

Notice of Proposed Rule Making Affecting Claims That Recite Alternatives

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Notice of Proposed Rule Making

“Examination of Patent Applications that Include Claims Containing Alternative Language”

published in the Federal Register Vol 72 No 154,

on 10 August 2007

with a 60 day public comment period.

<http://www.uspto.gov/web/offices/com/sol/notices/72fr44992.pdf>.

To Submit Comments

To be ensured consideration, comments must be received before 9 October 2007.

Comments should be marked to the attention of:

Kathleen Kahler Fonda, Legal Advisor, Office of the
Deputy Commissioner for Patent Examination Policy

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Alternative Claims NPR is a Necessary Complement to the Claims/Continuations Package

**“Changes to Practice for Continued Examination
Filings, Patent Applications Containing Patentably
Indistinct Claims and Examination of Claims in
Patent Applications”**

**Published in the Federal Register Vol. 72, No. 161,
on 21 August 2007.**

<http://www.uspto.gov/web/offices/com/sol/notices/72fr46716.pdf>.

Alternative Claims NPR Broadens Requirement to Identify Claims Entitled to the Benefit of an Earlier Date

Claims and Continuation Final Rule 1.75(d)(3) requires that if an application is identified as a continuation-in-part (CIP) application, the applicant must identify the claim or claims in the (CIP) application for which the subject matter is disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application.

Alternative Claims NPR Broadens Requirement to Identify Claims Entitled to the Benefit of an Earlier Date

Proposed Rule 1.75(d)(2) requires applicants to identify which claim(s) in an application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in a prior-filed application when the application seeks the benefit under title 35, United States Code of the prior-filed application and discloses subject matter that was not disclosed in the prior-filed application.

The proposed rule is not limited to applications identified as CIPs, and would apply to applications that claim the benefit of provisional applications, nonprovisional applications, foreign filed priority documents, PCTs or national stage applications.

Basis for the Office to Promulgate Alternative Claims Rules

35 USC 2(b) SPECIFIC POWERS

The Office

...(2) may establish regulations, not inconsistent with law, which-
(A) shall govern the conduct of proceedings in the Office

35 U.S.C § 121

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. (Emphasis added).

Basis for the Office to Promulgate Alternative Claims Rules

In re Weber, 580 F.2d 455, 198 USPQ 328, 331-32 (CCPA 1978)

“It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be "independent and distinct.”

“Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee.”

Basis for the Office to Promulgate Alternative Claims Rules

In re Harnisch, 631 F.2d 716, 722 n.6, 206 USPQ 300, 306 n.7 (CCPA 1980).

“Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rulemaking powers under 35 USC § 6(a), wherein the views of interested parties may be heard.”

35 U.S.C. § 6(a) is now 35 U.S.C. § 2(b).

Proposed Rule Changes Would Apply to All Claims that Use Alternative Language

- An alternative claim is any claim that lists alternatives, including “Markush” claims.
- Alternatives are commonly listed as:
 - selected from the group consisting of A, B and C
 - wherein the fastener is a nail, a screw or an adhesive.

Current Practice for Claims using Alternative Language

- Currently there is no explicit guidance for restricting among independent and distinct inventions when claimed in the alternative of a single claim.
- “Markush” practice permits the examiner to require a provisional election of species.
- If the elected species is found allowable, the examiner must extend the search and examination to the extent necessary to determine patentability of the claim, even if the claim lists independent and distinct inventions. **MPEP § 803.02**

The Proposal for Claims using Alternative Language

In an effort to level the playing field for all and provide for a more efficient, thorough and quality examination, the Office is considering requiring those applicants who chose to draft claims that recite alternatives or species to maintain a certain degree of relatedness among the alternatives.

