



UNITED STATES PATENT AND TRADEMARK OFFICE

PCT Unity of Invention with Pharmaceutical and Chemical Examples

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PCT Unity of Invention Applies to

Chapter I and Chapter II international applications filed under the PCT

National stage filings of international applications submitted under 35 U.S.C. 371

RCEs of National Stage applications



Resources and Guidance Available at

International Search and Examination Guidelines (ISPE Guidelines) published
January 2004

See Chapter 10, pp 75-103

<http://www.wipo.int/pct/en/texts/pdf/ispe.pdf>

MPEP Edition 8, Rev. 7 published July 2008

See Chapter 1800, sections 1850 and 1893.03(d)

<http://www.uspto.gov/web/offices/pac/mpep/index.html>

SPEs and QASs

PCT Legal Help Desk 571-272-4300



General Inventive Concept

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.1



Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

PCT Rule 13.2



Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

PCT Rule 13.2



Contribution over the Prior Art

Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature,” is considered with respect to

novelty and
inventive step.

ISPE Paragraph 10.02

3/2/09



Unity Assessed with respect to the group of inventions, considered as a whole

With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

PCT Rule 13.2



Lack of Unity “a priori”

For example, independent claims to

$A + X,$

$A + Y,$

$X + Y$

can be said to lack unity a priori as there is no subject matter common to all claims.

ISPE Paragraph 10.03



Example A: Unity Lacking “a priori”

Claim 1: A composition comprising aspirin and caffeine.

Claim 2: A composition comprising aspirin and morphine.

Claim 3: A composition comprising caffeine and morphine.

Unity of invention is lacking among claims 1, 2 and 3 a priori
as there is no subject matter common to all claims



Same or Corresponding Technical Feature Lacking Among Groups

Group I, Claim 1, drawn to a composition comprising aspirin and caffeine.

Group II, Claim 2, drawn to a composition comprising aspirin and morphine.

Group III, Claim 3, drawn to composition comprising caffeine and morphine.

Groups I, II and III lack unity of invention because the groups do not share the same or corresponding technical feature.



Reasons Required to Show Why Inventions Lack Unity

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I requires the technical feature of aspirin and caffeine, not required for Group II or III,

Group II requires the technical feature of aspirin and morphine, not required for Group I or III and

Group III requires the technical feature of caffeine and morphine not required for Group I or II.

FP 18.07

3/2/09



Unity Present “a priori”

In the case of independent claims to

$A + X$ and

$A + Y$,

unity of invention is present a priori as A is common to both claims.

ISPE Paragraph 10.03



Example B: Unity Present “a priori”

Claim 1: Compound A.

Claim 2: A liposome delivery product B comprising Compound A.

Claim 3: A vaccine C containing a liposome delivery product B comprising Compound A.

Unity exists between claims 1, 2, and 3.

The special technical feature common to all the claims is the Compound A.

Based upon ISPE Example 13



Example C: Compound and Composition

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2.

The special technical feature common to all the claims is compound A.

ISPE Example 15



Lack of Unity “a posteriori”

In the case of independent claims to $A + X$ and $A + Y$...

... if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

ISPE Guidelines Paragraph 10.03

3/2/09



Lack of Unity “a posteriori”

If...an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered.

If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised.

ISPE Paragraph 10.08

3/2/09



Example D: Unity lacking “a posteriori”

Claim 1: A composition comprising aspirin.

Claim 2: A composition comprising aspirin and caffeine.

Claim 3: A composition comprising aspirin and morphine.

Unity exists “a priori” between claims 1, 2, and 3.

The technical feature common to all the claims is aspirin.

However, if aspirin is known in the art, unity would be lacking “a posteriori” because there would not be a special technical feature common to all the claims.

Based upon ISPE Example 17

3/2/09



Example D: Unity lacking “a posteriori” (cont.)

Group I, Claim 2, drawn to a composition comprising aspirin and caffeine.

Group II, Claim 3, drawn to a composition comprising aspirin and morphine.

