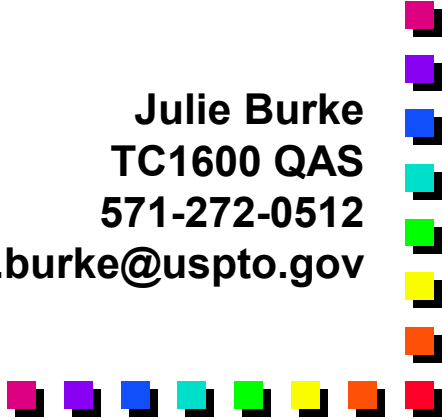




# REJOINDER PRACTICE

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# Objectives

- 1) To identify and handle situations where the restriction requirement should be withdrawn and non-elected inventions rejoined for examination.
- 2) To Identify the two types of rejoinder
  - Within same statutory category
  - Processes rejoined to allowable products
- 3) To understand the similarities between the two types of rejoinder.
- 4) To understand the differences between the two types of rejoinder.

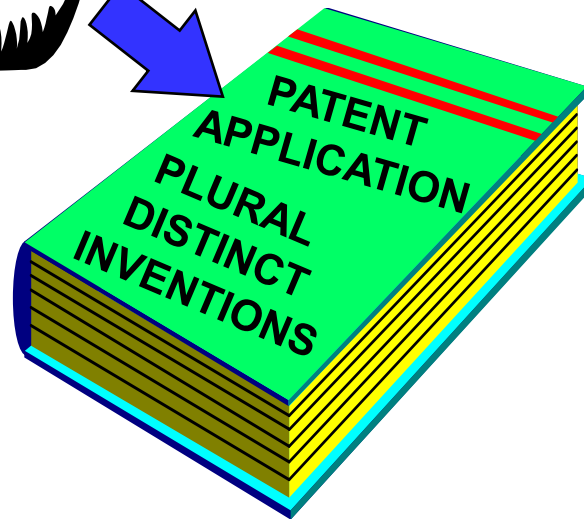
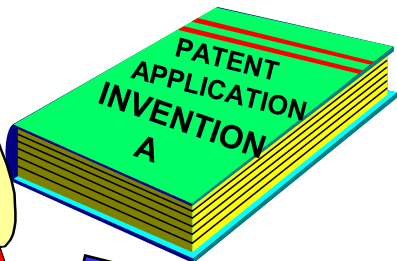
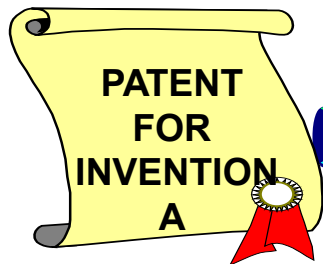
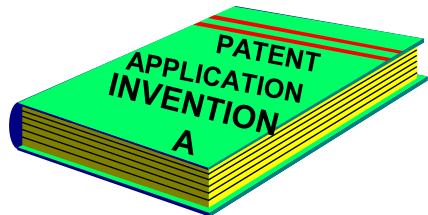


# 35 U.S.C. 101

**“Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,...”**



35 U.S.C. 101:  
WHOEVER INVENTS  
...MAY RECEIVE  
A PATENT



**DOUBLE PATENTING:**

- STATUTORY TYPE
  - 35 USC 101
- NON-STATUTORY
  - Obviousness-type Double Patenting

ONE  
PATENT  
FOR  
EACH  
INVENTION

**RESTRICTION**  
**35 U.S.C. 121**



# So what is *RESTRICTION*?

Restriction is the practice of requiring an applicant to elect a single invention for examination when an application discloses and claims plural inventions.

MPEP 802.02



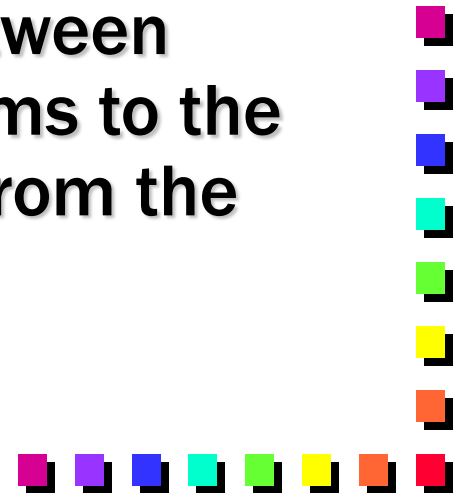
# What is “Rejoinder”?

- The process of withdrawing a restriction requirement between an allowable elected invention and a nonelected invention when all claims to a nonelected invention depend from or otherwise require all the limitations of an allowable claim. Rejoined claims must still be fully examined.
- MPEP 821.04



# Criteria for Distinct Inventions at Restriction, Examination and Allowance

- For restriction and examination, distinctness between related inventions requires that at least one invention would not have been obvious over the other.
- At time of allowance, distinction between related inventions requires that claims to the non-elected inventions are distinct from the elected, allowable invention.



# Historical Basis for Rejoinder within the same statutory category of invention

§ 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.



# Historical Basis for Rejoinder of Processes with Allowable Product

In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and In re Brouwer, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product.