72 Fed. Reg. 44992

Overview of Proposed Rule Changes

- 1) A claim must be limited to a single invention. **1.75(a) and 1.140(a)**
- 2) Intra-claim restriction will be permitted when a claim is not limited to a single invention. **1.140(a) and 1.142(b)**
- 3) Applicants may file a statement explaining how their claim is limited to a single invention. **1.140(b)**
- 4) A claim using alternative language must be in the proper format. **1.75(j)**
- 5) Claims must be self-contained. **1.75(k)**
- 6) Claims listing non-elected inventions will be subject to objection. **1.142(d)**
- 7) Applicants must identify the effective priority date for each claim that seeks the benefit of a prior filed application. **1.75(d)(2)**

1) A claim must be limited to a single invention.

An alternative-type claim is limited to a single invention when **either**:

(i) The alternatives share a substantial feature essential for a common utility,

OR

(ii) The alternatives are *prima facie* obvious over each other.

1.75(a) and 1.140(a)

2) Intra-claim restriction will be permitted when a claim is not limited to a single invention.

The propriety of a requirement for restriction shall be determined without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim.

1.140 (a) and 1.142(b)

3) Applicants may file a statement explaining how their claim is limited to a single invention.

The presentation of an alternative claim may be accompanied by a statement explaining why the claim is limited to a single invention if the statement is filed at the time of presentation of the claim or prior to the mailing of a restriction or action on the merits.

1.140(b)

4) A claim using alternative language must be in the proper format.

Objectionable Claim Formats:

- (i) The number and presentation of alternatives in a single claim must not make the claim difficult to construe. **1.75(j)(1)**
- (ii) No alternative may itself be defined as a set of further alternatives within the claim. **1.75(j)(2)**
- (iii) No alternative can be encompassed by any other alternative within a list of alternatives unless there is no other practical way to define the invention. **1.75(j)(3)**
- (iv) All Alternatives must be substitutable one for another. **1.75(j)(4)**

5) Claims must be self-contained.

A claim cannot incorporate a set of alternatives by reference to the specification or drawings unless there is no other practical way to define the invention.

For example:

Claim 1. A compound selected from Table 1.

(where Table 1 lists the formulas for 100 separate compounds)

- (ii) If a claim incorporates alternatives by reference to the specification, that claim will be treated as an alternative claim.

1.75(k)

6) Treatment of claims listing non-elected inventions: consistent with current restriction practice.

- (i) Any claim limited solely to a non-elected invention, if not canceled, is withdrawn from further consideration.
- (ii) Any claim that recites both elected and non-elected inventions will be subjected to an objection.
- (iii) Non-elected subject matter must be canceled from a claim before the claim is allowed.

**For Applications under 35 U.S.C. 111(a) – see 1.142(c) and (d)
For National Stage Applications- see 1.499(b) and (c)**

7) Applicants must identify the effective priority date for each claim that seeks the benefit of a prior filed application.

If an application seeks the benefit under title 35, United States Code of a prior-filed application and discloses subject matter that was not disclosed in the prior-filed application, the applicant must identify which claim or claims in the application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application.

1.75(d)(2)

More on Intra-Claim Restriction

- The proposed rule changes are intended to:
 - Limit each claim to a single invention.
 - Permit RESTRICTION within a single claim listing alternatives if the alternatives are not directed to a single invention:
 - When the alternatives share a substantial feature essential for a common utility or are obvious variants over each other.
- Standard “Markush” practice (election of species) would remain an option where the alternatives share a substantial feature essential for a common utility. **MPEP § 803.02**

To Identify Substantial Feature Essential for Common Utility

- The Markush grouping must be considered as a whole.
- The “feature” must be shared by all of the alternatives and is typically
 - A Structure for Products or
 - An Active Step for Processes.
- “Substantial” means a feature that
 - Specifically contributes towards the common utility or
 - Provides the same effect among the alternatives.
- The “common utility” is derived from the essential substantial feature and results in the same effect for every alternative
 - The common utility must meet the requirements of 35 U.S.C. 101, (e.g., be specific, substantial and credible).