Claim 1 would be placed in a linking claim FP, per 37 CFR 1.488(c).

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of a composition comprising aspirin, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Jones et al. See PNAS, Vol. 3, pages 6-8, Dec 1947.

Jones et al teaches a composition comprising aspirin, see Figure 3.

FP 18.07.02



Particular Situations

There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

- (i) combinations of different categories of claims;
- (ii) so-called “Markush practice;” and
- (iii) intermediate and final products.

ISPE Paragraph 10.11



Different Categories of Invention

When an application includes claims to more than one product, process, or apparatus, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the “main invention” in the claims.

FP 18.05



Different Categories of Invention (cont.)

An international application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(b)

3/2/09



Different Categories of Invention (cont.)

A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

ISPE Paragraph 10.12.



Example E: Claims in Different Categories

Claim 1: Method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The (method of) use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. Assuming X is novel and unobvious, the special technical feature to all the claims is substance X.

However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

ISPE Example 1



So-called “Markush Practice”

Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity; AND
- (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

ISPE Paragraph 10.17



Significant Structural Element

The phrase “significant structural element is shared by all of the alternatives” refers to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity.

ISPE Paragraph 10.17



Recognized Class of Chemical Compounds

The phrase “recognized class of chemical compounds” means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention, i.e. each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

ISPE Paragraph 10.17

3/2/09



Determination of Unity of Invention Not Affected by Manner of Claiming

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

PCT Rule 13.3, also see 37 CFR 1.475(e)



Election of Species in National Stage Applications Submitted Under 35 U.S.C. 371

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

FP 18.20



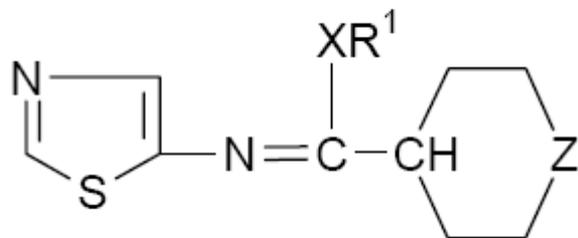
Where Genus Claim Avoids the Prior Art

...no problem [of unity of invention] arises in the case of a genus/ species situation where the genus claim avoids the prior art and satisfies the requirement of unity of invention.



Example F: Common Chemical Structure

Claim 1: A compound of the formula:



wherein R¹ is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

ISPE Example 20



Example F: Common Chemical Structure (cont.)

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

ISPE Example 20



Example F: Common Chemical Structure (cont.)

All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure.

Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

ISPE Example 20



Example G: No Common Chemical Structure

Claim 1: A pharmaceutical compound of the formula: A – B– C – D – E, wherein

A is selected from C1-C10 alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C5-C7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C1-C6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C3-C8 ether or thioether;

C is selected from C5-C8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C4-C8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

ISPE Example 24



Example G: No Common Chemical Structure (cont.)

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined.

Lack of unity exists between all of the various combinations.

The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C1 alkyl, B is C1 alkyl, C is a C5 saturated heterocycle having one O heteroatom, D is C1 alkyl, and E is a substituted phenyl.

ISPE Example 24



Alternatives Do Not Share a Common Structure or Belong to Recognized Class

The chemical compounds of Claim 1 are not regarded as being of similar nature because:

all the alternatives do not share a common structure and

(2) the alternatives do not all belong to a recognized class of chemical compounds.

Based on FP 18.07.03c

3/2/09



Example H: Common Chemical Structure does not make a contribution over prior art

Claim 1: A pharmaceutical compound of the formula: A – B – C – D – E, wherein

A is methyl;

B is selected from C1-C6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C3-C8 ether or thioether;

C is selected from C5-C8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C4-C8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.



Example H: Common Chemical Structure does not make a contribution over prior art (cont.)

Although the chemical compounds of Claim 1 share a common structure of A being a methyl group, the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinctive portion in view of Smith, which teaches a methyl group.

Further, the compounds of these groups do not belong to a recognized class of chemical compounds.