In both cases, the Federal Circuit held that the use of per se rules is improper in applying the test for obviousness under 35 U.S.C. 103. Rather, 35 U.S.C. 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art.

“A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious.” TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc., 336 F.3d 1322, 1327, 67 USPQ2d 1511, 1514 (Fed. Cir. 2003).

MPEP 2121



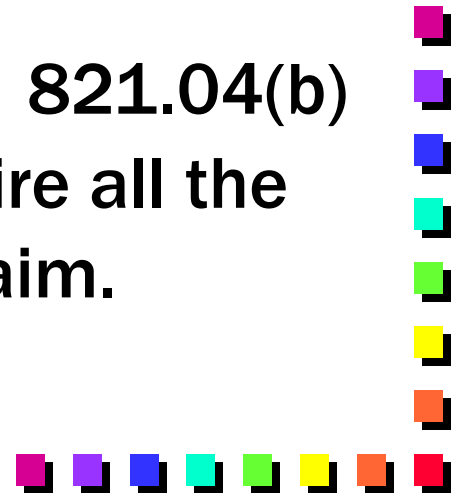
# Two Types of Rejoinder

## Same Statutory Category of Invention. 821.04(a)

- Allowable subcombination claim linking otherwise restrictable combination claims
- Allowable generic claim linking otherwise restrictable species

## Different Statutory Category of Invention 821.04(b)

- Rejoinder of process claims that require all the limitations of an allowable product claim.



## Rejoinder Practice applies to:

- 1) utility patent applications filed under 35 U.S.C. 111(a) and
- 2) national stage applications filed under 35 U.S.C. 371.

This slide applies to both types of rejoinder: same and different statutory categories of invention

**MPEP 821.04 and 1893.03(d)**



## Restriction Form Paragraphs include advice and guidance for applicants concerning

- opportunities for rejoinder and
- cautions placing applicants on notice about potential downstream double patenting.

This slide applies to both types of rejoinder: same and different statutory categories of invention





**Rejoinder Practice involves re-evaluation of the restriction requirement at time of allowance.**

**When all claims directed to the elected invention are in condition for allowance, the nonelected invention(s) should be considered for rejoinder.**

**The examiner is not required to rejoin claims to non-elected inventions until all claims directed to the elected invention are in condition for allowance.**

This slide applies to both types of rejoinder: same and different statutory categories of invention

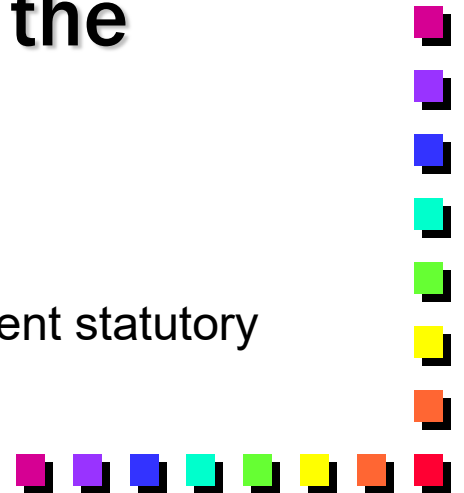
**MPEP 821.04**



# For Both Types of Rejoinder (cont'd)

- Rejoinder is the process of withdrawing a restriction requirement between an allowable elected invention and a nonelected invention and examining the formerly nonelected invention on the merits.

This slide applies to both types of rejoinder: same and different statutory categories of invention



# Eligibility for Rejoinder

- In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.
- Claims that do not require all the limitations of an allowable claim remain withdrawn from consideration.

This slide applies to both types of rejoinder: same and different statutory categories of invention



# Allowability of Rejoined Claims

- 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.

This slide applies to both types of rejoinder: same and different statutory categories of invention

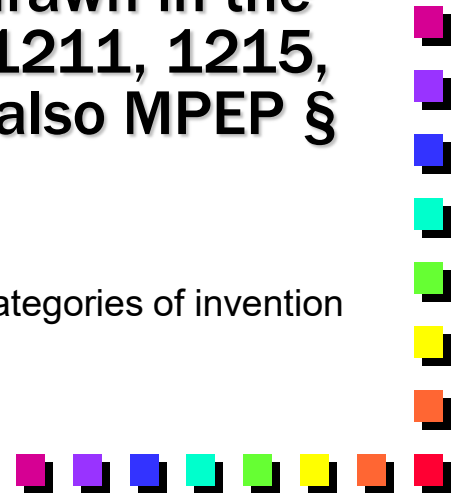
**MPEP 821.04**



# Double Patenting Concerns

- The requirement for restriction between rejoined inventions must be withdrawn.
- Any claims 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 non-statutory double patenting rejection if the restriction requirement has been 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.

This slide applies to both types of rejoinder: same and different statutory categories of invention



# Making Second Action Final

If rejoinder occurs after the first Office action on the merits, and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final where the new ground of rejection was necessitated by applicant's amendment.

This slide applies to both types of rejoinder: same and different statutory categories of invention

See MPEP § 706.07(a).



