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Restriction Practice for
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 Combinations and SubcombinationsJulie Burke
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## Objectives for This Talk

## Restriction:

- Subcombinations Useable Together
- Related Combinations
- Combination/Subcombination
- Subcombination essential to combination.
- Subcombination not essential to combination.
- Plural Combinations requiring a single subcombination
- Subcombination Not Claimed Separately
- Subcombination Claimed Separately
- Plural subcombinations used in a single combination



## 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.


## Distinction is typically a one－way test．

－Related inventions are distinct wherein at least one invention is PATENTABLE OVER THE OTHER．
－＂PATENTABLE＂means novel and nonobvious over each other．
－Two inventions may be distinct from each other even if neither is unpatentable over the prior art．

## Objectives for This Talk

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## Subcombinations Useable Together: A/B



## The specification discloses combination $A B$.

When $A$ and $B$ are claimed as separate subcombinations, distinction between subcombinations $A$ and $B$ may be shown using FP 8.16.
FP 8.16 only requires the examiner to find a separate use for one of the subcombinations.

## Example I: Subcombs Useable Together A/B

A Claim 1. An polypeptide comprising a tumor associated targeting domain.
B Claim 2. An polypeptide comprising a toxin.
The specification discloses that the tumor associated targeting domain and the toxin may be used together in a fusion protein for cancer therapy.

Claims 1 and 2 are drawn to subcombinations, disclosed as useable together. In this example, the fusion protein combination is not claimed.

Restriction between Claim 1 and Claim 2 may be proper because the tumor associated targeting domain may be combined with a label, for example, for separate use in a diagnostic method.

FP 8.16
MPEP 806.05(d)


## Subcombinations Useable Together: BC/DE



## Example II: Subcombs Useable Together BC/DE

BC Claim 1. A vaccine comprising a tetanus antigen and a botulism antigen.
DE Claim 2. A vaccine comprising a diptheria antigen and a measles antigen.

The discloses that the antigens are specific for four separate pathogens and that they may be used on their own or in pairs or combined to form a vaccine to immunize a subject against the four pathogens.

Restriction between Claim 1 and Claim 2 may be proper because the subcombination of claim 1, for example, may be used on its own or in combination with other antigens besides those recited in Claim 2.


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Rejoinder

## Related Combinations：$A B / B C$


$A B$ and $B C$ are related combinations．
Distinction may be shown using FP 8．14．01，related products．
Each combination requires＂$B$＂but is distinct from the other combination $\rfloor$ because
$A B$ requires＂$A$＂which is not required for $B C$ and
$B C$ requires＂$C$＂that is not required for $A B$ ．

## Example III: Related Combinations AB/BC

$A B$ Claim 1. A fusion protein comprising single chain antibody $B$ and label $A$.
$B C$ Claim 2. $A$ fusion protein comprising single chain antibody $B$ and toxin $C$.

Claims 1 and 2 are drawn to related products that both require antibody B.

Distinction between Claims 1 and 2 may be shown using FP 8.14.01:
Claim 1 requires label A not disclosed as being required for Claim 2.
Claim 2 requires toxin C not disclosed as being required for Claim 1.

## 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．


## Distinction usually requires a one-way test

- Related inventions are distinct wherein at least one invention is PATENTABLE OVER THE OTHER.
- "PATENTABLE" means novel and nonobvious over each other.
- Two inventions may be distinct even if neither is unpatentable over the prior art.

Distinction between combination and subcombination is an exception to the one-way tests.

- See MPEP § 806.05(c) (combination and subcombination) for an example of when a twoway test is required for distinctness.

MPEP 802.02(II)


## Test For Distinctness Between Combination and Subcombination

The inventions are distinct if it can be shown that the combination as claimed：
（A）does not require the particulars of the subcombination，as claimed，for patentability（to show novelty and unobviousness），and
（B）the subcombination，as claimed，can be shown to $\quad$－ have utility either by itself or in another materially $\quad \square$ different combination．

MPEP 806．05（c）FP 8．15．」 」


## Definitions

- A combination is an organization of which a subcombination or element is a part.
- A subcombination is a part of a combination.