Examples Illustrating Proposed Rule Changes

A Claim limited to a single invention:

- 1) Substantial Feature Essential for a Common Property
- 2) Alternatives are Obvious Variants

A Single Claim listing Plural Inventions:

- 3) Compounds
- 4) Biotech
- 5) Products
- 6) Processes

Examples Illustrating Proposed Rule Changes

Claim Format Concerns:

- 7) Claim Difficult to Construe
- 8) Nested Alternatives; no Common Feature
- 9) Genus, Subgenus, Species

Claims Should be Self-Contained:

- 10) Claim refers to Tables
- 11) Alternatives in the Sequence Listing

Effective Priority Date:

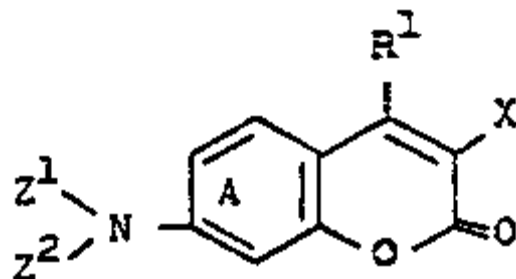
- 12) Complicated Priority Situation

Proposed Rule Changes Limited to Alternative Claims:

- 13) Practice for a True Generic Claim

Example 1: Compound Claim Limited to a Single Invention; Substantial Feature Essential for a Common Property

Claim 1. A compound having the formula



wherein

X represents aldehyde, azomethine, or hydrazone,

R¹ represents hydrogen or alkyl,

Z¹ represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3- membered alkylene radical connected to the 6-position of the coumarin ring and

Z² represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2- or 3- membered alkylene radical connected to the 8-position of the coumarin ring

and wherein

Z¹ and Z² conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, *like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dyestuff chemistry.*

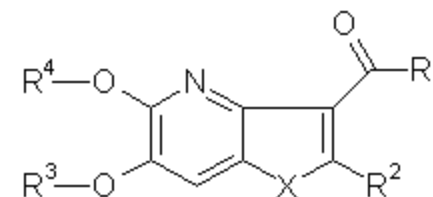
Example 2: Composition Claim is Limited to a Single Invention; Alternatives are Obvious Variants

Claim 1. A composition comprising a first ingredient having Formula I and a detergent, selected from the group consisting of Detergents 1-100.

The specification discloses that Detergents 1-100 are known in the prior art. It would be obvious to use any of these known detergents in a composition.

Example 3: Compound Claim Listing Plural Inventions.

Claim 1. A compound having the formula



wherein

X is O, N, S, CH₂, CH₂CH₂, or CH=CH;

R¹ is hydrogen, alkyl, cycloalkyl, hydroxyl, amino, substituted amino, aryl or heteroaryl;

R² is halo, cyano or nitro;

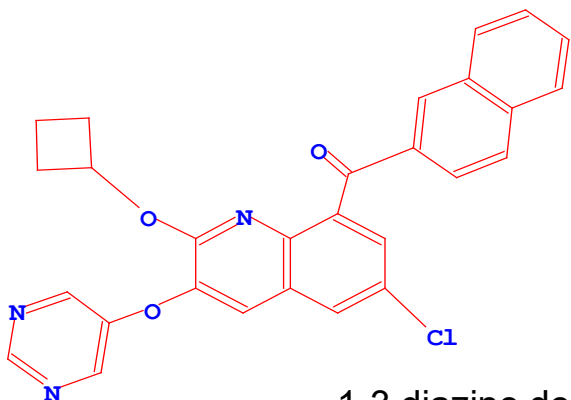
R³ is aryl or heteroaryl; and

R⁴ is hydrogen, lower alkyl, lower cycloalkyl, acyl, aroyl or heteroaroyl.

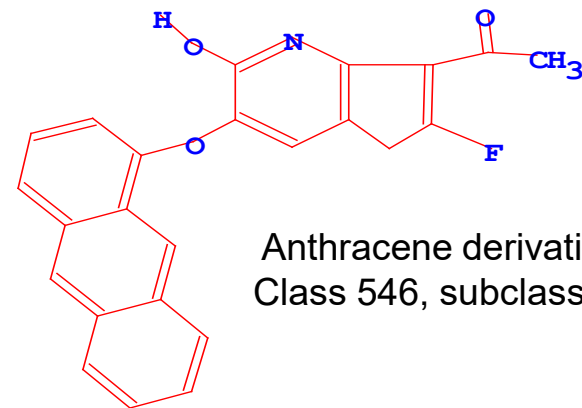
- This claim encompasses at least 2.63×10^{14} or 263,424,000,000,000 species

Example 3: Compound Claim Listing Plural Inventions. (cont.)