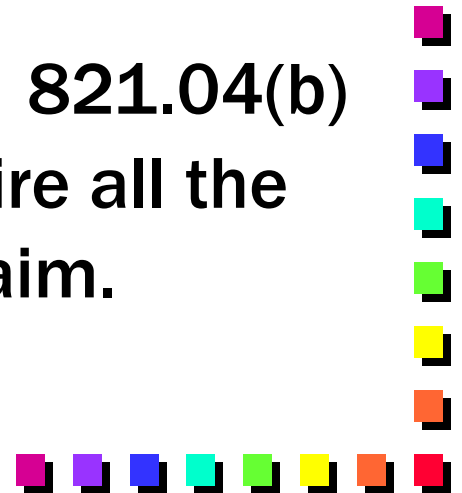
# Two Types of Rejoinder Practice

## Same Statutory Category of Invention. 821.04(a)

- Allowable subcombination claim linking otherwise restrictable combination claims
- Allowable generic claim linking otherwise restrictable species

## Different Statutory Category of Invention 821.04(b)

- Rejoinder of process claims that require all the limitations of an allowable product claim.



## Rejoinder Between Related Inventions in the same Statutory Category (i.e., “Products” or “Processes”)

- Rejoining claims to a combination that requires all the limitations of an allowable subcombination
- Rejoining claims to species which are encompassed by an allowable generic claim
- See MPEP 821.04(a)

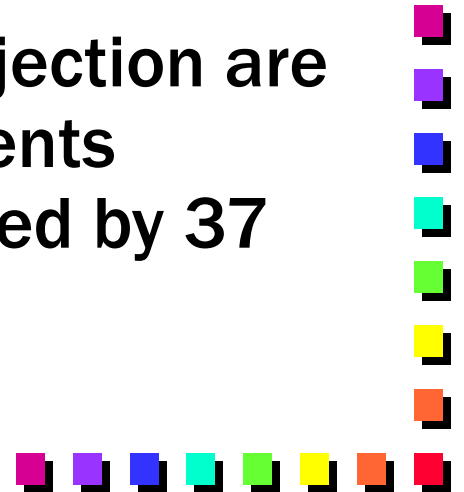




## Rejoinder within same statutory category of invention

- An amendment presenting additional claims that depend from or otherwise require all the limitations of an allowable claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.
- Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

See MPEP 821.04(a)



## Rejoinder within same statutory category of invention

- Once the elected invention is found to be allowable, an examiner should use FP 8.45, 8.49, or 8.50 to advise applicant of the status of the other inventions.

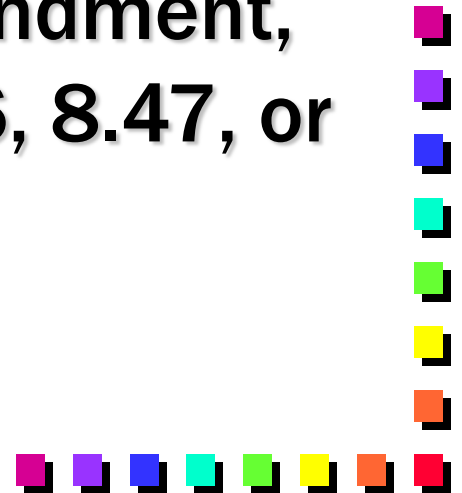
See MPEP 821.04(a)



## Rejoinder within same statutory category of invention

- If nonelected claims which depended from or otherwise required all the limitations of an allowable claim were cancelled by applicant and may be reinstated by submitting the claims in an amendment, the examiner should use FP 8.46, 8.47, or 8.47.01 to inform applicant.

MPEP 821.04(a)



# Rejoinder within same statutory category of invention

- Note that each additional invention is considered separately.
- When claims to one nonelected invention depend from or otherwise require all the limitations of an allowable claim, and claims to another nonelected invention do not, applicant must be advised as to which claims have been rejoined and which claims remain withdrawn from further consideration.

MPEP § 821.04(a)



## Rejoinder within same statutory category of invention

- Where the application claims an allowable invention and discloses but does not claim an additional invention that depends on or otherwise requires all the limitations of the allowable claim, applicant may add claims directed to such additional invention by way of amendment pursuant to 37 CFR 1.121.
- Amendments submitted after allowance are governed by 37 CFR 1.312.
- Amendments submitted after final rejection are governed by 37 CFR 1.116.

MPEP § 821.04(a)



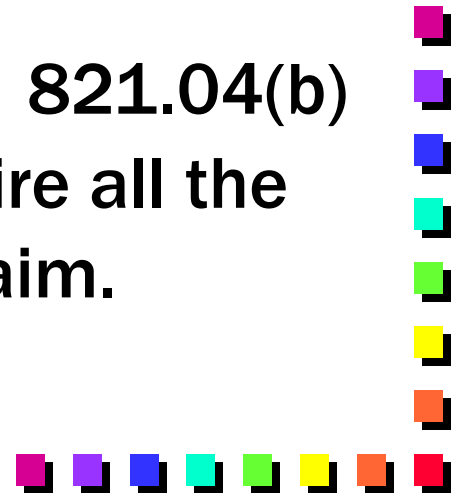
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- Allowable generic claim linking otherwise restrictable species