## Abbreviations

Combination ABsp（＂sp＂for＂specific＂）
Combination ABbr（＂br＂for＂broad＂）
Subcombination Bsp（＂sp＂for＂specific＂）
－Tip：Combination and subcombination must both be products or must both be processes．

MPEP 806．05（a）
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## Two Options for Comb/Subcomb Analysis

1. Identify the comb and subcomb claims.

2a. Find broadest subcomb, as claimed separately. Find the broadest subcomb required by a comb claim. If the comb requires a broader subcomb than subcomb as claimed separately, comb does not require particulars of subcomb for patentability.
2b. If the claim set includes claims to more than one subcomb, each subcomb claim may be used as evidence that the comb does not require any particular subcomb for $\square$ patentability.
3. Provide another utility for subcomb.
4. Show serious burden.

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Rejoinder
Summary

## SUBCOMBINATION ESSENTIAL TO COMBINATION

ABsp/Bsp No Restriction

Where a combination as claimed requires the details of a subcombination as separately claimed, there is usually no evidence that combination ABsp is patentable without the details of Bsp.

The inventions are not distinct and a requirement for restriction must not be made or maintained, even if the subcombination has separate utility.

## Subcombination and Combination ABsp／Bsp



This situation can be diagrammed as combination ABsp（＂sp＂for
＂specific＂），and subcombination Bsp．

Thus the specific characteristics required by the subcombination claim Bsp are also required by the combination claim．

## Example IVa Comb／Subcomb ABsp／Bsp

Bsp Claim 1．An isolated nucleic acid molecule having SEQ ID No 1.
ABsp Claim 2．A transgenic plant comprising the nucleic acid molecule of Claim 1.

Claim 1 is a subcombination drawn to a nucleic acid molecule．
Claim 2 is a combination of the plant and the nucleic acid molecule．
Both claims 1 and 2 require a nucleic acid molecule of equal breadth，i．e．，Bsp．
From this claim set，there is no evidence that the combination does not require the specific characteristics of subcombination for its patentability．

Claims 1 and 2 are NOT patentably distinct．Restriction would NOT be proper．

## Example IVb Comb/Subcomb ABsp/Bsp

Bsp Claim 1. Antibody XYZ.
ABsp Claim 2. A fusion protein comprising antibody XYZ and Toxin A.
Claim 1 is a subcombination drawn to a antibody XYZ.
Claim 2 is a combination of the antibody XYZ and Toxin A.
Both claims 1 and 2 require an antibody of equal breadth, i.e, Bsp.
In this claim set, the combination requires the specific characteristics of subcombination for its patentability.

Claims 1 and 2 are NOT patentably distinct. Restriction would NOT be proper.

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Rejoinder

## SUBCOMBINATION NOT ESSENTIAL TO COMBINATION

## ABbr/Bsp Restriction Proper

Where a combination as claimed does not require the details of the subcombination as separately claimed and the subcombination has separate utility, the inventions are distinct.

This situation can be diagrammed as combination ABbr ("br" for "broad"), and subcombination Bsp ("sp" for "specific").

Bbr indicates that in the combination the subcombination is broadly recited and that the specific characteristics required by the subcombination claim Bsp are not required by the combination claim.


## SUBCOMBINATION NOT ESSENTIAL TO COMBINATION

Since claims to both the subcombination and
combination are presented, the omission of details of
the claimed subcombination Bsp in the combination
claim ABbr is evidence that the combination does not
rely upon the specific limitations of the
subcombination for its patentability.
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## Subcombination and Combination ABbr/Bsp



## Example V Comb／subcomb ABbr／Bsp

Bsp Claim 1．Antibody XYZ．
ABbr Claim 2．A fusion protein comprising an antibody which binds to a tumor associated antigen and a toxin．

The specification discloses that Antibody XYZ binds to a specific tumor associated antigen XYZ．

Claim 2 is directed to a combination which requires any antibody that binds a tumor associated antigen．Claim 2 requires an antibody which is broader in scope than that of claim 1.

