#### Process and Apparatus

"If applicant proves or provides convincing argument that there is no material difference or that a process cannot be performed by hand (if examiner so argued), the burden is on the examiner to document another materially different process or apparatus or withdraw the requirement." MPEP 806.05(e)

Process of making and product made:

"If applicant convincingly traverses the requirement, the burden shifts to the examiner to document a viable alternative process or product, or withdraw the requirement." MPEP 806.05(f)



# Traversal and Reconsideration of a Restriction Requirement

#### Apparatus and Product Made

"If applicant either proves or provides convincing argument that the alternative example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement. MPEP 806.05(g)

#### Product and Process of Using:

"If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement. MPEP 806.05(h)



#### Making a Restriction Requirement FINAL

"Where the initial requirement is traversed, it should be reconsidered.

If, upon reconsideration, the examiner is still of the opinion that restriction is proper, it should be repeated and made final in the next Office action. (See MPEP § 803.01, emphasis added.)

In doing so, the examiner should reply to the reasons or arguments advanced by applicant in the traverse."

MPEP 821.01



#### **Questions?**

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