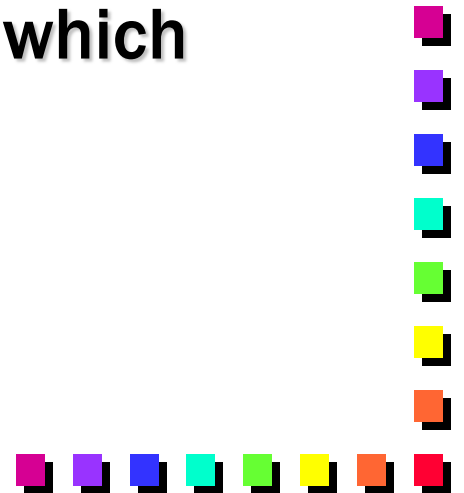
## Different Statutory Category of Invention 821.04(b)

- Rejoinder of process claims that require all the limitations of an allowable product claim.



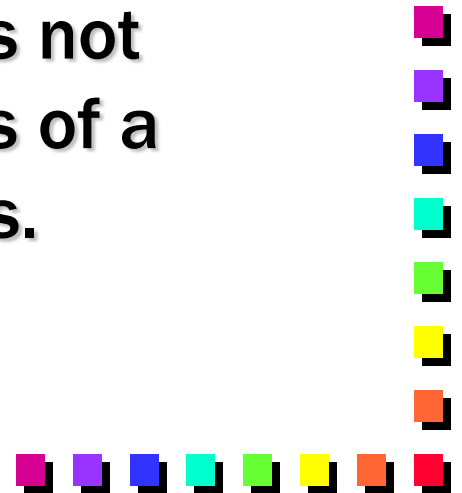
# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- Rejoining a process of making a product which requires an allowable product
- Rejoining a process of using a product which requires an allowable product
- See MPEP 821.04(b)



## Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- Applicant must elect the product invention.
- Non-elected Products are not considered for rejoinder upon allowance of a process invention.
- Allowability of a process invention does not correlate with novelty or unobviousness of a product made by or used in the process.
- See MPEP 821.04(b)





# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

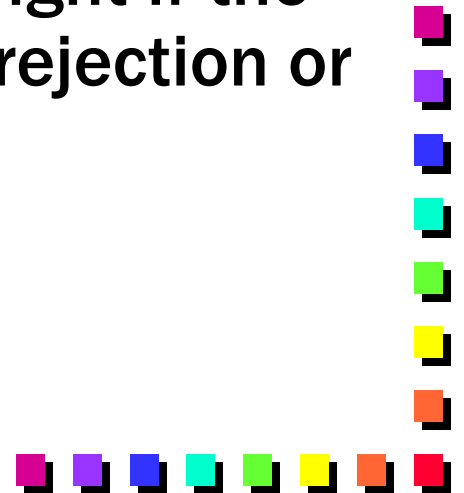
□ Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, applicant may present claims directed to the process of making and/or using the allowable product.

■ See MPEP 821.04(b)



# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- To expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution.
- Process claims which depend from or otherwise require all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.
- See MPEP 821.04(b)



# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- If an amendment adds claims to a process invention, and the amendment includes process claims which do not depend from or otherwise require all the limitations of an allowable product, all claims directed to that newly added invention may be withdrawn from consideration, via an election by original presentation.

**MPEP 821.03**



# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- If an amendment after final rejection that otherwise complies with the requirements of 37 CFR 1.116 would place all the elected product claim(s) in condition for allowance and thereby require rejoinder of process claims that raise new issues requiring further consideration (e.g., issues under 35 U.S.C. 101 or 112, first paragraph), the amendment could be denied entry.

MPEP 821.04(b)



# Rejoinder Between Related Inventions of different Statutory Categories (i.e., “Products” and “Processes”)

- Before mailing an advisory action in the above situation, it is recommended that applicant be called and given the opportunity to cancel the process claims to place the application in condition for allowance with the allowable product claims, or to file an RCE to continue prosecution of the process claims in the same application as the product claims.

**MPEP 821.04(b)**



## For 371 Applications

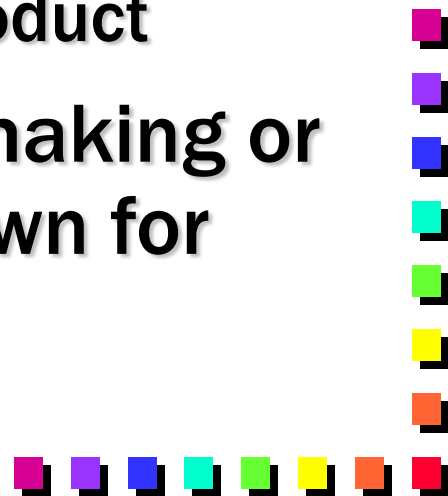
- If the 1<sup>st</sup> claimed product invention does not make a contribution over the prior art (there are reference(s) anticipating and rendering obvious the product as broadly claimed), then it would be proper to group all the methods separate from the product.