The combination ABbr does not requires the specific characteristics of subcombination Bsp for its patentability．

If we can provide a separate use for the subcombination，distinction between Claims 1 and 2 may be shown using FP 8．15．

## FP 8.15 Combination-Subcombination

Inventions [1] and [2 ] are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that
(1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and
(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)).

## SUBCOMBINATION NOT ESSENTIAL TO COMBINATION

## ABsp/ABbr/Bsp Restriction Proper

The presence of a claim to combination ABsp does not alter the propriety of a restriction requirement properly made between combination ABbr and subcombination Bsp.

Claim ABbr is an evidence claim which indicates that the combination does not rely upon the specific details of the subcombination for its patentability.


## Subcombination and Combination：ABbr／ABsp／Bsp

## ABbr <br> 

Groupings：
Group I，ABbr and ABsp
Group II，Bsp

Group combination claims ABbr and ABsp together． Presence of claim to＂ABsp＂does not require ABsp to be grouped with Bsp．


## Subcombination and Combination：ABbr／ABsp／Bsp

Groupings：
Group I，ABbr and ABsp
Group II，Bsp


If Group II is elected and Bsp found allowable，consider claims to ABsp for rejoinder．


12／07 BCP

## Example VI: Comb/subcomb ABbr/ABsp/Bsp

Bsp Claim 1. An isolated nucleic acid having SEQ ID NO:1.
ABsp Claim 2. A non-human transgenic animal comprising the nucleic acid of Claim 1.
ABbr Claim 3. A non-human transgenic animal comprising a nucleic acid that is at least $95 \%$ identical to the nucleic acid of Claim 1.

Combination Claim 3 "depends from" Claim 1 yet permits a nucleic acid molecule that is broader in scope than subcombination claim 1.

Object to Claim 3 using FP 7.36.


## Example VI: ABbr/ABsp/Bsp (cont.)

Bsp Claim 1. An isolated nucleic acid having SEQ ID No 1.
ABsp Claim 2. A non-human transgenic animal comprising the nucleic acid of Claim 1.
ABbr Claim 3. A non-human transgenic animal comprising a nucleic acid that is at least $95 \%$ identical to the nucleic acid of Claim 1.

Claim 2 is narrower in scope than, and must be grouped with, Claim 3.
Group I, Claim 1, drawn to a subcombination.
Group II, Claims 2 and 3, drawn to a combination.

## Example VI: ABbr/ABsp/Bsp (cont.)

Bsp Claim 1. An isolated nucleic acid having SEQ ID No 1.
ABsp Claim 2. A non-human transgenic animal comprising the nucleic acid of Claim 1.
ABbr Claim 3. A non-human transgenic animal comprising a nucleic acid that is at least $95 \%$ identical to the nucleic acid of Claim 1.

Group I, Claim 1, drawn to a subcombination of SEQ ID No 1.
Group II, Claims 2 and 3, drawn to a combination of SEQ ID NO 1 and an animal.

If we can provide another use for the nucleic acid, distinction between Group I and II may be shown using FP 8.15.

If Group I is elected and found allowable, Claim 2 would be considered for rejoinder, per MPEP 821.04(a).


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Plural Combinations, no Subcombination Claim: AB/CB


When a single subcombination is required by two or more combinations, the lack of a claim to the subcombination may be used as evidence that the subcombination is not required for patentability of either combination.

## Plural Combinations, No Subcombination Claim: AB/CB



## Groupings: Group I, AB Group II, CB

Distinction between Group I and II can be shown using FP 8.14.01:

Group I requires " $A$ " not required for Group II. $د$
Group II requires "C", not required for Group $1 . \frac{\mathrm{J}}{} \mathrm{J}$


## Example VIII: Related Products AB/CB

## $A B \quad$ Claim 1. A non-human transgenic animal comprising the nucleic acid having SEQ ID No 1. <br> CB Claim 2. A transgenic plant comprising the nucleic acid having SEQ ID No 1.

