



UNITED STATES PATENT AND TRADEMARK OFFICE

When is it NOT Appropriate to Restrict?

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35 U.S.C. 121 Divisional applications.

If 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.

Emphasis added



§ 1.141 Different inventions in one national application

- (a) **Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.**

Emphasis Added



§ 1.142 Requirement for restriction

- (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division).**

Emphasis Added



§ 1.145 Subsequent presentation of claims for different invention.

Subsequent presentation of claims for different invention.
If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

Emphasis Added



§ 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...

Emphasis Added



§ 1.146 Election of species.

...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.

Emphasis Added



MPEP 803 .01 Importance of Restriction

Since requirements for restriction under 35 U.S.C. 121 are discretionary with the Director, it becomes very important that the practice under this section be carefully administered. Notwithstanding the fact that this section of the statute apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, **IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION...**

MPEP 803.01, Emphasis in original



MPEP 803 .01 Review by Examiner with at Least Partial Signatory Authority

... Therefore, to guard against this possibility, only an examiner with permanent full signatory authority or temporary full signatory authority may sign final Office actions containing a final requirement for restriction. An examiner with permanent partial signatory authority or temporary partial signatory authority may sign non-final Office actions containing a final requirement for restriction.

MPEP 803.01



MPEP 803

Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j)).

MPEP 803, Emphasis added



General Principles Relating to Distinctness or Independence

The general principles relating to distinctness or independence may be summarized as follows:

- (A) Where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper, MPEP § 806.06.
- (B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper.
- (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.
- (D) A reasonable number of species may be claimed when there is an allowable claim generic thereto. 37 CFR 1.141, MPEP § 806.04.

MPEP 806, emphasis added



Compare Claimed Subject Matter

In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence.

MPEP 806.01



Example: 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).

MPEP 806.01



Single Embodiment, Claims Defining Same Essential Features

Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween 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



Species Must Be Patentably Distinct From 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 806.04(b)

Election of species should not be required between claimed species that are considered clearly unpatentable (obvious) over each other. MPEP 808.01



Example: 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.



An Express 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



Sufficiently Few in Number or So Closely Related

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



Provisional Election of Species

In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. 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



Examination Practice for a Markush Claim

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability.

MPEP 803.02



Examination Practice for a Markush Claim

If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

MPEP 803.02, Emphasis added



If Prior Art is Found On Elected Species

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.

MPEP 803.02, Emphasis added



If Prior Art is Found on Nonelected Species

If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

MPEP 803.02, Emphasis added



Removing an Elected Species from Markush Claim

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim.

MPEP 803.02



Two Exceptions to Election by Original Presentation Practice

The (election by original presentation) practice set forth in 821.03 is not applicable where a provisional election of a single species was made in accordance with MPEP § 803.02 and applicant amends the claims such that the elected species is cancelled, or where applicant presents claims that could not have been restricted from the claims drawn to other elected invention had they been presented earlier.

MPEP 821.03



Example: Election by Original Presentation Practice Does not Apply to Markush Claims

In response to a non-final art rejection on elected species of Protein X, applicants filed the following amendment to remove Protein X from the alternative of Claim 1.

Claim 1. A composition comprising [Protein X,] Protein Y or Protein Z.

Because applicant has amended the claims such that the elected species is cancelled from a Markush claim, the amended claim should be entered and examined, per MPEP 821.03. The Examiner extends the examination of the claim to the extent necessary to determine the patentability of the Markush claim, per MPEP 803.02.



Example: 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.



Example: Election by Original Presentation Practice Does not Apply to Newly Added Species Claims

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

Claim 1. A composition comprising Protein X.

Claim 2. A composition comprising Protein X and a compound having Formula I, II or III.

If claim 1 and claim 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.

The examiner may, however, require an election of species amongst the newly added alternative Formulas of Claim 2 using FP 8.02, per 808.01.



Election of Species Required After an Action on the Merits

If applicant presents species claims to more than one patentably distinct species of the invention after an Office action on only generic claims, with no restriction requirement, the Office may require the applicant to elect a single species for examination.

MPEP 808.01



Election of Species Required After an Action on the Merits

In applications where only generic claims are presented, restriction cannot be required unless the generic claims recite or encompass such a multiplicity of species that an unduly extensive and burdensome search would be necessary to search the entire scope of the claim. See MPEP § 803.02 and § 809.02(a).

MPEP 808.01



Importance of Burden

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 803.02

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. MPEP 808.02



Example: Restricting Amongst Examined Claims

Following an first action on the merits of all claims, the application is transferred to a second examiner who requires restriction amongst the already-examined claims.

This is not proper.

**If the Office has issued an Office action examining all the claims on the merits, a subsequent examiner cannot establish burden necessary to support the requirement.
MPEP 803.02 and 808.01**



Full Faith and Credit For Previous Examiner's Search and Action

When an examiner is assigned to act on an application which has received one or more actions by some other examiner, full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general the second examiner should not take an entirely new approach to the application or attempt to reorient the point of view of the previous examiner, or make a new search in the mere hope of finding something.

See MPEP § 704.01 and 719.05



Linking Claims Must be Examined with the Linked Invention

The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.



Retaining Claims to Non-elected Inventions

Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions.



Allowance of Linking or Generic Claims

Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or requires all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment.



Indicate Exactly How Application Is To Be Restricted

The examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121. *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003). See also MPEP § 804.01.



Make Requirement Complete

When making a restriction requirement every effort should be made to have the requirement complete.

MPEP 815



Applicant Must Make their Own Election

Applicant must make his or her own election; the examiner will not make the election for the applicant. 37 CFR 1.142, 37 CFR 1.143.

MPEP 818.03



Reconsideration of the Restriction Requirement at Time of Allowance

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder.

Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

MPEP 821.04



Rejoined claims must be fully examined for Patentability

Rejoined claims must be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

MPEP 821.04



When Requirement for Restriction Must be Withdrawn

The requirement for restriction between the rejoined inventions must be withdrawn.

Any claim(s) presented in a continuation or divisional application that are anticipated by, or rendered obvious over, the claims of the parent application may be subject to a double patenting rejection when the restriction requirement is withdrawn in the parent application. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

MPEP 821.04



How Applicants Can Preserve their Rights under 35 USC 121, third sentence

If applicant cancels all the claims directed to a nonelected process invention before rejoinder occurs, the examiner should not withdraw the restriction requirement. This will preserve applicant's rights under 35 U.S.C. 121.

MPEP 821.04(b)



Rejoinder Practice Applies to National Stage Applications filed in compliance with 35 USC 371

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder.

MPEP 1893.05(d)



Rejoinder Practice Applies to National Stage Applications filed in compliance with 35 USC 371

Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined.

Any nonelected processes of making and/or using an allowable product should be considered for rejoinder.

MPEP 1893.05(d)



Examination of Patent Applications Containing Nucleotide Sequences, US applications

For national applications filed under 35 USC 111(a), polynucleotide molecules will be subject to the standards for requiring a restriction or a provisional election of species set forth in MPEP Chapter 800 (except for 803.04 which is superseded by this Notice).

Polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for any other type of molecule.

OG Notice published March 27, 2007



Examination of Patent Applications Containing Nucleotide Sequences OG Notice, National Stage Applications

For international applications (PCTs) and national stage filings of international applications under 35 USC 371, unity of invention determination will be made in view of the PCT rules.

Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art.

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Questions?

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