- 37 CFR 1.475(d)



## For 371 Applications

- If the 1<sup>st</sup> claimed product invention makes a contribution over the prior art (novel and unobvious), then it would be grouped with and examined with
  - 1<sup>st</sup> claimed method of making the product and
  - 1<sup>st</sup> claimed method of using the product
- 2<sup>nd</sup> and subsequent methods of making or using the product may be withdrawn for lacking unity of invention.
- 37 CFR 1.475(d)



## For 371 Applications

- **When all the claims to the 1<sup>st</sup> claimed product invention all allowable, then the lack of unity determination would be withdrawn between the elected invention and any method inventions in which all claims depended from or otherwise require all the limitations of an allowable product claim.**
- **MPEP 821.04(b)**





# Rejoinder of Process Claims Requiring an Allowable Product

- Rejoinder may be appropriate when claims to an elected product are allowable and ALL claims to a nonelected process of making and/or using the product depend from or otherwise require all limitations of the allowable product claim.

MPEP 821.04(b)



# Rejoinder of Process Claims Requiring an Allowable Product

- In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention.
- Failure to do so may result in a loss of the right to rejoinder.

**MPEP 821.04(b)**



# Rejoinder of Process Claims Requiring an Allowable Product

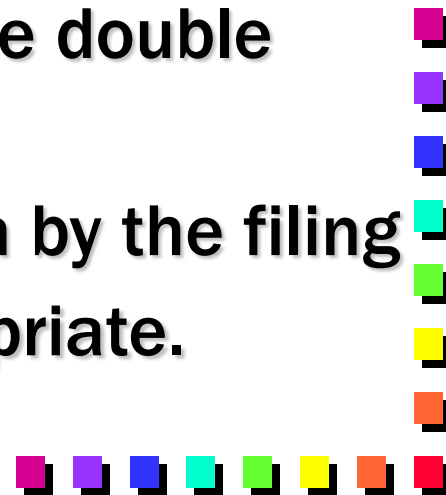
- If applicant cancels all claims to a nonelected process invention before rejoinder occurs, the examiner should not withdraw the restriction requirement between the product and process.
- This will preserve the applicant's rights under 35 USC 121 to file divisional applications without being subject to non-statutory double patenting rejections.

MPEP 821.04(b)



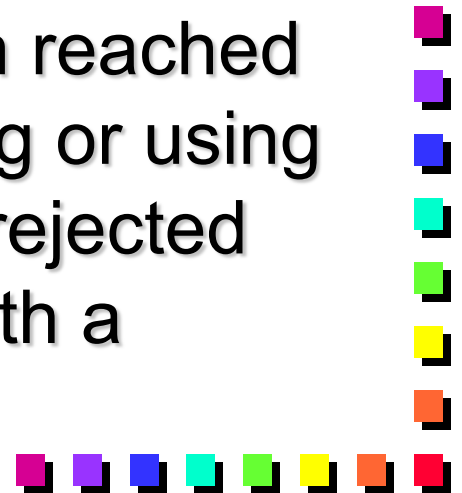
# Double Patenting Between Product and Process Inventions

- Where applicant voluntarily presents claims to the product and process in separate applications (i.e., no restriction requirement was made by the Office), and one of the applications issues as a patent, the remaining application may be rejected under the doctrine of obviousness-type double patenting.
- Applicant may overcome the rejection by the filing of a terminal disclaimer where appropriate.



# Double Patenting Between Product and Process Inventions

- If copending applications separately present product and process claims, provisional obviousness-type double patenting rejections should be made where appropriate.
- However, once a determination as to the patentability of the product has been reached any process claim directed to making or using an allowable product should not be rejected over prior art without consultation with a Technology Center Director.



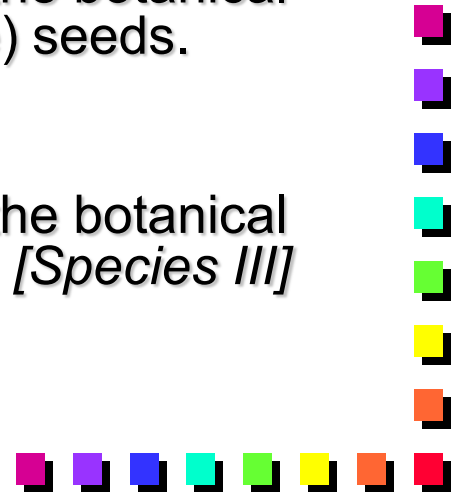
# Example 1: Claims

Claim 1. (Original) A method of reducing pain by administering to a patient a composition comprising a compound having Formula I and a botanical extract. *[Linking claim generic to species I, II and III]*

Claim 2. (Original) The method of claim 1, wherein the botanical extract is an aqueous extract of *Piper methysticum* (kava-kava). *[Species I]*

Claim 3. (Withdrawn) The method of claim 1, wherein the botanical extract is an aqueous extract of *Vitis vinefera* (grape) seeds. *[Species II]*

Claim 4. (Withdrawn) The method of claim 1, wherein the botanical extract is an alcohol extract of *Echinacea purpurea*. *[Species III]*



# Example 1: Rejoinder

- The examiner required an election of species I, II, or III. Species I was elected. Claims 3 and 4 are initially withdrawn from examination. Claims 1 and 2 are allowable.
- Because all claims to the elected invention are in condition for allowance, the examiner should withdraw the election of species requirement between Species I, II and III.
- The inventions defined by claim 3 and 4 should be rejoined with the invention of claim 1 because claim 1 is generic to Species I, II and III.