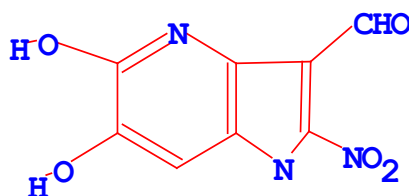
Variables Result in Structurally and Functionally Diverse Species



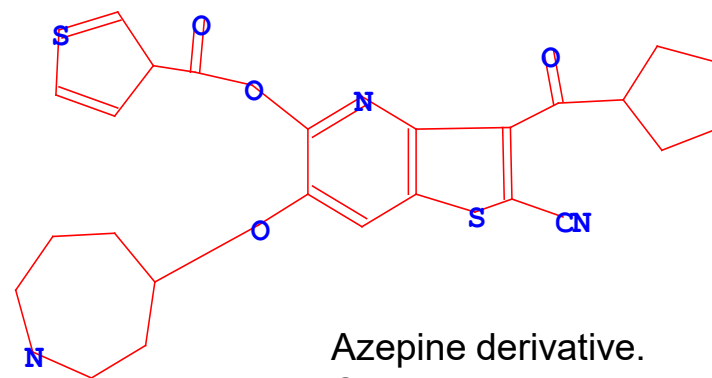
1-3 diazine derivative
Class 544, subclass 242



Anthracene derivative.
Class 546, subclass 183



Pyridyl-pyrrolo derivative
Class 546, subclass 113



Azepine derivative.
Class 540, subclass 484

Example 4: Biotech Claim Listing Plural Inventions.

Claim 1. An isolated nucleic acid probe selected from the group consisting of SEQ ID Nos:1-100.

The specification teaches that each probe binds to a different gene from a human liver library.

Example 5: A Single Claim Listing Plural Product Inventions; Claim Format

Claim 1. A composition of matter selected from the group consisting of

- a nucleic acid of SEQ ID NO:1,
- a polypeptide of SEQ ID NO:2,
- an antibody that binds to protein having SEQ ID NO:3,
- a ligand that binds to protein having SEQ ID NO:4,
- an antisense that inhibits expression of SEQ ID NO:1,
- an organophosphate molecule having Formula 1,
- a knock-out transgenic mouse that does not express endogenous SEQ ID NO:1 and
- a transgenic mouse that has increased levels of SEQ ID NO:1.

Example 6: A Single Claim Listing Plural Process Inventions; Claim Format

Claim 1. A process of

a first preamble, followed by active steps A, B and C or

a second preamble, followed by different active steps A', B' and C' or

a third preamble, followed by different active steps A'', B'' and C'' or

a fourth preamble, followed by different active steps A''', B''' and C'''.

Example 7A: Claim Difficult to Construe; Claim Format

Claim 1. A protein that inhibits X activity, selected from the group consisting of SEQ ID NOs:1-400, but not including those which inhibit Y activity.

Claim 2. A protein that inhibits X activity, selected from the group consisting of SEQ ID Nos: 2, 4, 56,158, 329, 346, 370 and 396.

The specification provides several lengthy tables and examples that taken together, show that only 8 of the 400 potential SEQ ID NOs listed in claim 1 actually meet the limitations required for claim 1.

Claim 2 recites the specific embodiments actually encompassed by claim 1 and is not difficult to construe.

Example 7B: Claim Difficult to Construe; Claim Format

Claim 1. A method of using a protein having SEQ ID NO:X as referenced in Table 1, or a polypeptide domain of SEQ ID NO:Y as referenced in Table 2, or an antigenic fragment of SEQ ID NO:Z as referenced in Table 3 to treat a patient suffering from a disease as referenced in Table 4.

To decipher claim 1, the examiner must review

Table 1 (18 pages long)

Table 2 (13 pages long)

Table 3 (13 pages long) and

Table 4 (5 pages long).