Claims 1 and 2 are directed to distinct combinations that share a common subcombination $B$ (SEQ ID NO 1).

The shared subcombination B is not separately claimed.
Distinction between Claims 1 and 2 may be established because of their mutually exclusive characteristics, using FP 8.14.01.

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## PLURAL COMBINATIONS REQUIRING A SUBCOMBINATION COMMON TO EACH COMBINATION

When an application includes a claim to a single subcombination, and that subcombination is required by plural claimed combinations that are properly restrictable, the subcombination claim is a linking claim and will be examined with the elected combination (see MPEP § 809.03).

The subcombination claim links the otherwise restrictable combination inventions and should be listed in form paragraph 8.12.

The claimed plural combinations are evidence that the subcombination has utility in more than one combination.


## Plural Combinations and a Single Subcombination $A B / C B / B$



When a single subcombination is claimed and required by two or more combinations, the


Plural Combinations and a Single Subcombination $A B / C B / B$


## Groupings： Group I，AB <br> Group II，CB

Distinction between Group I and II can be shown using FP 8．14．01．

The linking claim＂$B$＂is placed in FP 8．12．

## Plural Combinations and a Single Subcombination $A B / C B / B$



## Groupings： Group I，AB <br> Group II，CB

The linking claim to subcombination $B$ would be examined if either of Group I or II is elected．

The linking claim to subcombination B is allowable，$\frac{\square}{}$ the restriction requirement between Group I and II 」 must be withdrawn．

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## Example IX：Two combs and one subcomb AB／CB／B

B Claim 1．An isolated nucleic acid having SEQ ID No 1.
AB Claim 2．A transgenic plant comprising the nucleic acid of Claim 1.
CB Claim 3．A non－human transgenic animal comprising the nucleic acid of Claim 1 ．

Groupings：
Group I，Claim 2，drawn to a transgenic plant comprising SEQ ID No 1.
Group II，Claim 3，drawn to a non－human transgenic animal comprising SEQ ID No 1.

## Example IX：AB／CB／B（cont）

B Claim 1．An isolated nucleic acid having SEQ ID NO：1．

AB
CB Claim 2．A transgenic plant comprising the nucleic acid of Claim 1.
Claim 3．A non－human transgenic animal comprising the nucleic acid of Claim 1 ．

Claim 1 is a subcombination claim that is broader in scope than and links Groups I and II．

List Claim 1 in FP 8.12 as a linking claim．
If either Group I or Group II is elected，Claim 1 would be examined，as a linking claim．

If Claim 1 is allowable，the restriction requirement between Groups I and II would be withdrawn and non－elected invention would be examined．

## Example $X$ : $A B / C B / B$ plus genus claim

B Claim 1. An isolated nucleic acid having SEQ ID No 1.
XB
AB
CB Claim 2. A transgenic organism comprising nucleic acid of Claim 1. Claim 3. A transgenic plant comprising the nucleic acid of Claim 2.
Claim 4. A non-human transgenic animal comprising the nucleic acid of Claim 2.

Claim 1 is a subcombination claim.
Claims 2, 3 and 4 are directed to combinations.
Claim 2 is generic to claims 3 and 4 .
Claim 3 and 4 are distinct from each other.


## Example $\mathrm{X}: ~ A B / C B / B$ plus genus claim (cont.)

B Claim 1. An isolated nucleic acid having SEQ ID No 1.
XB Claim 2. A transgenic organism comprising the nucleic acid of Claim 1.
AB Claim 3. A transgenic plant comprising the nucleic acid of Claim 1.
CBClaim 4. A non-human transgenic animal comprising the nucleic acid of Claim 1.
Groupings:
Group I, Claim 3, drawn to a transgenic plant comprising SEQ ID No 1.
Group II, Claim 4, drawn to a non-human transgenic animal comprising SEQ ID No 1.