# Example 2: Claims

Claim 1. (Original) A method of reducing pain by administering to a patient a composition comprising a compound having Formula I and a botanical extract. *[Linking claim generic to species I, II and III]*

Claim 2. (Original) The method of claim 1, wherein the botanical extract is an aqueous extract of *Piper methysticum* (kava-kava). *[Species I]*

Claim 3. (Withdrawn) The method of claim 1, wherein the botanical extract is an aqueous extract of *Vitis vinefera* (grape) seeds. *[Species II]*

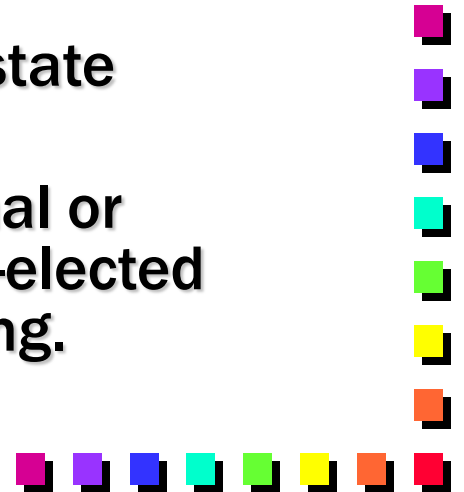
Claim 4. (Withdrawn) The method of claim 1, wherein the botanical extract is an alcohol extract of *Echinacea purpurea*. *[Species III]*





# Example 2: Re-Instating Cancelled Claims

- The examiner required an election of species I, II, or III. Species I was elected.
- Claims 3 and 4 were cancelled. Claims 1 and 2 are allowable.
- Because all claims directed to the elected invention are in condition for allowance, rejoinder is required.
- The election of species requirement among Species I, II and III must be withdrawn.
- Applicants must be given a chance to re-instate cancelled claims 3 and 4.
- Should Claims 3 and 4 be filed in a divisional or continuation application, the claims to non-elected species may be rejected for double patenting.



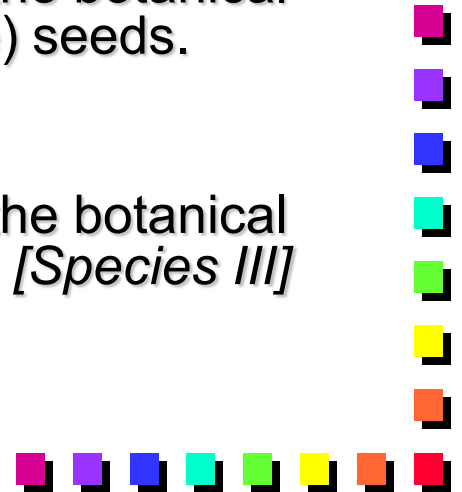
# Example 3: Claims

Claim 1. (Original) A method of reducing pain by administering to a patient a composition comprising a compound having Formula I and a botanical extract. *[Linking claim generic to species I, II and III]*

Claim 2. (Original) The method of claim 1, wherein the botanical extract is an aqueous extract of *Piper methysticum* (kava-kava). *[Species I]*

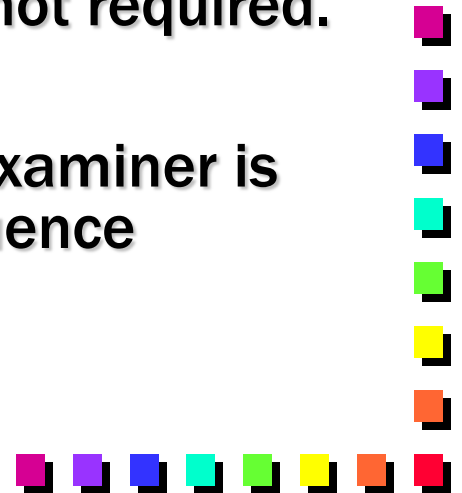
Claim 3. (Withdrawn) The method of claim 1, wherein the botanical extract is an aqueous extract of *Vitis vinefera* (grape) seeds. *[Species II]*

Claim 4. (Withdrawn) The method of claim 1, wherein the botanical extract is an alcohol extract of *Echinacea purpurea*. *[Species III]*



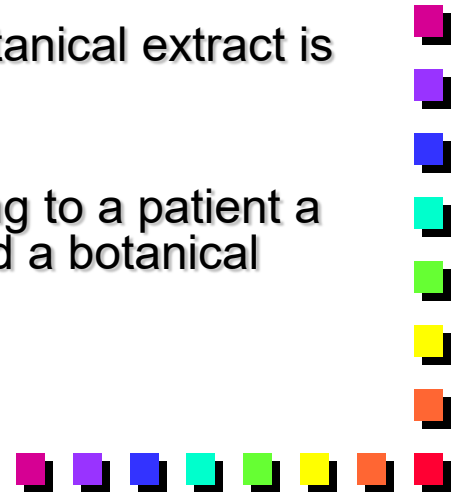
# Example 3: No Rejoinder

- The examiner required an election of species I, II, or III. Species I was elected. Claim 2 is allowable.
- Linking claim Claim 1 is unpatentable over prior art teaching an aqueous extract of aloe vera.
- Because not all claims directed to the elected invention are in condition for allowance, rejoinder is not required.
- Because the linking claim is rejected, the examiner is not required to examine second or subsequent species recited in claims 3 or 4.