From the knowledge in the art would lead one to expect that the various members within the claim scope would have distinct pharmaceutical activities. The methyl group of A does not define a specific pharmaceutical activity and each of the alternatives set forth under B-E would be expected to impart a different pharmaceutical activity. Therefore, one would not expect that each member within the claim scope could be substituted for the other to obtain the same intended result.



Example I: No Common Chemical Structure in Composition Claim

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of

(A) 2,4-D(2,4-dichloro-phenoxy acetic acid) and

(B) a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

ISPE Example 23



Example I: No Common Chemical Structure in Composition Claim (cont.)

The different components under B must be members of a recognized class of compounds.

Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

ISPE Example 23



Example I: No Common Chemical Structure in Composition Claim (cont.)

inorganic salts: copper sulfate sodium chlorate ammonium sulfamate

(b) organic salts and carboxylic acids: sodium trichloroacetate dichloropropionic acid 3-amino-2,5-dichlorobenzoic acid

(c) amides: diphenamid

(d) nitriles: ioxynil

(e) phenols: dinoseb

(f) amines: trifluralin

(g) heterocyclic: simazine

ISPE Example 23



Intermediate/Final Products

Rule 13.2 also governs the situation involving intermediate and final products.

The term “intermediate” is intended to mean intermediate or starting products.

Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity

ISPE Paragraph 10.18



Intermediate/Final Products (cont.)

Unity of invention is considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural element, in that:

- (1) the basic chemical structures of the intermediate and the final products are the same, or
- (2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

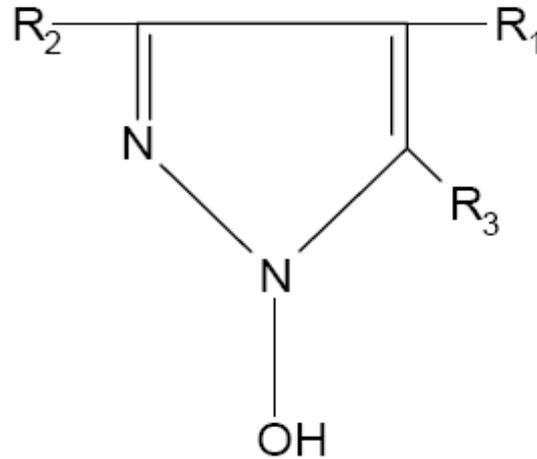
(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

ISPE Paragraph 10.18



Example J: Intermediate/Final Products

Claim 1:



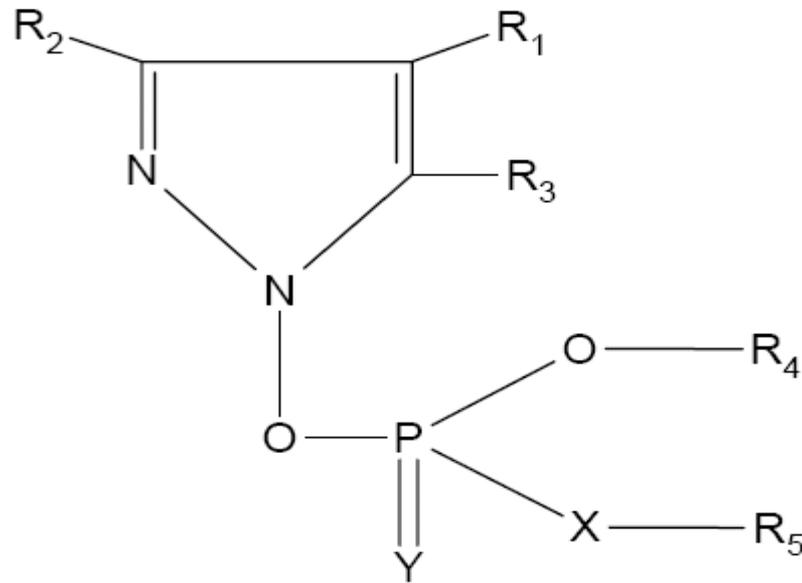
(intermediate)

Example 26



Example J: Intermediate/Final Products (cont.)