Distinction between Groups I and II may be shown because of their mutually exclusive characteristics using FP 8.14.01.

## Example $X$ : $A B / C B / B$ plus genus claim (cont.)

B Claim 1. An isolated nucleic acid having SEQ ID NO:1.of Claim 1 .

Claim 1 is a subcombination linking claim that should be placed in FP 8.12. Claim 2 is a generic linking claim that should be placed in FP 8.12.

If either of Groups I or II are elected, then claims 1 and 2 will be examined with the elected invention.

If claims 1 and 2 is allowable, the restriction requirement between Group I and Group II will be withdrawn and the non-elected invention rejoined.

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Rejoinder

## Plural Subcombination Claims Considered As Evidence Claims

Where claims to two or more subcombinations are presented along with a claim to a combination that includes the particulars of at least two subcombinations, the presence of the claim to the second subcombination is evidence that the details of the first subcombination are not required for patentability (and vice versa).

For example, if an application claims $A B C / B / C$ wherein $A B C$ is a combination claim and $B$ and $C$ are each subcombinations that are properly restrictable from each other, the presence of a claim to $C$ provides evidence that the details of $B$ are not required for the patentability of combination ABC.


Plural Subcombinations and a Shared Combination：B／C／BC


When two or more subcombinations are separately claimed along with a claimed combination，the presence of each subcombination claim may be used as evidence $\quad$ ． that the combination does not require any either
subcombination for its patentability．

Plural Subcombinations and a Shared Combination: B/C/BC
BC ........................BC is NOT a linking claim

The BC combination claim is narrower in scope than the subcombination claim.

Patentability of BC does not correlate one-to-one with patentability of either B or C.

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## Plural Subcombinations and a Shared Combination: B/C/BC



Groupings:
Group I, drawn to B
Group II, drawn to C
Group III, drawn to BC.

Distinction between Groups I and II may be shown using FP 8.16, subcombinations useable together.

Distinction between Group III and Groups (I and II) may be 」 shown using FP 8.15, combination and subcombination. 」

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Plural Subcombinations and a Shared Combination: B/C/BC


Groupings:
Group I, drawn to B
Group II, drawn to C
Group III, drawn to BC.

If either of Group I or II is elected and found allowable,

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## Example XI: Two Subcombs and one comb B/C/BC

B Claim 1. An isolated nucleic acid having SEQ ID NO:1.
C Claim 2. An isolated nucleic acid having SEQ ID NO:2.
BC Claim 3. A transgenic plant comprising the nucleic acid of Claim 1 and the nucleic acid of Claim 2.

Claims 1 and 2 are both subcombination claims.
Claim 3 is directed to a combination and depends upon both of claim 1 and claim 2.

## Example XI: B/C/BC (cont.)

B Claim 1. An isolated nucleic acid having SEQ ID NO:1.
C Claim 2. An isolated nucleic acid having SEQ ID NO:2.
BC
Claim 3. A transgenic plant comprising the nucleic acid of Claim 1 and the nucleic acid of Claim 2.

A multiple dependent claim must refer to the independent claim in the alternative only. Object to Claim 3 using FP 7.45.

Claim 3 may be amended as any of the following formats:
BC Claim 4. A transgenic plant comprising the nucleic acid of SEQ ID NO:1 and the nucleic acid having SEQ ID NO:2.
BC Claim 5. A transgenic plant comprising the nucleic acid of Claim 1 and the nucleic acid having SEQ ID NO:2.

## Example XI: B/C/BC (cont.)

B Claim 1. An isolated nucleic acid having SEQ ID No 1.
C Claim 2. An isolated nucleic acid having SEQ ID No 2.
BC Claim 3. A transgenic plant comprising the nucleic acid of Claim 1 and the isolated nucleic acid of Claim 2.