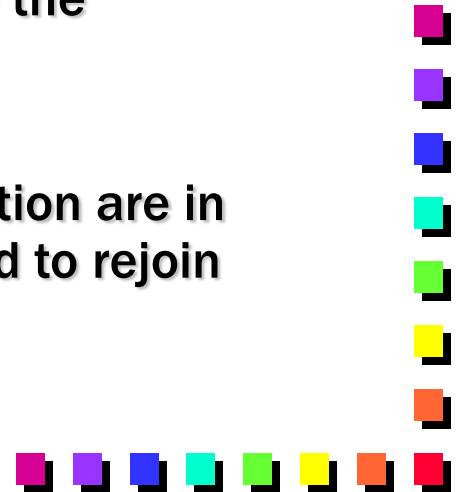
# Example 4: Claims

- Claim 1. (Original) A method of reducing pain by administering to a patient a composition comprising a compound having Formula I and a botanical extract. *[Linking claim generic to species I, II and III]*
- Claim 2. (Original) The method of claim 1, wherein the botanical extract is an aqueous extract of *Piper methysticum* (kava-kava). *[Species I]*
- Claim 3. (Withdrawn) The method of claim 1, wherein the botanical extract is an aqueous extract of *Vitis vinefera* (grape) seeds. *[Species II]*
- Claim 4. (Withdrawn) The method of claim 1, wherein the botanical extract is an alcohol extract of *Echinacea purpurea*. *[Species III]*
- Claim 5. (Original) A method of curing cancer by administering to a patient a composition comprising a compound having Formula I and a botanical extract. *[Linking claim generic to species I, II and III]*



# Example 4: No rejoinder

- The examiner required an election of species I, II, or III. Species I was elected. Claims 1, 2 and 5 read upon the elected invention.
- Claims 1 and 2 are allowable.
- Claims 3 and 4 recite all the limitations of allowable claims.
- However, claim 5 is rejected under 112, 1<sup>st</sup> because the specification has not enabled “curing cancer.”
- Because not all claims directed to the elected invention are in condition for allowance, the examiner is not required to rejoin claims 3 and 4.

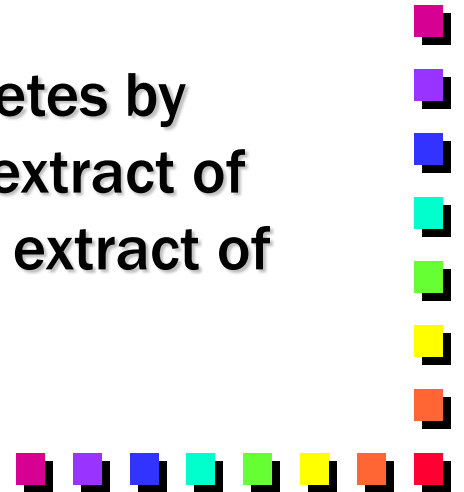


# Example 5: Claims

**Claim 1. (Original)** A composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.

**Claim 2. (Original)** A method of treating diabetes by administering composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.

**Claim 3. (Original)** A method of treating diabetes by administering composition comprising an extract of *Vitis vinefera* (grape) seeds and an alcohol extract of *Piper methysticum* (kava-kava).



# Example 5: Election

- **The examiner required restriction between product Invention Group I (claim 1) and process invention Group 2 (claim 2 and 3).**
- **Applicant elected Group I and amended claim 3 to the following:**



# Example 5: Amendment Prompts Rejoinder

**Claim 3. (Amended) A method of treating diabetes by administering composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds and an alcohol extract of *Piper methysticum* (kava-kava).**

- After claim 1 is determined to be allowable, the examiner should withdraw the restriction requirement.
- Claims 2 and 3 should be rejoined with claim 1 (see MPEP 821.04(b), FP 8.42, 8.43)).