A review of Table 4 requires reference to Table 5 (which lists 5 pages of medical disease reference codes and corresponding diseases).

The possible protein/disease combinations encompassed by claim 1: 500,000.

Example 8: Nested Alternatives, No Common Feature: Claim Format

Claim 1: A composition comprising at least two of the following elements selected from the group consisting of A, B and C,
wherein A may be A1, A2 or A3
wherein B may be B1, B2 or B3 and
wherein C may be C1, C2 or C3.

Claim 1 reads on compositions that share no common feature. For example:

composition of A1 and B1
composition of B3 and C2 or
composition of A2, B2 and C1.

Nested alternatives creates matrices within a claim that are comparable in format and complexity to matrices arising from improper multiple dependent claims.

Example 9: Genus, Subgenus and Species; Claim Format

Claim 1. A transgenic animal comprising SEQ ID NO:1, where the animal is selected from the group consisting of a mammal, a rodent, a mouse and a Balb/C mouse.

Applicants should file separate claims varying in scope from the broadest that they believe they are entitled to the narrowest that they are willing to accept.

Claim 2. A transgenic mammal comprising SEQ ID NO:1.

Claim 3. A transgenic rodent comprising SEQ ID NO:1.

Claim 4. A transgenic mouse comprising SEQ ID NO:1.

Claim 5. A transgenic Balb/C mouse comprising SEQ ID NO:1.

Example 10: Claim Refers to Tables; Claims Must Be Self-Contained.

Claim 1. A method of treating a disease selected from Table 1 by administering a compound having a formula from Table 2 to a patient in need thereof.

- Table 1 lists 100 diseases NOT linked by etiology or pathology.
- Table 2 lists formulas of 100 structurally and functionally diverse compounds.
- This claim encompasses 10,000 methods.
- The specification provides one example of treating Disease A (diabetes) using a compound having Formula I.

Example 11: Alternatives in Sequence Listing; Claims Must Be Self-Contained.

Claim 1. A polynucleotide comprising SEQ ID NO:1.

The sequence listing shows that SEQ ID NO:1 is:

ATGSTAMATR, where

S is G or C,

M is A or C and

R is G or A.

Example 11: Alternatives in Sequence Listing (cont.)

SEQ ID NO:1 encompasses eight distinct sequences:

ATGGTAAATG

ATGCTAAATG

ATGGTACATG

ATGCTACATG

ATGGTAAATA

ATGCTAAATA

ATGGTACATA

ATGCTACATA

The sequences should be claimed as:

Claim 1. A polynucleotide comprising SEQ ID NO:1 wherein the nucleic acid at position 4 is G or C, at position 7 is A or C and at position 10 is G or A.

**Example 12: Complicated Priority Situation;
Applicants Must Identify the Effective Priority Date for Each Claim.**

Claim 1. An isolated nucleic acid molecule comprising the polynucleotide sequence of SEQ ID No 54.

This application claims benefit of priority
to provisional application A, filed 1/1/05 and
to provisional application B, filed 3/1/05 and
to provisional application C, filed 6/1/05 and
to provisional application D, filed 9/1/05 and
to provisional application E, filed 12/1/05 and ...
list goes on for four pages.

Intra-claim restriction would be permitted only for claims which use alternative language.

Example 13: Practice for a True Generic Claim

Claim 1. A citrus fruit treated with fungicide ABC.

The specification discloses applying fungicide ABC to any citrus fruit.

A proposed restriction among the following groups,

Group I, claim 1, a lemon treated with fungicide ABC.

Group II, claim 1, a lime treated with fungicide ABC.

Group III, claim 1, an orange treated with fungicide ABC,

would be improper because the scope of Groups I, II and III, combined is less than the scope of claim 1. “Citrus Fruit” for, example, also encompasses “grapefruit” and other citrus fruit which is missing from groupings.

Examiners always have the discretion to keep inventions together for examination even if restricting among them would be proper.

See 35 U.S.C § 121 providing that the Director may require the application to be restricted to one of the inventions.

To Submit Comments

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Comments should be marked to the attention of:

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