Groupings:
Group I, Claim 1, drawn to subcombination of SEQ ID No 1.
Group II, Claim 2, drawn to subcombination of SEQ ID No 2.
Group III, Claim 3, drawn to combination of a transgenic plant

## Example XI: B/C/BC (cont.)

B Group I, Claim 1, drawn to subcombination of SEQ ID No 1. Group II, Claim 2, drawn to subcombination of SEQ ID No 2.
BC Group III, Claim 3, drawn to combination of a transgenic plant comprising SEQ ID NO:1 and SEQ ID NO:2.

Distinction between Group I and Group II may be shown using FP 8.16, subcombinations useable together if a separate use can be provided for one of the subcombinations.

Distinction between Group III and (Groups I and II) may be shown using FP 8.15 , subcombination/combination. Presence of both Claims 1 and 2 may be used as evidence that the patentability of Claim 3 does not depend upon the particulars of either of Claim 1 or 2.

If either claims 1 or 2 is elected and found allowable, Claim 3 must be considered for rejoinder.

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## Rejoinder

## Mid－Prosecution Rejoinder：

When a Subcombination becomes essential to a combination．
ABsp／ABbr／Bsp Restriction No Longer Proper
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．

If a claim to Bsp is determined to be allowable，any claims requiring Bsp，including any combination claims of the format ABsp，must be considered for rejoinder．See MPEP § 821．04．

## Linking Claims

－Definition：A linking claim is a claim which，if allowable， would prevent restriction between two or more otherwise properly restrictable inventions．
－Linking claims and linked inventions are usually either
－product claims linking properly restrictable product inventions，or
process claims linking properly restrictable process inventions．
$\square$ Most common types of linking claims are
－A genus claim linking species claims or
－A subcombination claim linking plural combinations

MPEP 809 and 809．03．

## Rejoinder Practice：When Subcombination is Elected

A subcombination claim may be a linking claim．
Upon determining that all claims directed to an elected subcombination invention are allowable，the examiner must reconsider the propriety of the restriction requirement．

If a subcombination is elected and determined to be allowable，nonelected claims requiring all the limitations of the allowable claim will be rejoined in accordance with MPEP § 821．04．


## Rejoinder Practice: When Combination is Elected

Upon determining that all claims directed to an elected combination invention are allowable, the examiner must reconsider the propriety of the restriction requirement.

Where the combination is allowable in view of the patentability of at least one of the subcombinations, the restriction requirement between the elected combination and patentable subcombination(s) will be $\quad$ withdrawn; furthermore, any subcombinations that b were searched and determined to be allowable must $\quad$ also be rejoined. $\rfloor$
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## Downstream Double Patenting Concerns

FP 8.15, FP 8.16 and several rejoinder FPs end with:
Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.


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Rejoinder
Summary

## Subcombinations Useable Together


$A$ and $B$ are subcombinations useable together. FP 8.16; MPEP 806.05(d)

## Subcombinations Useable Together


$A B$ and $C D$ are subcombinations useable together.
FP 8.16; MPEP 806.05(d)


## Related Combinations


$A B$ and $B C$ are considered related products. FP 8.14.01; MPEP 806.05(j)

## One Subcombination and Two Combinations


$B$ is a subcombination that links claims to related products AB and BC.

FP 8.12 for linking claim "B"


Two Subcombinations and A Combination

$B$ and $C$ are plural subcombinations used in a claimed combination.
$B$ and C may both be separately used as evidence that $B C$ does not require either for patentability.

FPs 8.15 and 8.16.


## Subcombination Elected and Allowable? Rejoin downward



If " $C$ " is elected and found allowable, any claims requiring must be considered for rejoinder per MPEP 821.04(a).

## Combination ABCDE Allowable Because of "A"? Rejoin upward



If examination of "ABCDE" determines that subcombination $A$ is novel and unobvious, the restriction requirement between the subcombinations $A, A B, A B C$ ABCD, ABCDE, etc, should be reconsidered in terms of burden and withdrawn if no serious burden exists.


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 Combinations and SubcombinationsJulie Burke
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