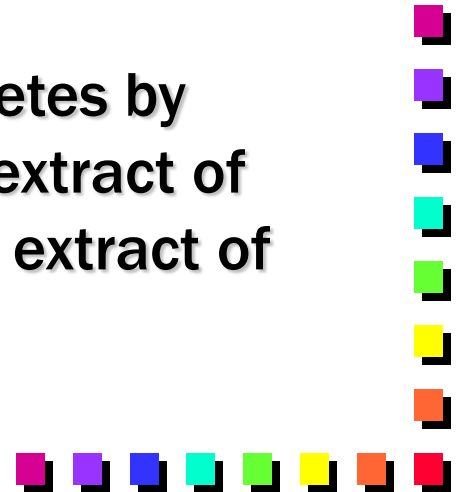


# Example 6: Claims

**Claim 1. (Original)** A composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.

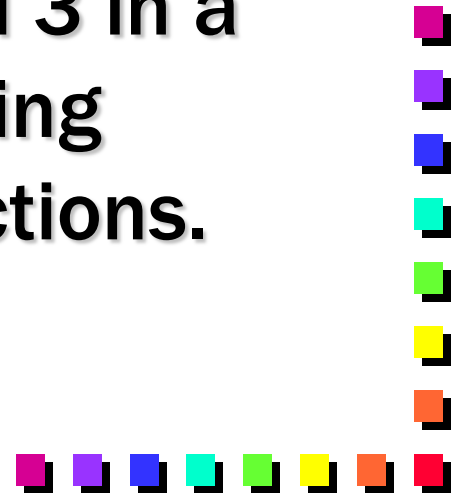
**Claim 2. (Original)** A method of treating diabetes by administering composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.

**Claim 3. (Original)** A method of treating diabetes by administering composition comprising an extract of *Vitis vinefera* (grape) seeds and an alcohol extract of *Piper methysticum* (kava-kava).



# Example 6: No Rejoinder

- After claim 1 is determined to be allowable, the examiner should NOT withdraw the restriction requirement.
- Claim 3 should not be rejoined.
- Applicants may file claims 2 and 3 in a divisional application without being subject to double patenting rejections.



# Example 7: Claims

**Claim 1. (Original) A composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.**

**Claim 2. (Original) A method of treating diabetes by administering composition comprising an alcohol extract of *Vitis vinefera* (grape) seeds.**



# Example 7: No Rejoinder

- The examiner required restriction between the product of Group I (claim 1) and Process of Group II (claim 2).
- Applicants elected to Process of Group II.
- Examiner finds Group II allowable.
- The examiner is not obligated to rejoin a product with an allowable process.
- Patentability of a process does not correlate with novelty and unobviousness of a product used in that that process.



# Importance of a Clear Record

- A clear and detailed record of the restriction requirement provides a clear demarcation between restricted inventions.
  - Applicants have adequate notice regarding the inventions subject to restriction.
  - If applicants seek relief from a restriction requirement by petition, a clear record simplifies the petition decision process.
  - An examiner/court can determine 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*, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003).



# Switching Inventions after Election

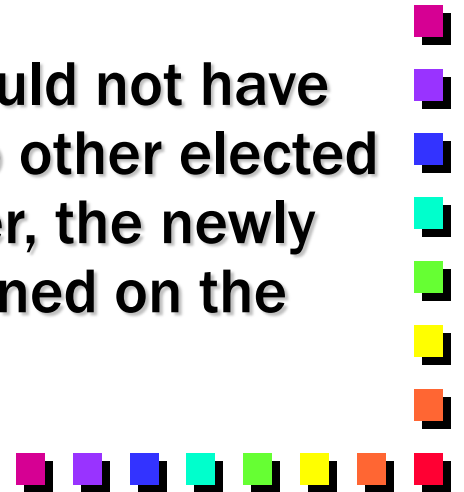
- Applicant is generally not permitted to switch to claiming a different invention after a first action on the merits.
  - Cancellation of all claims drawn to an elected invention and presentation of claims drawn to a non-elected invention is non-responsive. Use FP 8.26 which gives applicant one month or 30 days to file a responsive amendment.
  - An RCE may not be used as a matter of right to switch to an invention which is independent or distinct from the invention examined previously.

MPEP 819 and 821.03



# Constructive Election by original presentation

- Claims added after an Office action should be withdrawn as non-elected by original presentation **ONLY IF** those claims are drawn to an invention that is independent or distinct from the invention examined on the merits. Use FP 8.04 to inform applicant when a constructive election by original presentation has been made.
  - Where applicant presents claims that could not have been restricted from the claims drawn to other elected invention had they been presented earlier, the newly added claims (if entered) must be examined on the merits.

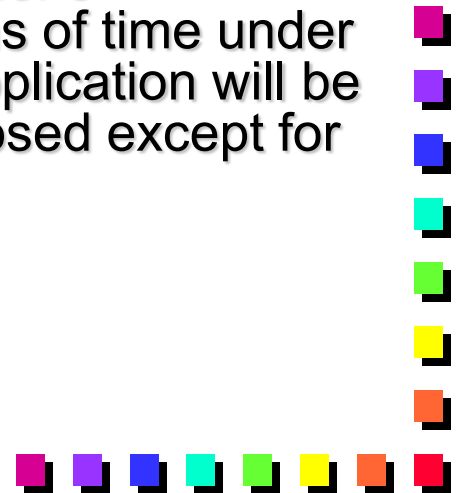


# Constructive Election by original presentation

## 8.03 In Condition for Allowance, Non-elected Claims Withdrawn with Traverse

This application is in condition for allowance except for the presence of claim [ 1 ] directed to an invention non-elected with traverse in the reply filed on [ 2 ]. Applicant is given ONE MONTH or THIRTY DAYS from the date of this letter, whichever is longer, to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue. The prosecution of this case is closed except for consideration of the above matter.

821.01







# REJOINDER PRACTICE

## QUESTIONS?

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