Claim 2:



(final product)

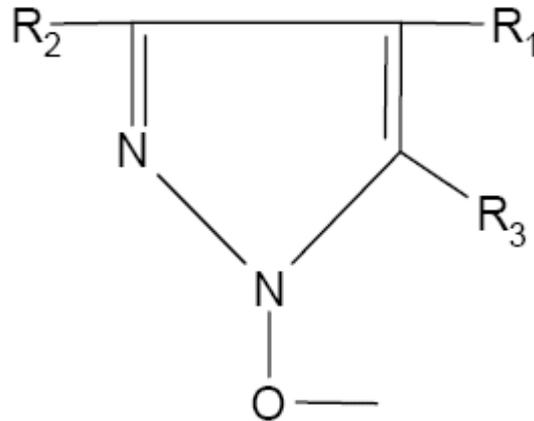
Example 26

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Example J: Intermediate/Final Products (cont.)

The chemical structure of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:



Therefore, unity exists between claims 1 and 2.

ISPE Example 26

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Combinations

Objection of lack of unity of invention does not normally arise if the combination of a number of individual elements is claimed in a single claim (as opposed to distinct embodiments . . .), even if these elements seem unrelated when considered individually (see paragraph 15.27).

ISPE Paragraph 10.10



Example K: A Single Combination

Claim 1: A composition comprising Compound A, Compound B and Compound C.

Claim 1 is directed to a single composition requiring three compounds. Even if the compounds seem unrelated one to another, unity of invention exists. PCT rules do not permit the examiner to require applicants to elect a single compound for examination.



Combination and Subcombinations

...no problem arises in the case of a combination/
subcombination situation where the subcombination claim
avoids the prior art and satisfies the requirement of unity
of invention and the combination claim includes all the
features of the subcombination.

ISPE Paragraph 10.07



Example L: Combination and Subcombinations

Claim 1: A composition comprising Compound A.

Claim 2: A composition comprising Compound B.

Claim 3: A composition comprising Compound A and Compound B.

Group I, Claim 1, drawn to a composition comprising Compound A.

Group II, Claim 2, drawn to a composition comprising Compound B.

Unity exists between claims 1 and 3 or between claims 2 and 3 but not between claims 1 and 2. Claim 3 will be examined with whichever Group is elected.

Compound A is a special technical feature and Compound B is another special technical feature.

Rejoinder provisions of MPEP 821.04 apply to national stage applications.

Based upon ISPE Example 10

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Contents

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Election by Original Presentation in National Stage Applications Submitted Under 35 U.S.C. 371

Newly submitted claim [1] directed to an invention that lacks unity with the invention originally claimed for the following reasons: [2]

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim [3] withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

FP 18.21



Requirement for Election and Means for Traversal in National Stage Applications Submitted Under 35 U.S.C. 371

Applicant is advised that the reply to this requirement to be complete must include

- (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and
- (ii) identification of the claims encompassing the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

FP 18.22



Requirement for Election and Means for Traversal in National Stage Applications Submitted Under 35 U.S.C. 371

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse.

If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

...Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof.



Requirement for Election and Means for Traversal in National Stage Applications Submitted Under 35 U.S.C. 371

Traversal must be presented at the time of election in order to be considered timely.

Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

FP 18.22



Requirement for Election and Means for Traversal in National Stage Applications Submitted Under 35 U.S.C. 371

Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case.

Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions 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 invention.



Rejoinder Practice following a Lack of Unity Determination

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 Edition 8, revision 7 section 1893.03(d)



Rejoinder Practice following a Lack of Unity Determination

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. See MPEP § [821.04](#) and § [821.04](#)(a).

Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04 *et seq.*

MPEP Edition 8, revision 7 section 1893.03(d)



Rejoinder Practice following Election of Species in National Stage Applications

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

FP 18.20



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PCT Unity of Invention with Pharmaceutical and Chemical Examples

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